BURST Statistical Per Protocol Report

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# Introduction

This is the report for the per protocol analysis of the BURST trial where patient 3-009 has been taken out (wrong inclusion). The data are based on an export from the Viedoc electronic data capture at 2023-09-19 system time stamped “\_20230919\_063242”.

The results in this report is according to the true random allocation.

There were 12 included patients of which 9 were randomised and included in the full analysis set.

# Demographics

## All randomised

| Demographics and baseline characteristics | |
| --- | --- |
| All included | |
|  | **all obs (N=12)** |
| **Site name** |  |
| Akademiska | 5 (41.67%) |
| OUS | 7 (58.33%) |
| **Gender** |  |
| Male | 2 (16.67%) |
| Female | 10 (83.33%) |
| **Age (years)** |  |
| n | 12 |
| Mean (sd) | 53.56 (6.78) |
| IQR | 6.75 |
| min - max | 38.90 - 66.70 |
| **Marital status** |  |
| Married | 5 (41.67%) |
| Single | 0 (0.00%) |
| Divorsed | 1 (8.33%) |
| Cohabitant | 5 (41.67%) |
| Partner | 1 (8.33%) |
| **Number of children** |  |
| n | 12 |
| Mean (sd) | 1.50 (1.09) |
| IQR | 1.00 |
| min - max | 0.00 - 4.00 |
| **Working?** |  |
| Yes | 7 (58.33%) |
| No | 5 (41.67%) |
| **Working hours per week** |  |
| n | 7 |
| Mean (sd) | 30.43 (15.21) |
| IQR | 12.50 |
| min - max | 0.00 - 40.00 |
| **Years not working** |  |
| n | 5 |
| Mean (sd) | 1.80 (0.84) |
| IQR | 1.00 |
| min - max | 1.00 - 3.00 |
| **Type of governmental support** |  |
| Alderstrygd, førtidspensjon (AFP) eller etterlattepensjon | 0 (0.00%) |
| Sykepenger helt (er helt sykmeldt) | 1 (8.33%) |
| Sykepenger delvis (er delvis sykmeldt) | 1 (8.33%) |
| Arbeidsavklaringspenger (AAP) | 4 (33.33%) |
| Uføreytelse/pensjon, hel | 1 (8.33%) |
| Uføreytelse/pensjon, delvis | 1 (8.33%) |
| Mottar ingen stønad, får lønn fra arbeidsgiver | 4 (33.33%) |
| **Completed education** |  |
| Grunnskole | 0 (0.00%) |
| Yrkesskole | 0 (0.00%) |
| Videregående/Gymnas | 6 (50.00%) |
| Høyskole, universitet < 4 år | 5 (41.67%) |
| Høyskole, universitet > 4 år | 1 (8.33%) |
| **PCS Total score** |  |
| n | 12 |
| Mean (sd) | 19.25 (6.68) |
| IQR | 11.50 |
| min - max | 8.00 - 28.00 |
| **PCS Rumination** |  |
| n | 12 |
| Mean (sd) | 8.08 (3.29) |
| IQR | 4.25 |
| min - max | 3.00 - 14.00 |
| **PCS Magnification** |  |
| n | 12 |
| Mean (sd) | 2.67 (1.67) |
| IQR | 3.00 |
| min - max | 0.00 - 5.00 |
| **PCS Helplessness** |  |
| n | 12 |
| Mean (sd) | 8.50 (3.23) |
| IQR | 4.00 |
| min - max | 4.00 - 14.00 |
| **PCS Total score dichotomised at 24** |  |
| PCS ≤ 24 | 8 (66.67%) |
| PCS > 24 | 4 (33.33%) |
| **Treatment for neuropatic pain?** |  |
| No | 8 (66.67%) |
| Yes | 4 (33.33%) |
| **Amitriptyline** |  |
| No | 11 (91.67%) |
| Yes | 1 (8.33%) |
| **Gabapentin** |  |
| No | 9 (75.00%) |
| Yes | 3 (25.00%) |
| **Pregabalin** |  |
| No | 11 (91.67%) |
| Yes | 1 (8.33%) |
| **Duloxetine** |  |
| No | 12 (100.00%) |
| **Treatment with other non-opoids?** |  |
| No | 2 (16.67%) |
| Yes | 10 (83.33%) |
| **Paracetamol** |  |
| No | 4 (33.33%) |
| Yes | 8 (66.67%) |
| **NSAIDs** |  |
| No | 8 (66.67%) |
| Yes | 4 (33.33%) |
| **Antidepressiva** |  |
| No | 12 (100.00%) |
| **Treatmetn with opoids?** |  |
| No | 7 (58.33%) |
| Yes | 5 (41.67%) |
| **Total daily morphine milligram equivalents** |  |
| n | 5 |
| Mean (sd) | 18.50 (9.97) |
| IQR | 17.00 |
| min - max | 7.50 - 30.00 |
| **Previous physiotherapy?** |  |
| Yes | 12 (100.00%) |
| **Previous chiropractor?** |  |
| No | 5 (41.67%) |
| Yes | 7 (58.33%) |
| **Previous psychologist?** |  |
| No | 10 (83.33%) |
| Yes | 2 (16.67%) |
| **Previous TENS?** |  |
| No | 2 (16.67%) |
| Yes | 10 (83.33%) |
| **Other previous treatment?** |  |
| No | 9 (75.00%) |
| Yes | 3 (25.00%) |
| **Other previous treatment, specify** |  |
| Dry needling, Blockad SI-led och rotblockad. | 1 |
| epidural injeksjon, iv infusjon lidokain, ketamin | 1 |
| Specialdiet via dietist, rotblockader x 2, ryggkirurgi, värmebad. | 1 |
| **Current physiotherapy?** |  |
| No | 9 (75.00%) |
| Yes | 3 (25.00%) |
| **Current chiropractor?** |  |
| No | 12 (100.00%) |
| **Current psychologist?** |  |
| No | 12 (100.00%) |
| **Current TENS** |  |
| No | 8 (66.67%) |
| Yes | 4 (33.33%) |
| **Other current treatment?** |  |
| No | 11 (91.67%) |
| Yes | 1 (8.33%) |
| **Other current treatment, specify** |  |
| Följer sjukgymnast-program hemma. | 1 |
| **Current back pain?** |  |
| No | 2 (16.67%) |
| Yes | 10 (83.33%) |
| **Duration of pain (years)** |  |
| n | 12 |
| Mean (sd) | 7.40 (10.17) |
| IQR | 8.20 |
| min - max | 0.40 - 36.00 |
| **Duration of current pain level (years)** |  |
| n | 12 |
| Mean (sd) | 2.76 (3.63) |
| IQR | 2.50 |
| min - max | 0.25 - 10.00 |
| **Weight (kg)** |  |
| n | 12 |
| Mean (sd) | 74.54 (12.25) |
| IQR | 18.50 |
| min - max | 54.00 - 92.50 |
| **Height (cm)** |  |
| n | 12 |
| Mean (sd) | 167.08 (8.02) |
| IQR | 7.25 |
| min - max | 155.00 - 183.00 |
| **BMI** |  |
| n | 12 |
| Mean (sd) | 26.61 (3.31) |
| IQR | 3.97 |
| min - max | 20.30 - 32.00 |

## Excluded from FAS

| Demographics and baseline characteristics | |
| --- | --- |
| Excluded before randomisation | |
|  | **all obs (N=3)** |
| **Site name** |  |
| Akademiska | 2 (66.67%) |
| OUS | 1 (33.33%) |
| **Gender** |  |
| Male | 0 (0.00%) |
| Female | 3 (100.00%) |
| **Age (years)** |  |
| n | 3 |
| Mean (sd) | 54.40 (4.51) |
| IQR | 4.05 |
| min - max | 49.20 - 57.30 |
| **Marital status** |  |
| Married | 0 (0.00%) |
| Single | 0 (0.00%) |
| Divorsed | 1 (33.33%) |
| Cohabitant | 2 (66.67%) |
| Partner | 0 (0.00%) |
| **Number of children** |  |
| n | 3 |
| Mean (sd) | 0.67 (0.58) |
| IQR | 0.50 |
| min - max | 0.00 - 1.00 |
| **Working?** |  |
| Yes | 2 (66.67%) |
| No | 1 (33.33%) |
| **Working hours per week** |  |
| n | 2 |
| Mean (sd) | 40.00 (0.00) |
| IQR | 0.00 |
| min - max | 40.00 - 40.00 |
| **Years not working** |  |
| n | 1 |
| Mean (sd) | 1.00 (NA) |
| IQR | 0.00 |
| min - max | 1.00 - 1.00 |
| **Type of governmental support** |  |
| Alderstrygd, førtidspensjon (AFP) eller etterlattepensjon | 0 (0.00%) |
| Sykepenger helt (er helt sykmeldt) | 0 (0.00%) |
| Sykepenger delvis (er delvis sykmeldt) | 1 (33.33%) |
| Arbeidsavklaringspenger (AAP) | 1 (33.33%) |
| Uføreytelse/pensjon, hel | 0 (0.00%) |
| Uføreytelse/pensjon, delvis | 0 (0.00%) |
| Mottar ingen stønad, får lønn fra arbeidsgiver | 1 (33.33%) |
| **Completed education** |  |
| Grunnskole | 0 (0.00%) |
| Yrkesskole | 0 (0.00%) |
| Videregående/Gymnas | 2 (66.67%) |
| Høyskole, universitet < 4 år | 1 (33.33%) |
| Høyskole, universitet > 4 år | 0 (0.00%) |
| **PCS Total score** |  |
| n | 3 |
| Mean (sd) | 24.33 (3.06) |
| IQR | 3.00 |
| min - max | 21.00 - 27.00 |
| **PCS Rumination** |  |
| n | 3 |
| Mean (sd) | 9.67 (1.53) |
| IQR | 1.50 |
| min - max | 8.00 - 11.00 |
| **PCS Magnification** |  |
| n | 3 |
| Mean (sd) | 4.00 (1.00) |
| IQR | 1.00 |
| min - max | 3.00 - 5.00 |
| **PCS Helplessness** |  |
| n | 3 |
| Mean (sd) | 10.67 (3.21) |
| IQR | 3.00 |
| min - max | 7.00 - 13.00 |
| **PCS Total score dichotomised at 24** |  |
| PCS ≤ 24 | 1 (33.33%) |
| PCS > 24 | 2 (66.67%) |
| **Treatment for neuropatic pain?** |  |
| No | 2 (66.67%) |
| Yes | 1 (33.33%) |
| **Amitriptyline** |  |
| No | 3 (100.00%) |
| Yes | 0 (0.00%) |
| **Gabapentin** |  |
| No | 2 (66.67%) |
| Yes | 1 (33.33%) |
| **Pregabalin** |  |
| No | 3 (100.00%) |
| Yes | 0 (0.00%) |
| **Duloxetine** |  |
| No | 3 (100.00%) |
| **Treatment with other non-opoids?** |  |
| No | 0 (0.00%) |
| Yes | 3 (100.00%) |
| **Paracetamol** |  |
| No | 0 (0.00%) |
| Yes | 3 (100.00%) |
| **NSAIDs** |  |
| No | 2 (66.67%) |
| Yes | 1 (33.33%) |
| **Antidepressiva** |  |
| No | 3 (100.00%) |
| **Treatmetn with opoids?** |  |
| No | 1 (33.33%) |
| Yes | 2 (66.67%) |
| **Total daily morphine milligram equivalents** |  |
| n | 2 |
| Mean (sd) | 8.75 (1.77) |
| IQR | 1.25 |
| min - max | 7.50 - 10.00 |
| **Previous physiotherapy?** |  |
| Yes | 3 (100.00%) |
| **Previous chiropractor?** |  |
| No | 2 (66.67%) |
| Yes | 1 (33.33%) |
| **Previous psychologist?** |  |
| No | 3 (100.00%) |
| Yes | 0 (0.00%) |
| **Previous TENS?** |  |
| No | 1 (33.33%) |
| Yes | 2 (66.67%) |
| **Other previous treatment?** |  |
| No | 3 (100.00%) |
| Yes | 0 (0.00%) |
| **Other previous treatment, specify** |  |
| s\_summary |  |
| **Current physiotherapy?** |  |
| No | 1 (33.33%) |
| Yes | 2 (66.67%) |
| **Current chiropractor?** |  |
| No | 3 (100.00%) |
| **Current psychologist?** |  |
| No | 3 (100.00%) |
| **Current TENS** |  |
| No | 3 (100.00%) |
| Yes | 0 (0.00%) |
| **Other current treatment?** |  |
| No | 3 (100.00%) |
| Yes | 0 (0.00%) |
| **Other current treatment, specify** |  |
| s\_summary |  |
| **Current back pain?** |  |
| No | 0 (0.00%) |
| Yes | 3 (100.00%) |
| **Duration of pain (years)** |  |
| n | 3 |
| Mean (sd) | 0.97 (0.55) |
| IQR | 0.55 |
| min - max | 0.40 - 1.50 |
| **Duration of current pain level (years)** |  |
| n | 3 |
| Mean (sd) | 0.53 (0.41) |
| IQR | 0.38 |
| min - max | 0.25 - 1.00 |
| **Weight (kg)** |  |
| n | 3 |
| Mean (sd) | 69.00 (15.52) |
| IQR | 15.50 |
| min - max | 54.00 - 85.00 |
| **Height (cm)** |  |
| n | 3 |
| Mean (sd) | 163.67 (1.15) |
| IQR | 1.00 |
| min - max | 163.00 - 165.00 |
| **BMI** |  |
| n | 3 |
| Mean (sd) | 25.77 (5.89) |
| IQR | 5.85 |
| min - max | 20.30 - 32.00 |

## Full analysis set

| Demographics and baseline characteristics | |
| --- | --- |
| Full analysis set (randomised) | |
|  | **all obs (N=9)** |
| **Site name** |  |
| Akademiska | 3 (33.33%) |
| OUS | 6 (66.67%) |
| **Gender** |  |
| Male | 2 (22.22%) |
| Female | 7 (77.78%) |
| **Age (years)** |  |
| n | 9 |
| Mean (sd) | 53.28 (7.60) |
| IQR | 6.00 |
| min - max | 38.90 - 66.70 |
| **Marital status** |  |
| Married | 5 (55.56%) |
| Single | 0 (0.00%) |
| Divorsed | 0 (0.00%) |
| Cohabitant | 3 (33.33%) |
| Partner | 1 (11.11%) |
| **Number of children** |  |
| n | 9 |
| Mean (sd) | 1.78 (1.09) |
| IQR | 1.00 |
| min - max | 0.00 - 4.00 |
| **Working?** |  |
| Yes | 5 (55.56%) |
| No | 4 (44.44%) |
| **Working hours per week** |  |
| n | 5 |
| Mean (sd) | 26.60 (16.82) |
| IQR | 18.00 |
| min - max | 0.00 - 40.00 |
| **Years not working** |  |
| n | 4 |
| Mean (sd) | 2.00 (0.82) |
| IQR | 0.50 |
| min - max | 1.00 - 3.00 |
| **Type of governmental support** |  |
| Alderstrygd, førtidspensjon (AFP) eller etterlattepensjon | 0 (0.00%) |
| Sykepenger helt (er helt sykmeldt) | 1 (11.11%) |
| Sykepenger delvis (er delvis sykmeldt) | 0 (0.00%) |
| Arbeidsavklaringspenger (AAP) | 3 (33.33%) |
| Uføreytelse/pensjon, hel | 1 (11.11%) |
| Uføreytelse/pensjon, delvis | 1 (11.11%) |
| Mottar ingen stønad, får lønn fra arbeidsgiver | 3 (33.33%) |
| **Completed education** |  |
| Grunnskole | 0 (0.00%) |
| Yrkesskole | 0 (0.00%) |
| Videregående/Gymnas | 4 (44.44%) |
| Høyskole, universitet < 4 år | 4 (44.44%) |
| Høyskole, universitet > 4 år | 1 (11.11%) |
| **PCS Total score** |  |
| n | 9 |
| Mean (sd) | 17.56 (6.78) |
| IQR | 10.00 |
| min - max | 8.00 - 28.00 |
| **PCS Rumination** |  |
| n | 9 |
| Mean (sd) | 7.56 (3.61) |
| IQR | 4.00 |
| min - max | 3.00 - 14.00 |
| **PCS Magnification** |  |
| n | 9 |
| Mean (sd) | 2.22 (1.64) |
| IQR | 2.00 |
| min - max | 0.00 - 5.00 |
| **PCS Helplessness** |  |
| n | 9 |
| Mean (sd) | 7.78 (3.07) |
| IQR | 4.00 |
| min - max | 4.00 - 14.00 |
| **PCS Total score dichotomised at 24** |  |
| PCS ≤ 24 | 7 (77.78%) |
| PCS > 24 | 2 (22.22%) |
| **Treatment for neuropatic pain?** |  |
| No | 6 (66.67%) |
| Yes | 3 (33.33%) |
| **Amitriptyline** |  |
| No | 8 (88.89%) |
| Yes | 1 (11.11%) |
| **Gabapentin** |  |
| No | 7 (77.78%) |
| Yes | 2 (22.22%) |
| **Pregabalin** |  |
| No | 8 (88.89%) |
| Yes | 1 (11.11%) |
| **Duloxetine** |  |
| No | 9 (100.00%) |
| **Treatment with other non-opoids?** |  |
| No | 2 (22.22%) |
| Yes | 7 (77.78%) |
| **Paracetamol** |  |
| No | 4 (44.44%) |
| Yes | 5 (55.56%) |
| **NSAIDs** |  |
| No | 6 (66.67%) |
| Yes | 3 (33.33%) |
| **Antidepressiva** |  |
| No | 9 (100.00%) |
| **Treatmetn with opoids?** |  |
| No | 6 (66.67%) |
| Yes | 3 (33.33%) |
| **Total daily morphine milligram equivalents** |  |
| n | 3 |
| Mean (sd) | 25.00 (6.24) |
| IQR | 6.00 |
| min - max | 18.00 - 30.00 |
| **Previous physiotherapy?** |  |
| Yes | 9 (100.00%) |
| **Previous chiropractor?** |  |
| No | 3 (33.33%) |
| Yes | 6 (66.67%) |
| **Previous psychologist?** |  |
| No | 7 (77.78%) |
| Yes | 2 (22.22%) |
| **Previous TENS?** |  |
| No | 1 (11.11%) |
| Yes | 8 (88.89%) |
| **Other previous treatment?** |  |
| No | 6 (66.67%) |
| Yes | 3 (33.33%) |
| **Other previous treatment, specify** |  |
| Dry needling, Blockad SI-led och rotblockad. | 1 |
| epidural injeksjon, iv infusjon lidokain, ketamin | 1 |
| Specialdiet via dietist, rotblockader x 2, ryggkirurgi, värmebad. | 1 |
| **Current physiotherapy?** |  |
| No | 8 (88.89%) |
| Yes | 1 (11.11%) |
| **Current chiropractor?** |  |
| No | 9 (100.00%) |
| **Current psychologist?** |  |
| No | 9 (100.00%) |
| **Current TENS** |  |
| No | 5 (55.56%) |
| Yes | 4 (44.44%) |
| **Other current treatment?** |  |
| No | 8 (88.89%) |
| Yes | 1 (11.11%) |
| **Other current treatment, specify** |  |
| Följer sjukgymnast-program hemma. | 1 |
| **Current back pain?** |  |
| No | 2 (22.22%) |
| Yes | 7 (77.78%) |
| **Duration of pain (years)** |  |
| n | 9 |
| Mean (sd) | 9.54 (11.02) |
| IQR | 7.20 |
| min - max | 1.20 - 36.00 |
| **Duration of current pain level (years)** |  |
| n | 9 |
| Mean (sd) | 3.51 (3.95) |
| IQR | 4.00 |
| min - max | 0.25 - 10.00 |
| **Weight (kg)** |  |
| n | 9 |
| Mean (sd) | 76.39 (11.43) |
| IQR | 18.00 |
| min - max | 60.00 - 92.50 |
| **Height (cm)** |  |
| n | 9 |
| Mean (sd) | 168.22 (9.07) |
| IQR | 11.00 |
| min - max | 155.00 - 183.00 |
| **BMI** |  |
| n | 9 |
| Mean (sd) | 26.89 (2.45) |
| IQR | 2.90 |
| min - max | 22.60 - 30.50 |

## Pain etc at baseline

| Mean pain etc at baseline | |
| --- | --- |
| Full analysis set (randomised) | |
|  | **all obs (N=9)** |
| **Strongest pain in leg** |  |
| n | 9 |
| Mean (sd) | 6.51 (0.97) |
| IQR | 1.29 |
| min - max | 5.43 - 8.00 |
| **Weakest pain in leg** |  |
| n | 9 |
| Mean (sd) | 3.97 (1.23) |
| IQR | 1.57 |
| min - max | 2.43 - 6.57 |
| **Most common pain in leg** |  |
| n | 9 |
| Mean (sd) | 5.13 (0.92) |
| IQR | 1.57 |
| min - max | 4.29 - 6.71 |
| **Pain now in leg** |  |
| n | 9 |
| Mean (sd) | 5.32 (0.95) |
| IQR | 1.45 |
| min - max | 4.14 - 6.71 |
| **Most common pain in back** |  |
| n | 7 |
| Mean (sd) | 4.98 (1.32) |
| IQR | 1.65 |
| min - max | 2.71 - 6.29 |
| **Pain unpleasantness** |  |
| n | 9 |
| Mean (sd) | 4.41 (1.42) |
| IQR | 2.24 |
| min - max | 2.00 - 6.29 |
| **Ability to do first activity (higher is better)** |  |
| n | 9 |
| Mean (sd) | 4.56 (0.51) |
| IQR | 0.43 |
| min - max | 3.57 - 5.14 |
| **Ability to do second activity (higher is better)** |  |
| n | 9 |
| Mean (sd) | 4.56 (0.72) |
| IQR | 1.00 |
| min - max | 3.57 - 5.86 |
| **Ability to do third activity (higher is better)** |  |
| n | 9 |
| Mean (sd) | 4.55 (0.69) |
| IQR | 0.43 |
| min - max | 3.71 - 5.83 |
| **Patient Specific Functional Scale (PSFS) Total Score** |  |
| n | 9 |
| Mean (sd) | 4.56 (0.53) |
| IQR | 0.76 |
| min - max | 3.90 - 5.38 |
| **EQ-5D-5L Utility index (Danish value set)** |  |
| n | 9 |
| Mean (sd) | 0.69 (0.16) |
| IQR | 0.30 |
| min - max | 0.48 - 0.87 |
| **EQ-5D-5L VAS** |  |
| n | 9 |
| Mean (sd) | 46.56 (16.03) |
| IQR | 25.00 |
| min - max | 26.00 - 70.00 |
| **Hopkins Symptom Checklist-25 mean score** |  |
| n | 9 |
| Mean (sd) | 1.74 (0.24) |
| IQR | 0.32 |
| min - max | 1.32 - 2.04 |
| **Insomnia Severity Index score** |  |
| n | 9 |
| Mean (sd) | 10.89 (1.90) |
| IQR | 3.00 |
| min - max | 8.00 - 14.00 |
| **HSCL score categorised at 1.75** |  |
| HSCL ≤ 1.75 | 4 (44.44%) |
| HSCL > 1.75 | 5 (55.56%) |
| **ISI score categorised at 15** |  |
| ISI 8-14 | 9 (100.00%) |
| ISI 15-28 | 0 (0.00%) |

# Treatment information

## Amplitude for sensory threshod

| Period | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
| Amplitude for sensory treshold | | | | | | |
|  | **1** | **2** | **3** | **4** | **5** | **6** |
| **2-01** |  |  |  |  |  |  |
|  | 0.75 | 0.8 | 0.85 | 0.85 | 0.95 | 0.9 |
| **2-03** |  |  |  |  |  |  |
|  | 1.75 | 2.15 | 1.7 | 1.75 | 1.75 | 1.3 |
| **2-04** |  |  |  |  |  |  |
|  | 1.3 | 1.5 | 1.6 | 1.35 | 1.3 | 1.3 |
| **2-05** |  |  |  |  |  |  |
|  | 0.95 | 2.35 | 2.3 | 2.8 | 1.65 | 2.5 |
| **2-06** |  |  |  |  |  |  |
|  | 1.3 | 1.7 | 2.2 | 2.2 | 2.5 | 2.4 |
| **2-07** |  |  |  |  |  |  |
|  | 2.45 | 2.65 | 2.7 | 2.65 | 2.6 | 3.15 |
| **3-002** |  |  |  |  |  |  |
|  | 0.35 | 0.25 | 0.1 | 0.2 | 0.2 | 0.3 |
| **3-004** |  |  |  |  |  |  |
|  | 0.5 | 0.85 | 0.35 | 1.8 | NA | 1.5 |
| **3-008** |  |  |  |  |  |  |
|  | 0.85 | 0.85 | 0.8 | 0.8 | 1 | 1 |

## Impedance

| Period | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
| Impedance | | | | | | |
|  | **1** | **2** | **3** | **4** | **5** | **6** |
| **2-01** |  |  |  |  |  |  |
|  | 400 | 412 | 400 | 412 | 387 | 400 |
| **2-03** |  |  |  |  |  |  |
|  | 375 | 362 | 425 | 375 | 387 | 437 |
| **2-04** |  |  |  |  |  |  |
|  | 400 | 400 | 400 | 387 | 375 | 400 |
| **2-05** |  |  |  |  |  |  |
|  | 450 | 425 | 450 | 462 | 437 | 425 |
| **2-06** |  |  |  |  |  |  |
|  | 437 | 450 | 425 | 412 | 435 | 425 |
| **2-07** |  |  |  |  |  |  |
|  | 275 | 300 | 362 | 362 | 312 | 375 |
| **3-002** |  |  |  |  |  |  |
|  | 482 | 425 | 462 | 475 | 475 | 512 |
| **3-004** |  |  |  |  |  |  |
|  | 450 | 512 | 412 | 450 | NA | 487 |
| **3-008** |  |  |  |  |  |  |
|  | 350 | 375 | 337 | 387 | 362 | 362 |

## Stimulation Amplitude as set before treatment period

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
|  | 0 | 0.45 | 0 | 0.5 | 0 | 0.55 | 0 |
| **2-03** |  |  |  |  |  |  |  |
|  | 0 | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-04** |  |  |  |  |  |  |  |
|  | 0 | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-05** |  |  |  |  |  |  |  |
|  | 0 | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-06** |  |  |  |  |  |  |  |
|  | 0 | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-07** |  |  |  |  |  |  |  |
|  | 0 | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **3-002** |  |  |  |  |  |  |  |
|  | 0 | 0.2 | 0 | 0.05 | 0 | 0.1 | 0 |
| **3-004** |  |  |  |  |  |  |  |
|  | 0 | 0.3 | 0 | 0.15 | 0 | 0.6 | 0 |
| **3-008** |  |  |  |  |  |  |  |
|  | 0 | 0.5 | 0 | 0.25 | 0 | 0.6 | 0 |

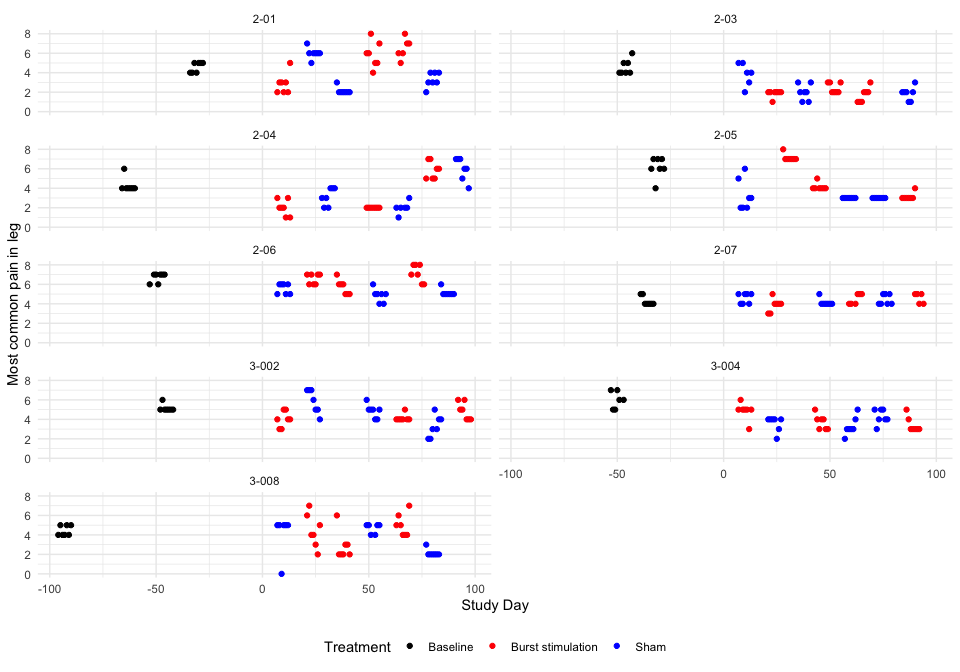
## Stimulation amplitude as registered after treatment period

| Full analysis set | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Stimulation Amplitude from previous period | | | | | | |
|  | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |
|  | 0.45 | 0 | 0.5 | 0 | 0.55 | 0 |
| **2-03** |  |  |  |  |  |  |
|  | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-04** |  |  |  |  |  |  |
|  | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-05** |  |  |  |  |  |  |
|  | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-06** |  |  |  |  |  |  |
|  | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **2-07** |  |  |  |  |  |  |
|  | 0.6 | 0 | 0.6 | 0 | 0.6 | 0 |
| **3-002** |  |  |  |  |  |  |
|  | 0.2 | 0 | 0.05 | 0 | 0.1 | 0 |
| **3-004** |  |  |  |  |  |  |
|  | 0.3 | 0 | 0.15 | 0 | 0.6 | NA |
| **3-008** |  |  |  |  |  |  |
|  | 0.5 | 0 | 0.25 | 0 | 0.6 | NA |

# Analysis

## Primary outcome: Usual pain intensity in lower extremity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Most common pain in leg | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.57 (0.53) | 2.86 (1.07) | 6.00 (0.58) | 5.86 (1.35) | 2.14 (0.38) | 6.50 (1.05) | 3.29 (0.76) |
| IQR | 1.00 | 1.00 | 0.00 | 1.50 | 0.00 | 1.00 | 1.00 |
| min - max | 4.00 - 5.00 | 2.00 - 5.00 | 5.00 - 7.00 | 4.00 - 8.00 | 2.00 - 3.00 | 5.00 - 8.00 | 2.00 - 4.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.57 (0.79) | 1.86 (0.38) | 3.83 (1.17) | 2.43 (0.53) | 2.00 (0.82) | 1.71 (0.76) | 1.86 (0.69) |
| IQR | 1.00 | 0.00 | 1.50 | 1.00 | 1.00 | 1.00 | 0.50 |
| min - max | 4.00 - 6.00 | 1.00 - 2.00 | 2.00 - 5.00 | 2.00 - 3.00 | 1.00 - 3.00 | 1.00 - 3.00 | 1.00 - 3.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.29 (0.76) | 2.00 (0.82) | 3.14 (0.90) | 2.00 (0.00) | 2.00 (0.63) | 5.86 (0.90) | 6.00 (1.15) |
| IQR | 0.00 | 1.00 | 1.50 | 0.00 | 0.00 | 1.50 | 1.50 |
| min - max | 4.00 - 6.00 | 1.00 - 3.00 | 2.00 - 4.00 | 2.00 - 2.00 | 1.00 - 3.00 | 5.00 - 7.00 | 4.00 - 7.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.14 (1.07) | 7.14 (0.38) | 3.29 (1.60) | 4.14 (0.38) | 3.00 (0.00) | 3.14 (0.38) | 3.00 (0.00) |
| IQR | 1.00 | 0.00 | 2.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| min - max | 4.00 - 7.00 | 7.00 - 8.00 | 2.00 - 6.00 | 4.00 - 5.00 | 3.00 - 3.00 | 3.00 - 4.00 | 3.00 - 3.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.71 (0.49) | 6.57 (0.53) | 5.57 (0.53) | 5.71 (0.76) | 4.86 (0.69) | 7.14 (0.90) | 5.14 (0.38) |
| IQR | 0.50 | 1.00 | 1.00 | 1.00 | 0.50 | 1.50 | 0.00 |
| min - max | 6.00 - 7.00 | 6.00 - 7.00 | 5.00 - 6.00 | 5.00 - 7.00 | 4.00 - 6.00 | 6.00 - 8.00 | 5.00 - 6.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 4.29 (0.49) | 3.86 (0.69) | 4.57 (0.53) | 4.50 (0.55) | 4.14 (0.38) | 4.60 (0.55) | 4.43 (0.53) |
| IQR | 0.50 | 0.50 | 1.00 | 1.00 | 0.00 | 1.00 | 1.00 |
| min - max | 4.00 - 5.00 | 3.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.14 (0.38) | 4.00 (0.82) | 5.86 (1.21) | 4.14 (0.38) | 4.86 (0.69) | 4.86 (0.90) | 3.29 (1.11) |
| IQR | 0.00 | 1.00 | 2.00 | 0.00 | 0.50 | 1.50 | 1.50 |
| min - max | 5.00 - 6.00 | 3.00 - 5.00 | 4.00 - 7.00 | 4.00 - 5.00 | 4.00 - 6.00 | 4.00 - 6.00 | 2.00 - 5.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.00 (0.89) | 4.86 (0.90) | 3.57 (0.79) | 3.71 (0.76) | 3.29 (0.95) | 3.43 (0.79) | 4.29 (0.76) |
| IQR | 1.50 | 0.00 | 0.50 | 1.00 | 0.50 | 0.50 | 1.00 |
| min - max | 5.00 - 7.00 | 3.00 - 6.00 | 2.00 - 4.00 | 3.00 - 5.00 | 2.00 - 5.00 | 3.00 - 5.00 | 3.00 - 5.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.43 (0.53) | 4.43 (1.72) | 4.17 (2.04) | 2.86 (1.46) | 4.67 (0.52) | 5.00 (1.15) | 2.14 (0.38) |
| IQR | 1.00 | 2.00 | 0.00 | 1.00 | 0.75 | 1.50 | 0.00 |
| min - max | 4.00 - 5.00 | 2.00 - 7.00 | 0.00 - 5.00 | 2.00 - 6.00 | 4.00 - 5.00 | 4.00 - 7.00 | 2.00 - 3.00 |

### Hypothesis test

Most common pain in leg

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -3.143 | 3.714 | 3.214 | 1.262 |
| 2-03 | -1.976 | 0.429 | -0.143 | -0.563 |
| 2-04 | -1.143 | 0.000 | -0.143 | -0.429 |
| 2-05 | 3.857 | 1.143 | 0.143 | 1.714 |
| 2-06 | 1.000 | 0.857 | 2.000 | 1.286 |
| 2-07 | -0.714 | 0.357 | 0.171 | -0.062 |
| 3-002 | -1.857 | -0.714 | 1.571 | -0.333 |
| 3-004 | 1.286 | 0.429 | -0.857 | 0.286 |
| 3-008 | 0.262 | -1.810 | 2.857 | 0.436 |

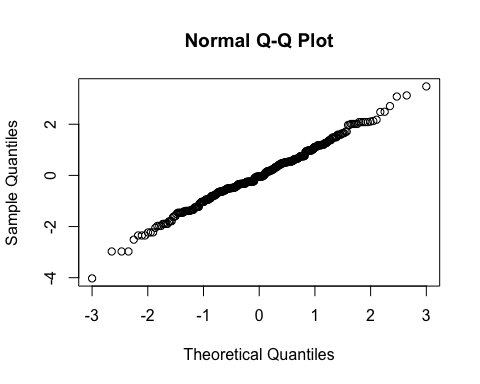
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.24.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.058 | 0.278 | 0.000 | 0.513 | 1.603 |
| 2-03 | -0.355 | 0.278 | 0.202 | -0.900 | 0.190 |
| 2-04 | -0.290 | 0.278 | 0.296 | -0.836 | 0.255 |
| 2-05 | 1.475 | 0.278 | 0.000 | 0.930 | 2.020 |
| 2-06 | 1.125 | 0.278 | 0.000 | 0.579 | 1.670 |
| 2-07 | 0.004 | 0.278 | 0.989 | -0.541 | 0.549 |
| 3-002 | -0.200 | 0.278 | 0.473 | -0.745 | 0.345 |
| 3-004 | 0.307 | 0.278 | 0.270 | -0.238 | 0.852 |
| 3-008 | 0.484 | 0.278 | 0.082 | -0.061 | 1.029 |

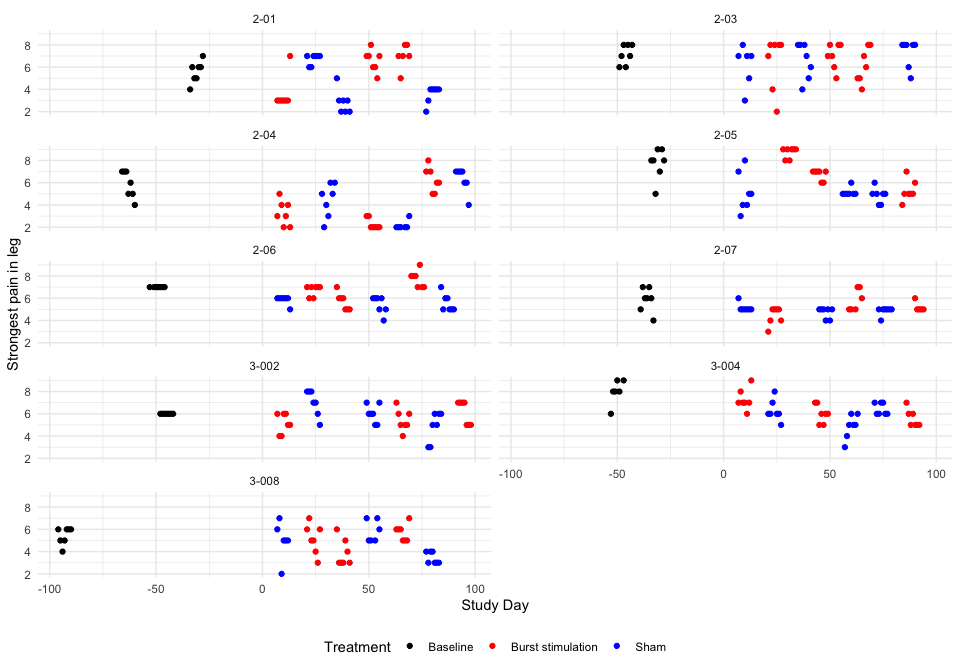
Overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.858 | 0.345 | 0 | 3.181 | 4.534 |
| Burst stimulation | 4.263 | 0.345 | 0 | 3.587 | 4.940 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.406 | 0.278 | 0.145 | -0.139 | 0.951 |

## Secondary outcome: Highest pain intensity in lower extremity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Strongest pain in leg | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 5.57 (0.98) | 3.57 (1.51) | 6.71 (0.49) | 6.57 (0.98) | 2.86 (1.07) | 7.00 (1.10) | 3.57 (0.79) |
| IQR | 1.00 | 0.00 | 0.50 | 1.00 | 1.00 | 0.75 | 0.50 |
| min - max | 4.00 - 7.00 | 3.00 - 7.00 | 6.00 - 7.00 | 5.00 - 8.00 | 2.00 - 5.00 | 5.00 - 8.00 | 2.00 - 4.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 7.14 (0.90) | 6.43 (2.44) | 6.17 (1.83) | 7.00 (1.15) | 6.57 (1.62) | 6.14 (1.57) | 7.29 (1.25) |
| IQR | 1.50 | 2.50 | 1.50 | 1.50 | 2.50 | 2.50 | 1.00 |
| min - max | 6.00 - 8.00 | 2.00 - 8.00 | 3.00 - 8.00 | 5.00 - 8.00 | 4.00 - 8.00 | 4.00 - 8.00 | 5.00 - 8.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 5.86 (1.21) | 3.29 (1.11) | 4.43 (1.51) | 2.29 (0.49) | 2.17 (0.41) | 6.29 (1.11) | 6.29 (1.11) |
| IQR | 2.00 | 1.50 | 2.00 | 0.50 | 0.00 | 1.50 | 1.00 |
| min - max | 4.00 - 7.00 | 2.00 - 5.00 | 2.00 - 6.00 | 2.00 - 3.00 | 2.00 - 3.00 | 5.00 - 8.00 | 4.00 - 7.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 7.71 (1.38) | 8.71 (0.49) | 5.14 (1.77) | 6.71 (0.49) | 5.14 (0.38) | 5.29 (0.95) | 4.86 (0.69) |
| IQR | 1.00 | 0.50 | 2.00 | 0.50 | 0.00 | 0.50 | 0.50 |
| min - max | 5.00 - 9.00 | 8.00 - 9.00 | 3.00 - 8.00 | 6.00 - 7.00 | 5.00 - 6.00 | 4.00 - 7.00 | 4.00 - 6.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 7.00 (0.00) | 6.71 (0.49) | 5.86 (0.38) | 5.71 (0.76) | 5.43 (0.79) | 7.71 (0.76) | 5.57 (0.79) |
| IQR | 0.00 | 0.50 | 0.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| min - max | 7.00 - 7.00 | 6.00 - 7.00 | 5.00 - 6.00 | 5.00 - 7.00 | 4.00 - 6.00 | 7.00 - 9.00 | 5.00 - 7.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 5.86 (1.07) | 4.43 (0.79) | 5.14 (0.38) | 5.83 (0.98) | 4.71 (0.49) | 5.20 (0.45) | 4.86 (0.38) |
| IQR | 1.00 | 1.00 | 0.00 | 1.75 | 0.50 | 0.00 | 0.00 |
| min - max | 4.00 - 7.00 | 3.00 - 5.00 | 5.00 - 6.00 | 5.00 - 7.00 | 4.00 - 5.00 | 5.00 - 6.00 | 4.00 - 5.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.00 (0.00) | 5.14 (0.90) | 7.00 (1.15) | 5.43 (0.98) | 6.00 (0.82) | 6.14 (1.07) | 4.86 (1.35) |
| IQR | 0.00 | 1.50 | 1.50 | 1.00 | 1.00 | 2.00 | 2.00 |
| min - max | 6.00 - 6.00 | 4.00 - 6.00 | 5.00 - 8.00 | 4.00 - 7.00 | 5.00 - 7.00 | 5.00 - 7.00 | 3.00 - 6.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 8.00 (1.10) | 7.29 (0.95) | 6.29 (0.95) | 6.00 (0.82) | 4.86 (1.07) | 5.57 (0.79) | 6.43 (0.53) |
| IQR | 0.75 | 0.50 | 0.50 | 1.00 | 1.00 | 1.00 | 1.00 |
| min - max | 6.00 - 9.00 | 6.00 - 9.00 | 5.00 - 8.00 | 5.00 - 7.00 | 3.00 - 6.00 | 5.00 - 7.00 | 6.00 - 7.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 5.43 (0.79) | 5.14 (1.35) | 5.00 (1.67) | 3.86 (1.21) | 5.83 (0.98) | 5.71 (0.76) | 3.43 (0.53) |
| IQR | 1.00 | 1.50 | 0.75 | 1.50 | 1.75 | 1.00 | 1.00 |
| min - max | 4.00 - 6.00 | 3.00 - 7.00 | 2.00 - 7.00 | 3.00 - 6.00 | 5.00 - 7.00 | 5.00 - 7.00 | 3.00 - 4.00 |

### Hypothesis test

Strongest pain in leg

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -3.143 | 3.714 | 3.429 | 1.333 |
| 2-03 | 0.262 | 0.429 | -1.143 | -0.151 |
| 2-04 | -1.143 | 0.119 | 0.000 | -0.341 |
| 2-05 | 3.571 | 1.571 | 0.429 | 1.857 |
| 2-06 | 0.857 | 0.286 | 2.143 | 1.095 |
| 2-07 | -0.714 | 1.119 | 0.343 | 0.249 |
| 3-002 | -1.857 | -0.571 | 1.286 | -0.381 |
| 3-004 | 1.000 | 1.143 | -0.857 | 0.429 |
| 3-008 | 0.143 | -1.976 | 2.286 | 0.151 |

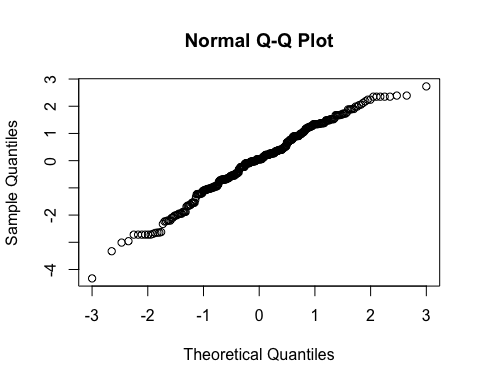
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.15.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.070 | 0.263 | 0.000 | 0.555 | 1.585 |
| 2-03 | -0.001 | 0.263 | 0.997 | -0.516 | 0.514 |
| 2-04 | -0.157 | 0.263 | 0.551 | -0.671 | 0.358 |
| 2-05 | 1.506 | 0.263 | 0.000 | 0.991 | 2.021 |
| 2-06 | 0.936 | 0.263 | 0.000 | 0.421 | 1.451 |
| 2-07 | 0.287 | 0.263 | 0.274 | -0.227 | 0.802 |
| 3-002 | -0.167 | 0.263 | 0.524 | -0.682 | 0.347 |
| 3-004 | 0.438 | 0.263 | 0.096 | -0.077 | 0.953 |
| 3-008 | 0.275 | 0.263 | 0.295 | -0.240 | 0.790 |

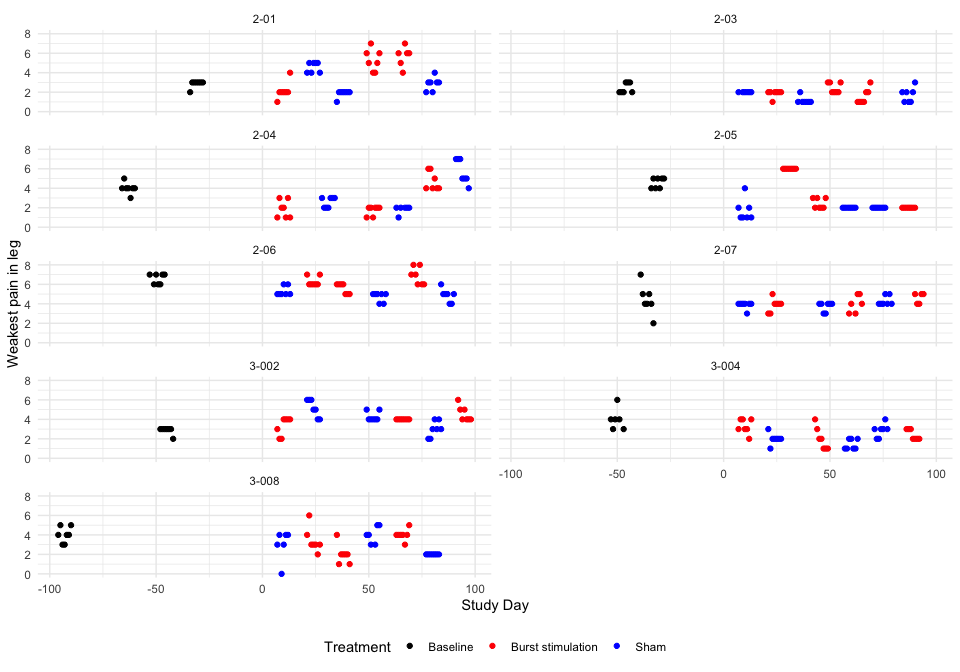
By treatment and Overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.284 | 0.297 | 0 | 4.701 | 5.866 |
| Burst stimulation | 5.753 | 0.297 | 0 | 5.170 | 6.335 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.469 | 0.263 | 0.074 | -0.046 | 0.984 |

## Secondary outcome: Lowest pain intensity in lower extremity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Weakest pain in leg | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 2.86 (0.38) | 2.14 (0.90) | 4.57 (0.53) | 5.29 (1.11) | 1.86 (0.38) | 5.67 (1.03) | 2.86 (0.69) |
| IQR | 0.00 | 0.00 | 1.00 | 1.50 | 0.00 | 0.75 | 0.50 |
| min - max | 2.00 - 3.00 | 1.00 - 4.00 | 4.00 - 5.00 | 4.00 - 7.00 | 1.00 - 2.00 | 4.00 - 7.00 | 2.00 - 4.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 2.43 (0.53) | 1.86 (0.38) | 2.00 (0.00) | 2.43 (0.53) | 1.14 (0.38) | 1.57 (0.79) | 1.71 (0.76) |
| IQR | 1.00 | 0.00 | 0.00 | 1.00 | 0.00 | 1.00 | 1.00 |
| min - max | 2.00 - 3.00 | 1.00 - 2.00 | 2.00 - 2.00 | 2.00 - 3.00 | 1.00 - 2.00 | 1.00 - 3.00 | 1.00 - 3.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.00 (0.58) | 1.86 (0.90) | 2.57 (0.53) | 1.71 (0.49) | 1.83 (0.41) | 4.71 (0.95) | 5.71 (1.25) |
| IQR | 0.00 | 1.50 | 1.00 | 0.50 | 0.00 | 1.50 | 2.00 |
| min - max | 3.00 - 5.00 | 1.00 - 3.00 | 2.00 - 3.00 | 1.00 - 2.00 | 1.00 - 2.00 | 4.00 - 6.00 | 4.00 - 7.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.57 (0.53) | 6.00 (0.00) | 1.71 (1.11) | 2.43 (0.53) | 2.00 (0.00) | 2.00 (0.00) | 2.00 (0.00) |
| IQR | 1.00 | 0.00 | 1.00 | 1.00 | 0.00 | 0.00 | 0.00 |
| min - max | 4.00 - 5.00 | 6.00 - 6.00 | 1.00 - 4.00 | 2.00 - 3.00 | 2.00 - 2.00 | 2.00 - 2.00 | 2.00 - 2.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.57 (0.53) | 6.29 (0.49) | 5.29 (0.49) | 5.57 (0.53) | 4.71 (0.49) | 6.86 (0.90) | 4.86 (0.69) |
| IQR | 1.00 | 0.50 | 0.50 | 1.00 | 0.50 | 1.50 | 0.50 |
| min - max | 6.00 - 7.00 | 6.00 - 7.00 | 5.00 - 6.00 | 5.00 - 6.00 | 4.00 - 5.00 | 6.00 - 8.00 | 4.00 - 6.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 4.43 (1.51) | 3.86 (0.69) | 3.86 (0.38) | 4.00 (0.89) | 3.71 (0.49) | 4.60 (0.55) | 4.29 (0.49) |
| IQR | 1.00 | 0.50 | 0.00 | 1.50 | 0.50 | 1.00 | 0.50 |
| min - max | 2.00 - 7.00 | 3.00 - 5.00 | 3.00 - 4.00 | 3.00 - 5.00 | 3.00 - 4.00 | 4.00 - 5.00 | 4.00 - 5.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 2.86 (0.38) | 3.29 (0.95) | 5.14 (0.90) | 4.00 (0.00) | 4.29 (0.49) | 4.57 (0.79) | 3.00 (0.82) |
| IQR | 0.00 | 1.50 | 1.50 | 0.00 | 0.50 | 1.00 | 1.00 |
| min - max | 2.00 - 3.00 | 2.00 - 4.00 | 4.00 - 6.00 | 4.00 - 4.00 | 4.00 - 5.00 | 4.00 - 6.00 | 2.00 - 4.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.00 (1.10) | 3.29 (0.76) | 2.00 (0.58) | 2.00 (1.15) | 1.43 (0.53) | 2.43 (0.53) | 2.86 (0.69) |
| IQR | 0.75 | 1.00 | 0.00 | 1.50 | 1.00 | 1.00 | 0.50 |
| min - max | 3.00 - 6.00 | 2.00 - 4.00 | 1.00 - 3.00 | 1.00 - 4.00 | 1.00 - 2.00 | 2.00 - 3.00 | 2.00 - 4.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.00 (0.82) | 3.43 (1.27) | 3.00 (1.55) | 2.00 (1.00) | 4.00 (0.89) | 4.00 (0.58) | 2.00 (0.00) |
| IQR | 1.00 | 0.50 | 1.00 | 0.50 | 1.50 | 0.00 | 0.00 |
| min - max | 3.00 - 5.00 | 2.00 - 6.00 | 0.00 - 4.00 | 1.00 - 4.00 | 3.00 - 5.00 | 3.00 - 5.00 | 2.00 - 2.00 |

### Hypothesis test

Weakest pain in leg

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -2.429 | 3.429 | 2.810 | 1.270 |
| 2-03 | -0.143 | 1.286 | -0.143 | 0.333 |
| 2-04 | -0.714 | -0.119 | -1.000 | -0.611 |
| 2-05 | 4.286 | 0.429 | 0.000 | 1.572 |
| 2-06 | 1.000 | 0.857 | 2.000 | 1.286 |
| 2-07 | 0.000 | 0.286 | 0.314 | 0.200 |
| 3-002 | -1.857 | -0.286 | 1.571 | -0.191 |
| 3-004 | 1.286 | 0.571 | -0.429 | 0.476 |
| 3-008 | 0.429 | -2.000 | 2.000 | 0.143 |

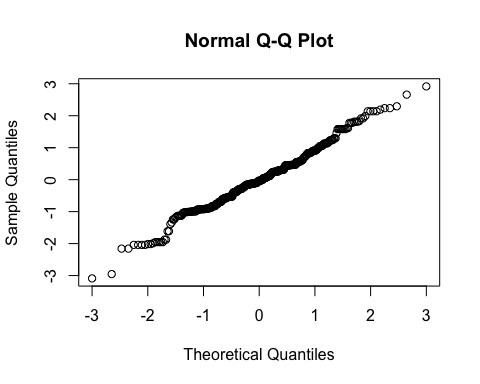
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.11.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.093 | 0.244 | 0.000 | 0.615 | 1.571 |
| 2-03 | 0.373 | 0.244 | 0.126 | -0.105 | 0.851 |
| 2-04 | -0.423 | 0.244 | 0.083 | -0.901 | 0.055 |
| 2-05 | 1.377 | 0.244 | 0.000 | 0.899 | 1.855 |
| 2-06 | 1.143 | 0.244 | 0.000 | 0.665 | 1.621 |
| 2-07 | 0.246 | 0.244 | 0.313 | -0.232 | 0.724 |
| 3-002 | -0.066 | 0.244 | 0.786 | -0.544 | 0.412 |
| 3-004 | 0.480 | 0.244 | 0.049 | 0.002 | 0.958 |
| 3-008 | 0.252 | 0.244 | 0.302 | -0.226 | 0.730 |

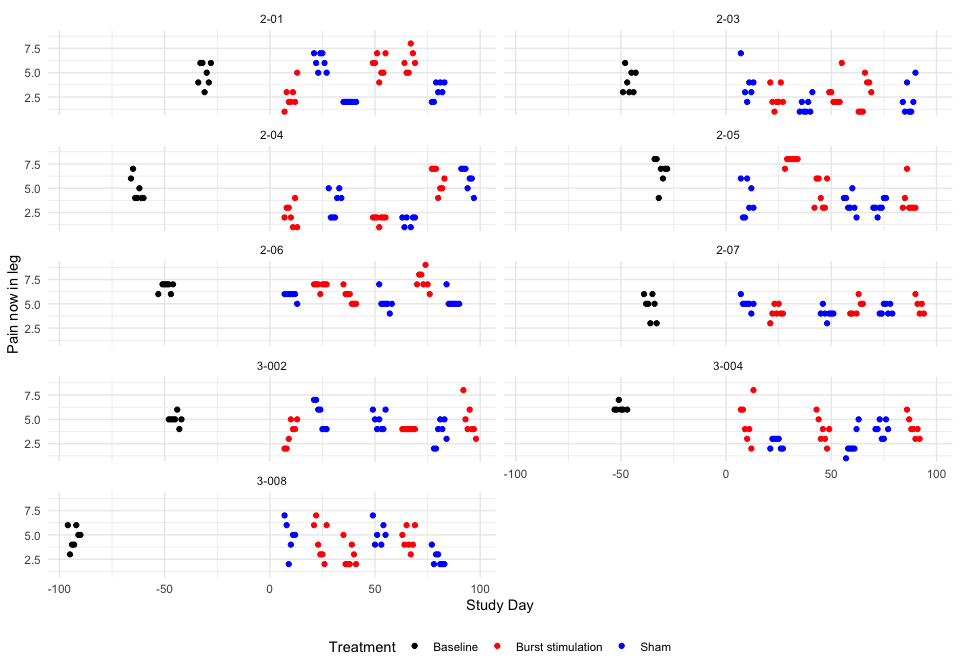
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.119 | 0.397 | 0 | 2.341 | 3.896 |
| Burst stimulation | 3.620 | 0.397 | 0 | 2.843 | 4.398 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.502 | 0.244 | 0.04 | 0.024 | 0.98 |

## Secondary outcome: Current pain intensity in lower extremity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Pain now in leg | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.86 (1.21) | 2.57 (1.27) | 6.14 (0.90) | 5.71 (1.11) | 2.00 (0.00) | 6.17 (1.17) | 3.14 (0.90) |
| IQR | 2.00 | 1.00 | 1.50 | 1.50 | 0.00 | 1.50 | 1.50 |
| min - max | 3.00 - 6.00 | 1.00 - 5.00 | 5.00 - 7.00 | 4.00 - 7.00 | 2.00 - 2.00 | 5.00 - 8.00 | 2.00 - 4.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.14 (1.21) | 2.43 (1.13) | 3.83 (1.72) | 2.86 (1.46) | 1.57 (0.79) | 2.71 (1.70) | 2.29 (1.60) |
| IQR | 2.00 | 1.00 | 1.00 | 1.00 | 1.00 | 3.00 | 2.00 |
| min - max | 3.00 - 6.00 | 1.00 - 4.00 | 2.00 - 7.00 | 2.00 - 6.00 | 1.00 - 3.00 | 1.00 - 5.00 | 1.00 - 5.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.86 (1.21) | 2.29 (1.11) | 3.43 (1.40) | 1.86 (0.38) | 1.67 (0.52) | 5.86 (1.21) | 6.00 (1.15) |
| IQR | 1.50 | 1.50 | 2.50 | 0.00 | 0.75 | 2.00 | 1.50 |
| min - max | 4.00 - 7.00 | 1.00 - 4.00 | 2.00 - 5.00 | 1.00 - 2.00 | 1.00 - 2.00 | 4.00 - 7.00 | 4.00 - 7.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.71 (1.38) | 7.86 (0.38) | 3.86 (1.77) | 4.43 (1.51) | 3.43 (0.98) | 3.71 (1.50) | 3.14 (0.69) |
| IQR | 1.00 | 0.00 | 3.00 | 3.00 | 1.00 | 0.50 | 0.50 |
| min - max | 4.00 - 8.00 | 7.00 - 8.00 | 2.00 - 6.00 | 3.00 - 6.00 | 2.00 - 5.00 | 3.00 - 7.00 | 2.00 - 4.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.71 (0.49) | 6.86 (0.38) | 5.86 (0.38) | 5.71 (0.76) | 5.14 (0.90) | 7.43 (0.98) | 5.29 (0.76) |
| IQR | 0.50 | 0.00 | 0.00 | 1.00 | 0.00 | 1.00 | 0.00 |
| min - max | 6.00 - 7.00 | 6.00 - 7.00 | 5.00 - 6.00 | 5.00 - 7.00 | 4.00 - 7.00 | 6.00 - 9.00 | 5.00 - 7.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 4.71 (1.25) | 4.14 (0.69) | 5.00 (0.58) | 4.67 (0.82) | 4.00 (0.58) | 4.80 (0.84) | 4.43 (0.53) |
| IQR | 1.50 | 0.50 | 0.00 | 1.00 | 0.00 | 1.00 | 1.00 |
| min - max | 3.00 - 6.00 | 3.00 - 5.00 | 4.00 - 6.00 | 4.00 - 6.00 | 3.00 - 5.00 | 4.00 - 6.00 | 4.00 - 5.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.00 (0.58) | 3.57 (1.27) | 5.43 (1.40) | 4.00 (0.00) | 4.86 (0.90) | 4.86 (1.68) | 3.57 (1.27) |
| IQR | 0.00 | 2.00 | 2.50 | 0.00 | 1.50 | 1.50 | 2.00 |
| min - max | 4.00 - 6.00 | 2.00 - 5.00 | 4.00 - 7.00 | 4.00 - 4.00 | 4.00 - 6.00 | 3.00 - 8.00 | 2.00 - 5.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.17 (0.41) | 4.71 (2.06) | 2.57 (0.53) | 3.86 (1.35) | 2.57 (1.40) | 4.14 (1.07) | 4.00 (0.82) |
| IQR | 0.00 | 2.50 | 1.00 | 1.50 | 1.00 | 1.00 | 1.00 |
| min - max | 6.00 - 7.00 | 2.00 - 8.00 | 2.00 - 3.00 | 2.00 - 6.00 | 1.00 - 5.00 | 3.00 - 6.00 | 3.00 - 5.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.71 (1.11) | 4.43 (1.90) | 4.83 (1.72) | 2.86 (1.21) | 5.17 (1.17) | 4.57 (1.13) | 2.57 (0.79) |
| IQR | 1.50 | 3.00 | 1.50 | 1.50 | 1.50 | 1.50 | 1.00 |
| min - max | 3.00 - 6.00 | 2.00 - 7.00 | 2.00 - 7.00 | 2.00 - 5.00 | 4.00 - 7.00 | 3.00 - 6.00 | 2.00 - 4.00 |

### Hypothesis test

Pain now in leg

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -3.571 | 3.714 | 3.024 | 1.056 |
| 2-03 | -1.405 | 1.286 | 0.429 | 0.103 |
| 2-04 | -1.143 | 0.190 | -0.143 | -0.365 |
| 2-05 | 4.000 | 1.000 | 0.571 | 1.857 |
| 2-06 | 1.000 | 0.571 | 2.143 | 1.238 |
| 2-07 | -0.857 | 0.667 | 0.371 | 0.060 |
| 3-002 | -1.857 | -0.857 | 1.286 | -0.476 |
| 3-004 | 2.143 | 1.286 | 0.143 | 1.191 |
| 3-008 | -0.405 | -2.310 | 2.000 | -0.238 |

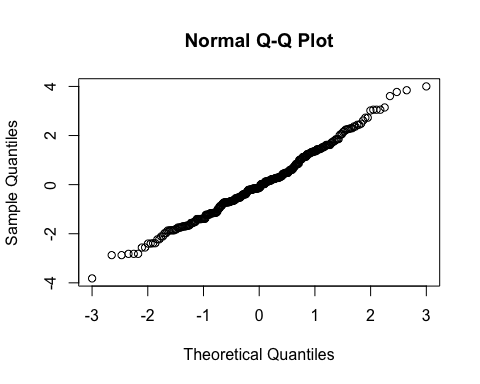
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.16.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 0.871 | 0.282 | 0.002 | 0.319 | 1.423 |
| 2-03 | 0.231 | 0.282 | 0.412 | -0.321 | 0.783 |
| 2-04 | -0.165 | 0.282 | 0.557 | -0.717 | 0.386 |
| 2-05 | 1.513 | 0.282 | 0.000 | 0.961 | 2.064 |
| 2-06 | 1.050 | 0.282 | 0.000 | 0.498 | 1.602 |
| 2-07 | 0.148 | 0.282 | 0.600 | -0.404 | 0.699 |
| 3-002 | -0.232 | 0.282 | 0.411 | -0.783 | 0.320 |
| 3-004 | 1.014 | 0.282 | 0.000 | 0.462 | 1.566 |
| 3-008 | 0.003 | 0.282 | 0.992 | -0.549 | 0.555 |

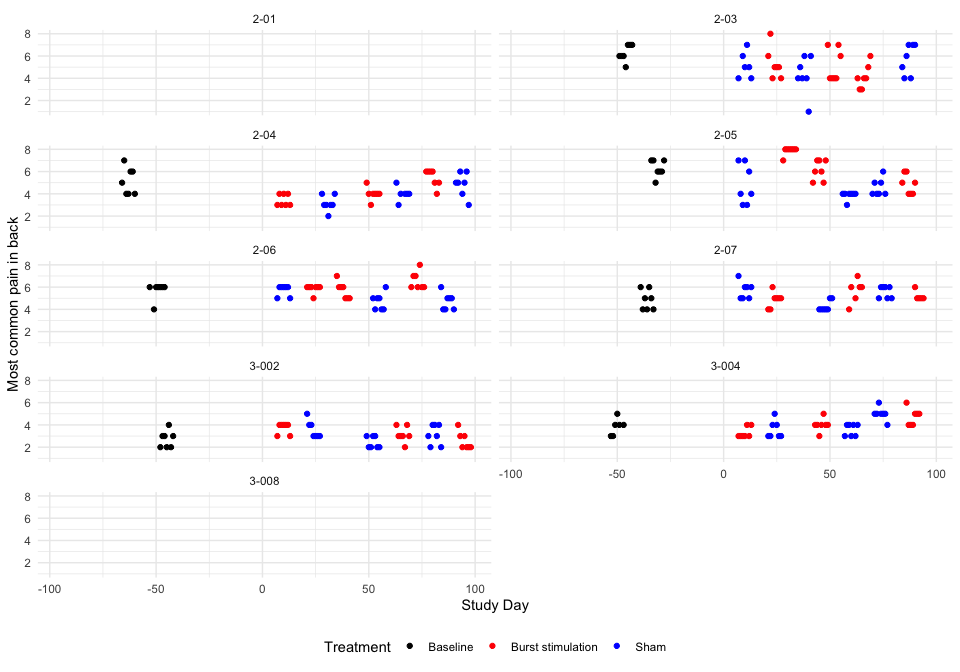
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.909 | 0.341 | 0 | 3.241 | 4.577 |
| Burst stimulation | 4.408 | 0.341 | 0 | 3.740 | 5.076 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.499 | 0.282 | 0.076 | -0.053 | 1.051 |

## Secondary outcome: Usual pain intensity in the back (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Most common pain in back | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean (sd) | NA | NA | NA | NA | NA | NA | NA |
| IQR | NA | NA | NA | NA | NA | NA | NA |
| min - max | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.29 (0.76) | 5.29 (1.38) | 5.17 (1.17) | 5.14 (1.46) | 4.29 (1.70) | 4.14 (1.07) | 5.71 (1.38) |
| IQR | 1.00 | 1.00 | 1.50 | 2.50 | 1.50 | 1.00 | 2.50 |
| min - max | 5.00 - 7.00 | 4.00 - 8.00 | 4.00 - 7.00 | 4.00 - 7.00 | 1.00 - 6.00 | 3.00 - 6.00 | 4.00 - 7.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 5.14 (1.21) | 3.43 (0.53) | 3.14 (0.69) | 4.00 (0.58) | 4.00 (0.63) | 5.43 (0.79) | 4.86 (1.07) |
| IQR | 2.00 | 1.00 | 0.50 | 0.00 | 0.00 | 1.00 | 1.00 |
| min - max | 4.00 - 7.00 | 3.00 - 4.00 | 2.00 - 4.00 | 3.00 - 5.00 | 3.00 - 5.00 | 4.00 - 6.00 | 3.00 - 6.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.29 (0.76) | 7.86 (0.38) | 4.86 (1.77) | 6.14 (0.90) | 3.86 (0.38) | 4.86 (0.90) | 4.57 (0.79) |
| IQR | 1.00 | 0.00 | 3.00 | 1.50 | 0.00 | 1.50 | 1.00 |
| min - max | 5.00 - 7.00 | 7.00 - 8.00 | 3.00 - 7.00 | 5.00 - 7.00 | 3.00 - 4.00 | 4.00 - 6.00 | 4.00 - 6.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.71 (0.76) | 5.86 (0.38) | 5.71 (0.49) | 5.71 (0.76) | 4.71 (0.76) | 6.57 (0.79) | 4.71 (0.76) |
| IQR | 0.00 | 0.00 | 0.50 | 1.00 | 1.00 | 1.00 | 1.00 |
| min - max | 4.00 - 6.00 | 5.00 - 6.00 | 5.00 - 6.00 | 5.00 - 7.00 | 4.00 - 6.00 | 6.00 - 8.00 | 4.00 - 6.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 4.86 (0.90) | 4.86 (0.69) | 5.71 (0.76) | 5.67 (1.03) | 4.29 (0.49) | 5.20 (0.45) | 5.57 (0.53) |
| IQR | 1.50 | 0.50 | 1.00 | 0.75 | 0.50 | 0.00 | 1.00 |
| min - max | 4.00 - 6.00 | 4.00 - 6.00 | 5.00 - 7.00 | 4.00 - 7.00 | 4.00 - 5.00 | 5.00 - 6.00 | 5.00 - 6.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 2.71 (0.76) | 3.71 (0.49) | 3.57 (0.79) | 3.14 (0.69) | 2.43 (0.53) | 2.57 (0.79) | 3.14 (0.90) |
| IQR | 1.00 | 0.50 | 1.00 | 0.50 | 1.00 | 1.00 | 1.50 |
| min - max | 2.00 - 4.00 | 3.00 - 4.00 | 3.00 - 5.00 | 2.00 - 4.00 | 2.00 - 3.00 | 2.00 - 4.00 | 2.00 - 4.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.83 (0.75) | 3.29 (0.49) | 3.57 (0.79) | 4.00 (0.58) | 3.57 (0.53) | 4.71 (0.76) | 5.00 (0.58) |
| IQR | 0.75 | 0.50 | 1.00 | 0.00 | 1.00 | 1.00 | 0.00 |
| min - max | 3.00 - 5.00 | 3.00 - 4.00 | 3.00 - 5.00 | 3.00 - 5.00 | 3.00 - 4.00 | 4.00 - 6.00 | 4.00 - 6.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean (sd) | NA | NA | NA | NA | NA | NA | NA |
| IQR | NA | NA | NA | NA | NA | NA | NA |
| min - max | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf | Inf - -Inf |

### Hypothesis test

Most common pain in back

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | NaN | NaN | NaN | NaN |
| 2-03 | 0.119 | 0.857 | -1.571 | -0.198 |
| 2-04 | 0.286 | 0.000 | 0.571 | 0.286 |
| 2-05 | 3.000 | 2.286 | 0.286 | 1.857 |
| 2-06 | 0.143 | 1.000 | 1.857 | 1.000 |
| 2-07 | -0.857 | 1.381 | -0.371 | 0.051 |
| 3-002 | 0.143 | 0.714 | -0.571 | 0.095 |
| 3-004 | -0.286 | 0.429 | -0.286 | -0.048 |
| 3-008 | NaN | NaN | NaN | NaN |

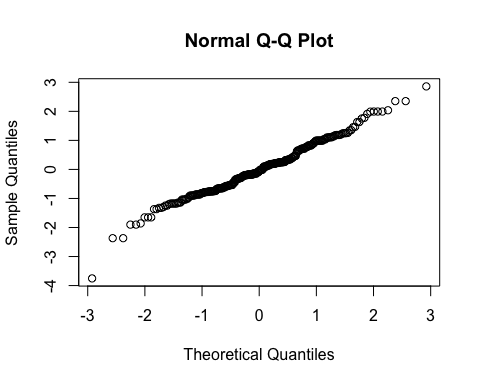
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.075.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-03 | -0.105 | 0.28 | 0.706 | -0.654 | 0.443 |
| 2-04 | 0.315 | 0.28 | 0.260 | -0.233 | 0.864 |
| 2-05 | 1.641 | 0.28 | 0.000 | 1.092 | 2.189 |
| 2-06 | 0.914 | 0.28 | 0.001 | 0.365 | 1.463 |
| 2-07 | 0.101 | 0.28 | 0.718 | -0.448 | 0.650 |
| 3-002 | 0.147 | 0.28 | 0.600 | -0.402 | 0.695 |
| 3-004 | 0.026 | 0.28 | 0.927 | -0.523 | 0.574 |

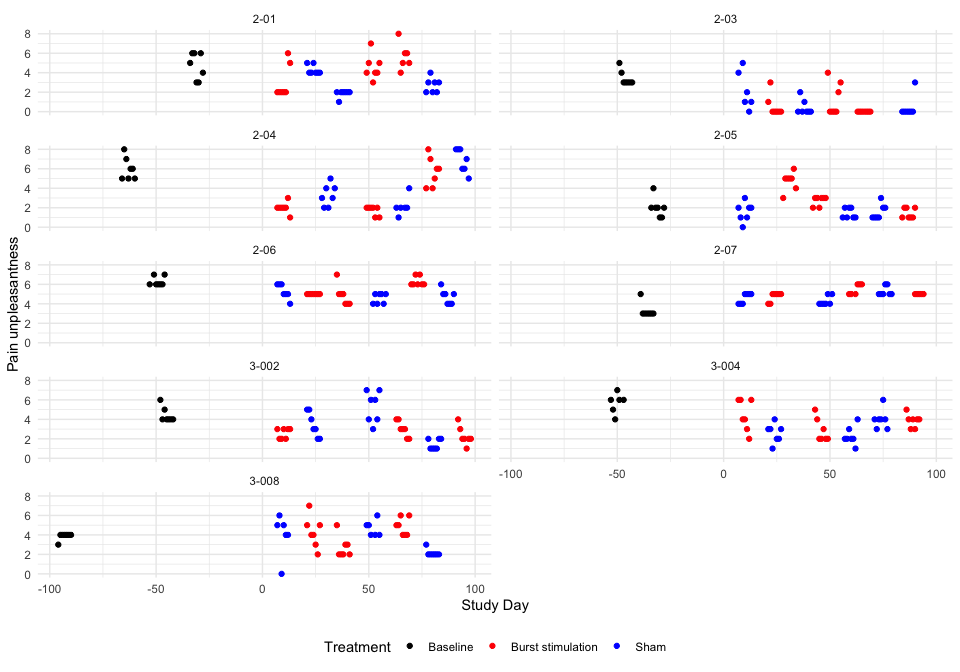
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 4.393 | 0.365 | 0 | 3.677 | 5.109 |
| Burst stimulation | 4.832 | 0.365 | 0 | 4.116 | 5.549 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.44 | 0.28 | 0.116 | -0.109 | 0.988 |

## Secondary outcome: Pain unpleasantness (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Pain unpleasantness | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.71 (1.38) | 3.00 (1.73) | 4.29 (0.49) | 4.57 (1.27) | 1.86 (0.38) | 5.67 (1.37) | 2.71 (0.76) |
| IQR | 2.50 | 1.50 | 0.50 | 1.00 | 0.00 | 1.00 | 1.00 |
| min - max | 3.00 - 6.00 | 2.00 - 6.00 | 4.00 - 5.00 | 3.00 - 7.00 | 1.00 - 2.00 | 4.00 - 8.00 | 2.00 - 4.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.43 (0.79) | 0.57 (1.13) | 2.17 (1.94) | 1.29 (1.70) | 0.43 (0.79) | 0.00 (0.00) | 0.43 (1.13) |
| IQR | 0.50 | 0.50 | 2.50 | 2.50 | 0.50 | 0.00 | 0.00 |
| min - max | 3.00 - 5.00 | 0.00 - 3.00 | 0.00 - 5.00 | 0.00 - 4.00 | 0.00 - 2.00 | 0.00 - 0.00 | 0.00 - 3.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 6.00 (1.15) | 2.00 (0.58) | 3.29 (1.11) | 1.71 (0.49) | 2.17 (0.98) | 5.71 (1.50) | 6.86 (1.21) |
| IQR | 1.50 | 0.00 | 1.50 | 0.50 | 0.00 | 2.00 | 2.00 |
| min - max | 5.00 - 8.00 | 1.00 - 3.00 | 2.00 - 5.00 | 1.00 - 2.00 | 1.00 - 4.00 | 4.00 - 8.00 | 5.00 - 8.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 2.00 (1.00) | 4.71 (0.95) | 1.57 (0.98) | 2.71 (0.49) | 1.43 (0.53) | 1.43 (0.53) | 1.57 (0.79) |
| IQR | 0.50 | 0.50 | 1.00 | 0.50 | 1.00 | 1.00 | 1.00 |
| min - max | 1.00 - 4.00 | 3.00 - 6.00 | 0.00 - 3.00 | 2.00 - 3.00 | 1.00 - 2.00 | 1.00 - 2.00 | 1.00 - 3.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 6.29 (0.49) | 5.00 (0.00) | 5.29 (0.76) | 4.86 (1.07) | 4.57 (0.53) | 6.29 (0.49) | 4.71 (0.76) |
| IQR | 0.50 | 0.00 | 1.00 | 1.00 | 1.00 | 0.50 | 1.00 |
| min - max | 6.00 - 7.00 | 5.00 - 5.00 | 4.00 - 6.00 | 4.00 - 7.00 | 4.00 - 5.00 | 6.00 - 7.00 | 4.00 - 6.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 3.29 (0.76) | 4.71 (0.49) | 4.57 (0.53) | 5.50 (0.55) | 4.29 (0.49) | 5.00 (0.00) | 5.29 (0.49) |
| IQR | 0.00 | 0.50 | 1.00 | 1.00 | 0.50 | 0.00 | 0.50 |
| min - max | 3.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 5.00 - 6.00 | 4.00 - 5.00 | 5.00 - 5.00 | 5.00 - 6.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.43 (0.79) | 2.57 (0.53) | 3.43 (1.27) | 3.00 (0.82) | 5.29 (1.60) | 2.29 (0.95) | 1.43 (0.53) |
| IQR | 0.50 | 1.00 | 2.00 | 1.00 | 2.50 | 0.50 | 1.00 |
| min - max | 4.00 - 6.00 | 2.00 - 3.00 | 2.00 - 5.00 | 2.00 - 4.00 | 3.00 - 7.00 | 1.00 - 4.00 | 1.00 - 2.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.67 (1.03) | 4.43 (1.62) | 2.57 (0.98) | 2.86 (1.21) | 2.29 (0.95) | 3.86 (0.69) | 4.00 (1.00) |
| IQR | 0.75 | 2.50 | 1.00 | 1.50 | 0.50 | 0.50 | 0.50 |
| min - max | 4.00 - 7.00 | 2.00 - 6.00 | 1.00 - 4.00 | 2.00 - 5.00 | 1.00 - 4.00 | 3.00 - 5.00 | 3.00 - 6.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 3.86 (0.38) | 4.29 (1.60) | 4.00 (2.10) | 2.71 (1.11) | 4.67 (0.82) | 4.86 (0.90) | 2.14 (0.38) |
| IQR | 0.00 | 1.50 | 1.00 | 1.00 | 1.00 | 1.50 | 0.00 |
| min - max | 3.00 - 4.00 | 2.00 - 7.00 | 0.00 - 6.00 | 2.00 - 5.00 | 4.00 - 6.00 | 4.00 - 6.00 | 2.00 - 3.00 |

### Hypothesis test

Pain unpleasantness

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -1.286 | 2.714 | 2.952 | 1.460 |
| 2-03 | -1.595 | 0.857 | -0.429 | -0.389 |
| 2-04 | -1.286 | -0.452 | -1.143 | -0.960 |
| 2-05 | 3.143 | 1.286 | -0.143 | 1.429 |
| 2-06 | -0.286 | 0.286 | 1.571 | 0.524 |
| 2-07 | 0.143 | 1.214 | -0.286 | 0.357 |
| 3-002 | -0.857 | -2.286 | 0.857 | -0.762 |
| 3-004 | 1.857 | 0.571 | -0.143 | 0.762 |
| 3-008 | 0.286 | -1.952 | 2.714 | 0.349 |

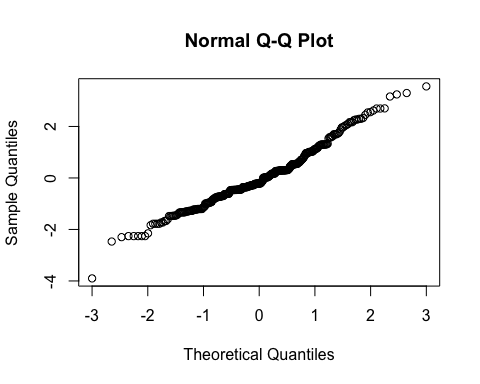
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.3.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
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## Warning: For this model type, `marginaleffects` only takes into account the  
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## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.223 | 0.289 | 0.000 | 0.656 | 1.790 |
| 2-03 | -0.238 | 0.289 | 0.410 | -0.805 | 0.329 |
| 2-04 | -0.751 | 0.289 | 0.009 | -1.318 | -0.184 |
| 2-05 | 1.235 | 0.289 | 0.000 | 0.668 | 1.802 |
| 2-06 | 0.487 | 0.289 | 0.092 | -0.080 | 1.054 |
| 2-07 | 0.355 | 0.289 | 0.220 | -0.212 | 0.922 |
| 3-002 | -0.575 | 0.289 | 0.047 | -1.142 | -0.008 |
| 3-004 | 0.684 | 0.289 | 0.018 | 0.117 | 1.251 |
| 3-008 | 0.397 | 0.289 | 0.170 | -0.170 | 0.964 |

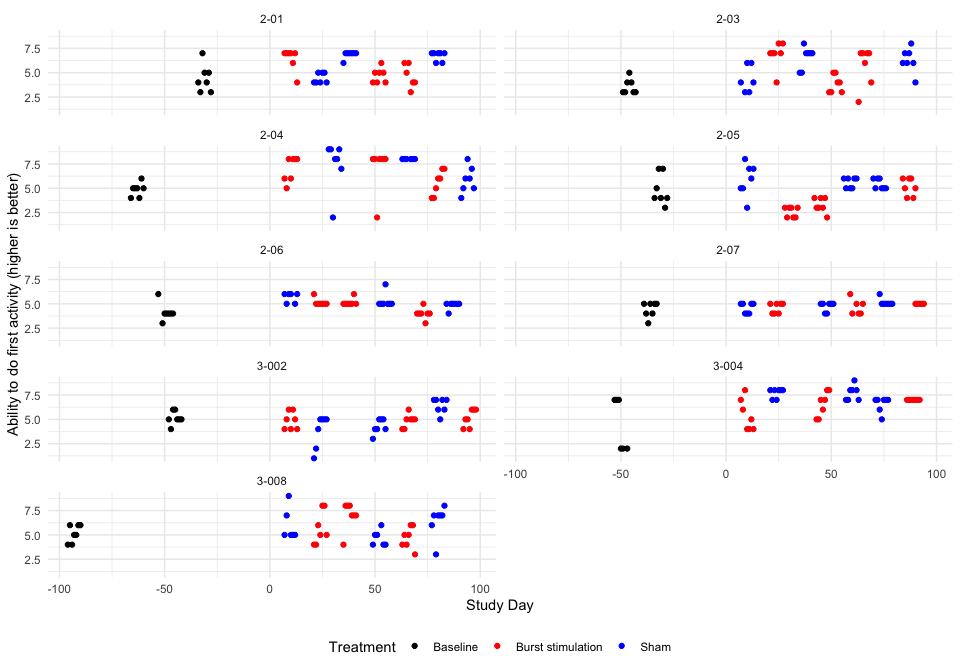
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.214 | 0.46 | 0 | 2.312 | 4.116 |
| Burst stimulation | 3.528 | 0.46 | 0 | 2.626 | 4.430 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.314 | 0.289 | 0.278 | -0.253 | 0.881 |

## Secondary outcome: Ability to do first activity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ability to do first activity (higher is better) | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.43 (1.40) | 6.43 (1.13) | 4.43 (0.53) | 4.71 (0.76) | 6.86 (0.38) | 4.67 (1.21) | 6.71 (0.49) |
| IQR | 1.50 | 0.50 | 1.00 | 1.00 | 0.00 | 1.75 | 0.50 |
| min - max | 3.00 - 7.00 | 4.00 - 7.00 | 4.00 - 5.00 | 4.00 - 6.00 | 6.00 - 7.00 | 3.00 - 6.00 | 6.00 - 7.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.57 (0.79) | 6.86 (1.35) | 4.33 (1.37) | 3.86 (0.90) | 6.57 (1.13) | 5.71 (1.98) | 6.29 (1.25) |
| IQR | 1.00 | 0.50 | 2.25 | 1.50 | 1.00 | 2.00 | 1.00 |
| min - max | 3.00 - 5.00 | 4.00 - 8.00 | 3.00 - 6.00 | 3.00 - 5.00 | 5.00 - 8.00 | 2.00 - 7.00 | 4.00 - 8.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.86 (0.69) | 7.00 (1.29) | 7.43 (2.51) | 7.14 (2.27) | 8.00 (0.00) | 5.57 (1.27) | 5.86 (1.35) |
| IQR | 0.50 | 2.00 | 1.50 | 0.00 | 0.00 | 2.00 | 1.50 |
| min - max | 4.00 - 6.00 | 5.00 - 8.00 | 2.00 - 9.00 | 2.00 - 8.00 | 8.00 - 8.00 | 4.00 - 7.00 | 4.00 - 8.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.86 (1.57) | 2.57 (0.53) | 5.86 (1.68) | 3.29 (0.76) | 5.57 (0.53) | 5.14 (0.90) | 5.43 (0.53) |
| IQR | 2.00 | 1.00 | 2.00 | 1.00 | 1.00 | 1.50 | 1.00 |
| min - max | 3.00 - 7.00 | 2.00 - 3.00 | 3.00 - 8.00 | 2.00 - 4.00 | 5.00 - 6.00 | 4.00 - 6.00 | 5.00 - 6.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.14 (0.90) | 5.14 (0.38) | 5.67 (0.52) | 5.14 (0.38) | 5.29 (0.76) | 4.00 (0.58) | 4.86 (0.38) |
| IQR | 0.00 | 0.00 | 0.75 | 0.00 | 0.00 | 0.00 | 0.00 |
| min - max | 3.00 - 6.00 | 5.00 - 6.00 | 5.00 - 6.00 | 5.00 - 6.00 | 5.00 - 7.00 | 3.00 - 5.00 | 4.00 - 5.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 4.43 (0.79) | 4.57 (0.53) | 4.57 (0.53) | 4.67 (0.82) | 4.71 (0.49) | 5.00 (0.00) | 5.14 (0.38) |
| IQR | 1.00 | 1.00 | 1.00 | 1.00 | 0.50 | 0.00 | 0.00 |
| min - max | 3.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 6.00 | 4.00 - 5.00 | 5.00 - 5.00 | 5.00 - 6.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.14 (0.69) | 4.86 (0.90) | 3.86 (1.68) | 4.86 (0.69) | 4.29 (0.76) | 5.14 (0.90) | 6.43 (0.79) |
| IQR | 0.50 | 1.50 | 2.00 | 0.50 | 1.00 | 1.50 | 1.00 |
| min - max | 4.00 - 6.00 | 4.00 - 6.00 | 1.00 - 5.00 | 4.00 - 6.00 | 3.00 - 5.00 | 4.00 - 6.00 | 5.00 - 7.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.50 (2.74) | 5.43 (1.62) | 7.71 (0.49) | 6.57 (1.27) | 7.71 (0.76) | 7.00 (0.00) | 6.57 (0.79) |
| IQR | 5.00 | 2.50 | 0.50 | 2.00 | 1.00 | 0.00 | 0.50 |
| min - max | 2.00 - 7.00 | 4.00 - 8.00 | 7.00 - 8.00 | 5.00 - 8.00 | 7.00 - 9.00 | 7.00 - 7.00 | 5.00 - 7.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 5.14 (0.90) | 5.71 (1.70) | 6.00 (1.67) | 7.00 (1.41) | 4.67 (0.82) | 4.71 (1.11) | 6.43 (1.62) |
| IQR | 1.50 | 2.50 | 1.50 | 1.00 | 1.00 | 1.50 | 0.50 |
| min - max | 4.00 - 6.00 | 4.00 - 8.00 | 5.00 - 9.00 | 4.00 - 8.00 | 4.00 - 6.00 | 3.00 - 6.00 | 3.00 - 8.00 |

### Hypothesis test

Ability to do first activity (higher is better)

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | 2.000 | -2.143 | -2.048 | -0.730 |
| 2-03 | 2.524 | -2.714 | -0.571 | -0.254 |
| 2-04 | -0.429 | -0.857 | -0.286 | -0.524 |
| 2-05 | -3.286 | -2.286 | -0.286 | -1.953 |
| 2-06 | -0.524 | -0.143 | -0.857 | -0.508 |
| 2-07 | 0.000 | -0.048 | -0.143 | -0.064 |
| 3-002 | 1.000 | 0.571 | -1.286 | 0.095 |
| 3-004 | -2.286 | -1.143 | 0.429 | -1.000 |
| 3-008 | -0.286 | 2.333 | -1.714 | 0.111 |

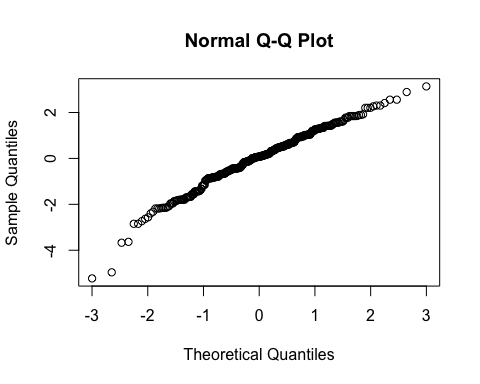
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.067.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.640 | 0.215 | 0.003 | -1.060 | -0.219 |
| 2-03 | -0.407 | 0.215 | 0.058 | -0.827 | 0.014 |
| 2-04 | -0.516 | 0.215 | 0.016 | -0.936 | -0.095 |
| 2-05 | -1.432 | 0.215 | 0.000 | -1.853 | -1.011 |
| 2-06 | -0.517 | 0.215 | 0.016 | -0.937 | -0.096 |
| 2-07 | -0.248 | 0.215 | 0.247 | -0.669 | 0.173 |
| 3-002 | -0.141 | 0.215 | 0.512 | -0.562 | 0.280 |
| 3-004 | -0.832 | 0.215 | 0.000 | -1.252 | -0.411 |
| 3-008 | -0.166 | 0.215 | 0.440 | -0.586 | 0.255 |

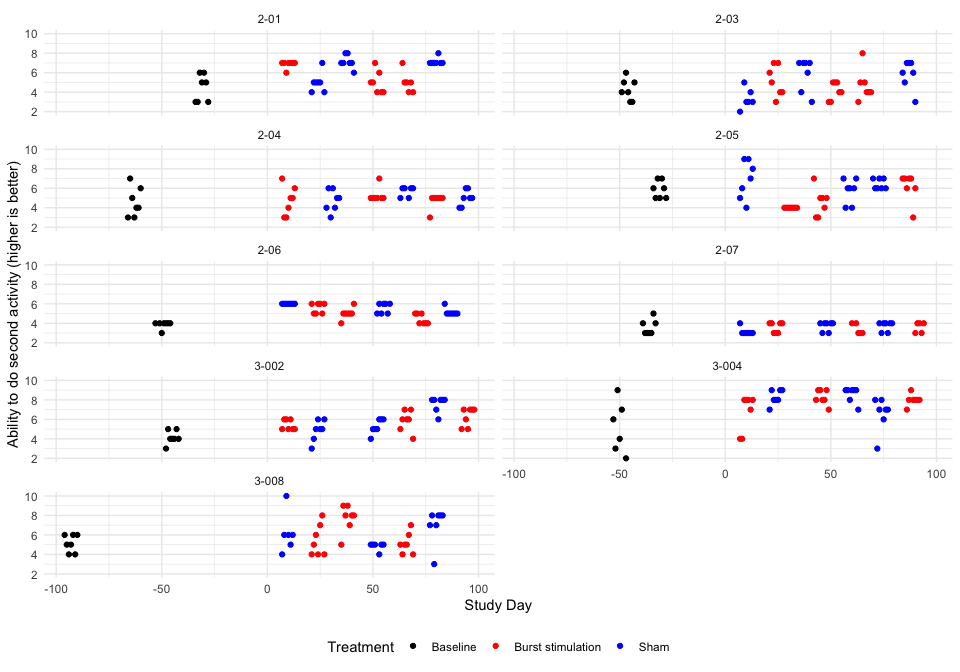
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.836 | 0.296 | 0 | 5.256 | 6.416 |
| Burst stimulation | 5.287 | 0.296 | 0 | 4.707 | 5.867 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.549 | 0.215 | 0.011 | -0.97 | -0.128 |

## Secondary outcome: Ability to do second activity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ability to do second activity (higher is better) | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.43 (1.40) | 6.86 (0.38) | 5.00 (1.00) | 5.00 (1.15) | 7.14 (0.69) | 5.00 (1.10) | 7.14 (0.38) |
| IQR | 2.50 | 0.00 | 0.50 | 1.50 | 0.50 | 0.75 | 0.00 |
| min - max | 3.00 - 6.00 | 6.00 - 7.00 | 4.00 - 7.00 | 4.00 - 7.00 | 6.00 - 8.00 | 4.00 - 7.00 | 7.00 - 8.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.29 (1.11) | 5.14 (1.57) | 3.33 (1.03) | 4.14 (0.90) | 5.86 (1.68) | 4.71 (1.60) | 5.86 (1.46) |
| IQR | 1.50 | 2.50 | 0.75 | 1.50 | 2.00 | 1.00 | 1.50 |
| min - max | 3.00 - 6.00 | 3.00 - 7.00 | 2.00 - 5.00 | 3.00 - 5.00 | 3.00 - 7.00 | 3.00 - 8.00 | 3.00 - 7.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.57 (1.51) | 4.71 (1.50) | 4.71 (1.11) | 5.29 (0.76) | 5.67 (0.52) | 4.71 (0.76) | 5.00 (0.82) |
| IQR | 2.00 | 2.00 | 1.50 | 0.00 | 0.75 | 0.00 | 1.00 |
| min - max | 3.00 - 7.00 | 3.00 - 7.00 | 3.00 - 6.00 | 5.00 - 7.00 | 5.00 - 6.00 | 3.00 - 5.00 | 4.00 - 6.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.86 (0.90) | 4.00 (0.00) | 6.86 (1.95) | 4.57 (1.40) | 5.71 (1.25) | 6.14 (1.46) | 6.43 (0.53) |
| IQR | 1.50 | 0.00 | 3.00 | 1.50 | 1.50 | 1.00 | 1.00 |
| min - max | 5.00 - 7.00 | 4.00 - 4.00 | 4.00 - 9.00 | 3.00 - 7.00 | 4.00 - 7.00 | 3.00 - 7.00 | 6.00 - 7.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.86 (0.38) | 5.57 (0.53) | 6.00 (0.00) | 5.00 (0.58) | 5.57 (0.53) | 4.43 (0.53) | 5.14 (0.38) |
| IQR | 0.00 | 1.00 | 0.00 | 0.00 | 1.00 | 1.00 | 0.00 |
| min - max | 3.00 - 4.00 | 5.00 - 6.00 | 6.00 - 6.00 | 4.00 - 6.00 | 5.00 - 6.00 | 4.00 - 5.00 | 5.00 - 6.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 5 | 7 | 5 | 7 |
| Mean (sd) | 3.57 (0.79) | 3.57 (0.53) | 3.14 (0.38) | 3.40 (0.55) | 3.71 (0.49) | 3.60 (0.55) | 3.71 (0.49) |
| IQR | 1.00 | 1.00 | 0.00 | 1.00 | 0.50 | 1.00 | 0.50 |
| min - max | 3.00 - 5.00 | 3.00 - 4.00 | 3.00 - 4.00 | 3.00 - 4.00 | 3.00 - 4.00 | 3.00 - 4.00 | 3.00 - 4.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.14 (0.69) | 5.43 (0.53) | 4.86 (1.07) | 5.86 (1.07) | 5.29 (0.76) | 6.29 (0.95) | 7.57 (0.79) |
| IQR | 0.50 | 1.00 | 1.00 | 1.00 | 1.00 | 1.50 | 0.50 |
| min - max | 3.00 - 5.00 | 5.00 - 6.00 | 3.00 - 6.00 | 4.00 - 7.00 | 4.00 - 6.00 | 5.00 - 7.00 | 6.00 - 8.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.17 (2.64) | 6.71 (1.89) | 8.29 (0.76) | 8.29 (0.76) | 8.57 (0.79) | 8.00 (0.58) | 6.57 (1.72) |
| IQR | 3.50 | 2.50 | 1.00 | 1.00 | 0.50 | 0.00 | 1.00 |
| min - max | 2.00 - 9.00 | 4.00 - 8.00 | 7.00 - 9.00 | 7.00 - 9.00 | 7.00 - 9.00 | 7.00 - 9.00 | 3.00 - 8.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 5.14 (0.90) | 5.43 (1.62) | 6.17 (2.04) | 7.71 (1.38) | 4.83 (0.41) | 5.14 (1.07) | 7.00 (1.83) |
| IQR | 1.50 | 2.50 | 0.75 | 1.00 | 0.00 | 1.00 | 1.00 |
| min - max | 4.00 - 6.00 | 4.00 - 8.00 | 4.00 - 10.00 | 5.00 - 9.00 | 4.00 - 5.00 | 4.00 - 7.00 | 3.00 - 8.00 |

### Hypothesis test

Ability to do second activity (higher is better)

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | 1.857 | -2.143 | -2.143 | -0.810 |
| 2-03 | 1.810 | -1.714 | -1.143 | -0.349 |
| 2-04 | 0.000 | -0.381 | -0.286 | -0.222 |
| 2-05 | -2.857 | -1.143 | -0.286 | -1.429 |
| 2-06 | -0.429 | -0.571 | -0.714 | -0.571 |
| 2-07 | 0.429 | -0.314 | -0.114 | 0.000 |
| 3-002 | 0.571 | 0.571 | -1.286 | -0.048 |
| 3-004 | -1.571 | -0.286 | 1.429 | -0.143 |
| 3-008 | -0.738 | 2.881 | -1.857 | 0.095 |

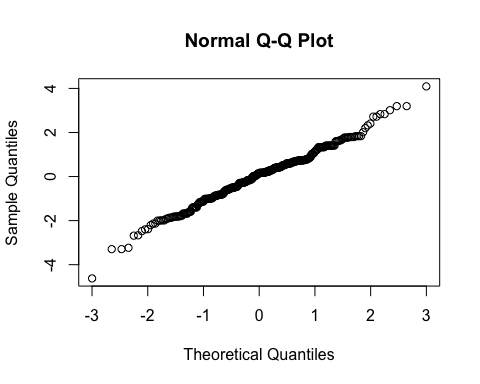
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.15.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
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## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.537 | 0.161 | 0.001 | -0.852 | -0.221 |
| 2-03 | -0.401 | 0.161 | 0.013 | -0.717 | -0.085 |
| 2-04 | -0.325 | 0.161 | 0.044 | -0.640 | -0.009 |
| 2-05 | -0.789 | 0.161 | 0.000 | -1.105 | -0.473 |
| 2-06 | -0.461 | 0.161 | 0.004 | -0.777 | -0.146 |
| 2-07 | -0.238 | 0.161 | 0.139 | -0.554 | 0.077 |
| 3-002 | -0.261 | 0.161 | 0.105 | -0.577 | 0.054 |
| 3-004 | -0.298 | 0.161 | 0.065 | -0.613 | 0.018 |
| 3-008 | -0.230 | 0.161 | 0.152 | -0.546 | 0.085 |

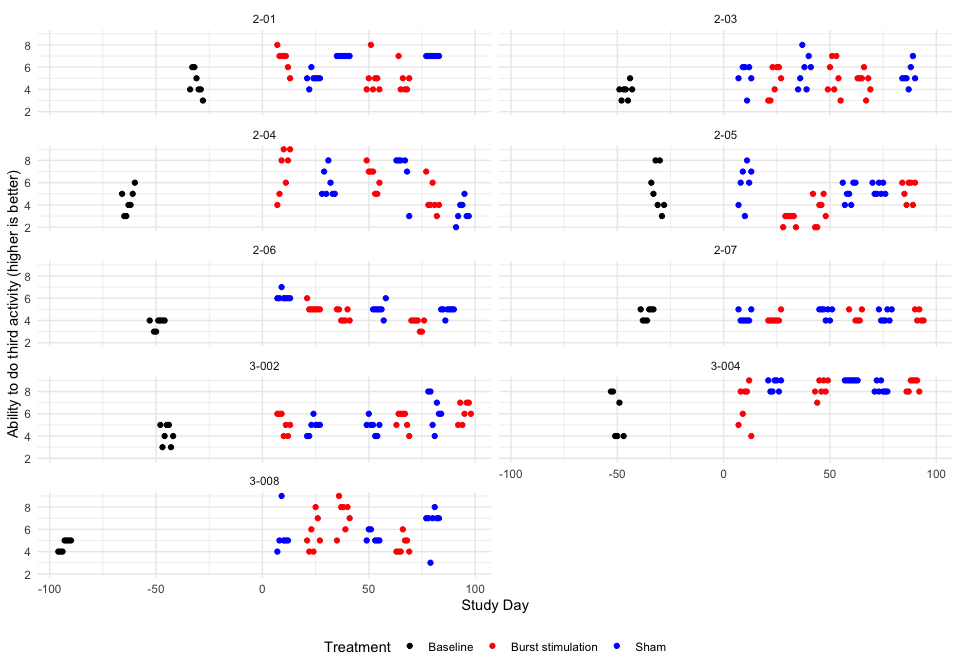
By treatment group and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.780 | 0.387 | 0 | 5.021 | 6.539 |
| Burst stimulation | 5.384 | 0.387 | 0 | 4.625 | 6.144 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.396 | 0.161 | 0.014 | -0.711 | -0.08 |

## Secondary outcome: Ability to do third activity (NRS)

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ability to do third activity (higher is better) | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.57 (1.13) | 6.71 (0.95) | 5.00 (0.58) | 5.00 (1.41) | 7.00 (0.00) | 4.83 (1.17) | 7.00 (0.00) |
| IQR | 1.50 | 0.50 | 0.00 | 1.00 | 0.00 | 1.00 | 0.00 |
| min - max | 3.00 - 6.00 | 5.00 - 8.00 | 4.00 - 6.00 | 4.00 - 8.00 | 7.00 - 7.00 | 4.00 - 7.00 | 7.00 - 7.00 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.86 (0.69) | 4.71 (1.38) | 5.17 (1.17) | 5.14 (1.57) | 5.71 (1.50) | 4.71 (0.95) | 5.29 (0.95) |
| IQR | 0.50 | 2.50 | 1.00 | 2.50 | 2.00 | 0.50 | 0.50 |
| min - max | 3.00 - 5.00 | 3.00 - 6.00 | 3.00 - 6.00 | 3.00 - 7.00 | 4.00 - 8.00 | 3.00 - 6.00 | 4.00 - 7.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.29 (1.11) | 7.00 (2.00) | 5.86 (1.21) | 6.43 (1.13) | 7.00 (2.00) | 4.57 (1.40) | 3.43 (0.98) |
| IQR | 1.50 | 3.00 | 1.50 | 1.50 | 0.75 | 1.00 | 1.00 |
| min - max | 3.00 - 6.00 | 4.00 - 9.00 | 5.00 - 8.00 | 5.00 - 8.00 | 3.00 - 8.00 | 3.00 - 7.00 | 2.00 - 5.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.43 (1.99) | 2.71 (0.49) | 5.86 (1.77) | 3.57 (1.27) | 5.14 (0.90) | 5.29 (0.95) | 5.43 (0.53) |
| IQR | 3.00 | 0.50 | 2.00 | 2.00 | 1.50 | 1.50 | 1.00 |
| min - max | 3.00 - 8.00 | 2.00 - 3.00 | 3.00 - 8.00 | 2.00 - 5.00 | 4.00 - 6.00 | 4.00 - 6.00 | 5.00 - 6.00 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.71 (0.49) | 5.14 (0.38) | 6.14 (0.38) | 4.43 (0.53) | 5.00 (0.58) | 3.71 (0.49) | 4.86 (0.38) |
| IQR | 0.50 | 0.00 | 0.00 | 1.00 | 0.00 | 0.50 | 0.00 |
| min - max | 3.00 - 4.00 | 5.00 - 6.00 | 6.00 - 7.00 | 4.00 - 5.00 | 4.00 - 6.00 | 3.00 - 4.00 | 4.00 - 5.00 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 5 | 7 | 5 | 7 |
| Mean (sd) | 4.57 (0.53) | 4.14 (0.38) | 4.29 (0.49) | 4.40 (0.55) | 4.71 (0.49) | 4.40 (0.55) | 4.43 (0.53) |
| IQR | 1.00 | 0.00 | 0.50 | 1.00 | 0.50 | 1.00 | 1.00 |
| min - max | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 | 4.00 - 5.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.14 (0.90) | 5.14 (0.90) | 4.86 (0.69) | 5.43 (0.79) | 4.86 (0.69) | 6.14 (0.90) | 6.29 (1.50) |
| IQR | 1.50 | 1.50 | 0.50 | 1.00 | 0.50 | 1.50 | 2.00 |
| min - max | 3.00 - 5.00 | 4.00 - 6.00 | 4.00 - 6.00 | 4.00 - 6.00 | 4.00 - 6.00 | 5.00 - 7.00 | 4.00 - 8.00 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.83 (2.04) | 6.86 (1.86) | 8.57 (0.53) | 8.29 (0.76) | 9.00 (0.00) | 8.57 (0.53) | 8.29 (0.49) |
| IQR | 3.75 | 2.50 | 1.00 | 1.00 | 0.00 | 1.00 | 0.50 |
| min - max | 4.00 - 8.00 | 4.00 - 9.00 | 8.00 - 9.00 | 7.00 - 9.00 | 9.00 - 9.00 | 8.00 - 9.00 | 8.00 - 9.00 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.57 (0.53) | 5.57 (1.51) | 5.50 (1.76) | 7.29 (1.38) | 5.33 (0.52) | 4.57 (0.79) | 6.57 (1.62) |
| IQR | 1.00 | 2.00 | 0.00 | 1.50 | 0.75 | 1.00 | 0.00 |
| min - max | 4.00 - 5.00 | 4.00 - 8.00 | 4.00 - 9.00 | 5.00 - 9.00 | 5.00 - 6.00 | 4.00 - 6.00 | 3.00 - 8.00 |

### Hypothesis test

Ability to do third activity (higher is better)

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | 1.714 | -2.000 | -2.167 | -0.818 |
| 2-03 | -0.452 | -0.571 | -0.571 | -0.531 |
| 2-04 | 1.143 | -0.571 | 1.143 | 0.572 |
| 2-05 | -3.143 | -1.571 | -0.143 | -1.619 |
| 2-06 | -1.000 | -0.571 | -1.143 | -0.905 |
| 2-07 | -0.143 | -0.314 | -0.029 | -0.162 |
| 3-002 | 0.286 | 0.571 | -0.143 | 0.238 |
| 3-004 | -1.714 | -0.714 | 0.286 | -0.714 |
| 3-008 | 0.071 | 1.952 | -2.000 | 0.008 |

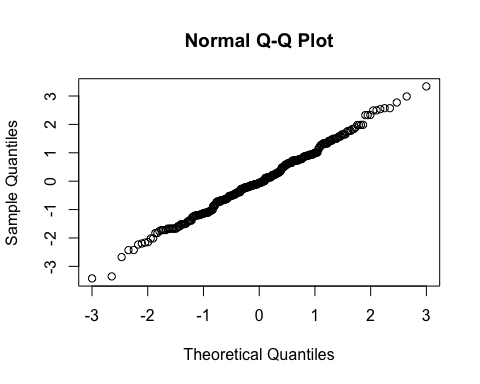
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.069.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
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## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.687 | 0.225 | 0.002 | -1.127 | -0.246 |
| 2-03 | -0.508 | 0.225 | 0.024 | -0.948 | -0.067 |
| 2-04 | 0.317 | 0.225 | 0.158 | -0.123 | 0.758 |
| 2-05 | -1.295 | 0.225 | 0.000 | -1.735 | -0.854 |
| 2-06 | -0.776 | 0.225 | 0.001 | -1.217 | -0.336 |
| 2-07 | -0.240 | 0.225 | 0.286 | -0.680 | 0.200 |
| 3-002 | 0.053 | 0.225 | 0.814 | -0.387 | 0.493 |
| 3-004 | -0.638 | 0.225 | 0.005 | -1.079 | -0.198 |
| 3-008 | -0.156 | 0.225 | 0.488 | -0.596 | 0.284 |

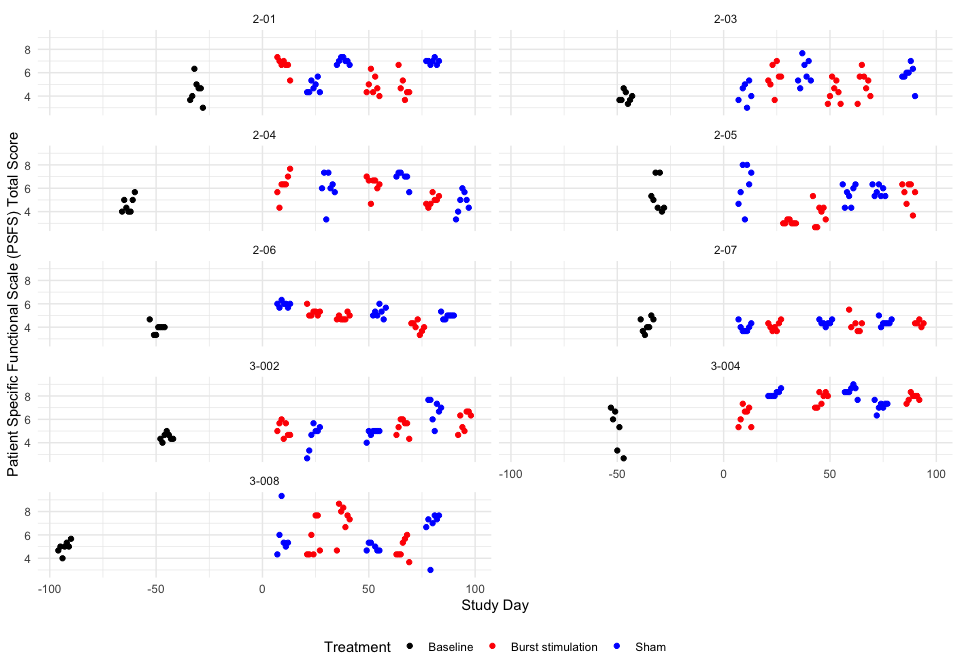
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.813 | 0.396 | 0 | 5.037 | 6.588 |
| Burst stimulation | 5.371 | 0.396 | 0 | 4.595 | 6.147 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.441 | 0.225 | 0.049 | -0.882 | -0.001 |

## Post-hoc outcome: Patient Specific Functional Scale (PSFS) total score

### Plot



### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Patient Specific Functional Scale (PSFS) Total Score | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 7 |
| Mean (sd) | 4.48 (1.07) | 6.67 (0.64) | 4.81 (0.54) | 4.90 (0.83) | 7.00 (0.27) | 4.83 (1.05) | 6.95 (0.23) |
| IQR | 1.00 | 0.33 | 0.83 | 1.00 | 0.33 | 0.83 | 0.17 |
| min - max | 3.00 - 6.33 | 5.33 - 7.33 | 4.33 - 5.67 | 4.00 - 6.33 | 6.67 - 7.33 | 3.67 - 6.67 | 6.67 - 7.33 |
| **2-03** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.90 (0.46) | 5.57 (1.10) | 4.28 (0.88) | 4.38 (0.91) | 6.05 (1.08) | 5.05 (1.13) | 5.81 (0.92) |
| IQR | 0.50 | 1.00 | 1.17 | 1.33 | 1.50 | 1.33 | 0.50 |
| min - max | 3.33 - 4.67 | 3.67 - 7.00 | 3.00 - 5.33 | 3.33 - 5.67 | 4.67 - 7.67 | 3.33 - 6.67 | 4.00 - 7.00 |
| **2-04** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.57 (0.66) | 6.24 (1.05) | 6.00 (1.35) | 6.29 (0.78) | 6.89 (0.62) | 4.95 (0.45) | 4.76 (0.94) |
| IQR | 1.00 | 0.67 | 1.00 | 0.50 | 0.25 | 0.50 | 1.17 |
| min - max | 4.00 - 5.67 | 4.33 - 7.67 | 3.33 - 7.33 | 4.67 - 7.00 | 5.67 - 7.33 | 4.33 - 5.67 | 3.33 - 6.00 |
| **2-05** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.38 (1.41) | 3.10 (0.16) | 6.19 (1.76) | 3.81 (0.98) | 5.48 (0.86) | 5.52 (1.02) | 5.76 (0.46) |
| IQR | 2.00 | 0.17 | 2.50 | 1.33 | 1.33 | 1.17 | 0.83 |
| min - max | 4.00 - 7.33 | 3.00 - 3.33 | 3.33 - 8.00 | 2.67 - 5.33 | 4.33 - 6.33 | 3.67 - 6.33 | 5.33 - 6.33 |
| **2-06** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 3.90 (0.46) | 5.29 (0.36) | 5.95 (0.23) | 4.86 (0.26) | 5.29 (0.45) | 4.05 (0.45) | 4.95 (0.23) |
| IQR | 0.33 | 0.33 | 0.17 | 0.33 | 0.50 | 0.50 | 0.17 |
| min - max | 3.33 - 4.67 | 5.00 - 6.00 | 5.67 - 6.33 | 4.67 - 5.33 | 4.67 - 6.00 | 3.33 - 4.67 | 4.67 - 5.33 |
| **2-07** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 6 | 7 | 5 | 7 |
| Mean (sd) | 4.19 (0.60) | 4.10 (0.37) | 4.00 (0.38) | 4.25 (0.68) | 4.38 (0.23) | 4.33 (0.24) | 4.43 (0.32) |
| IQR | 0.83 | 0.50 | 0.50 | 0.58 | 0.17 | 0.00 | 0.17 |
| min - max | 3.33 - 5.00 | 3.67 - 4.67 | 3.67 - 4.67 | 3.67 - 5.50 | 4.00 - 4.67 | 4.00 - 4.67 | 4.00 - 5.00 |
| **3-002** |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 4.48 (0.33) | 5.14 (0.63) | 4.52 (1.10) | 5.38 (0.65) | 4.81 (0.38) | 5.86 (0.84) | 6.76 (0.98) |
| IQR | 0.33 | 1.00 | 1.17 | 0.83 | 0.17 | 1.33 | 1.17 |
| min - max | 4.00 - 5.00 | 4.33 - 6.00 | 2.67 - 5.67 | 4.33 - 6.00 | 4.00 - 5.00 | 4.67 - 6.67 | 5.00 - 7.67 |
| **3-004** |  |  |  |  |  |  |  |
| n | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| Mean (sd) | 5.17 (1.79) | 6.33 (0.79) | 8.19 (0.26) | 7.71 (0.59) | 8.43 (0.42) | 7.86 (0.33) | 7.14 (0.42) |
| IQR | 2.67 | 1.17 | 0.33 | 1.00 | 0.33 | 0.33 | 0.33 |
| min - max | 2.67 - 7.00 | 5.33 - 7.33 | 8.00 - 8.67 | 7.00 - 8.33 | 7.67 - 9.00 | 7.33 - 8.33 | 6.33 - 7.67 |
| **3-008** |  |  |  |  |  |  |  |
| n | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| Mean (sd) | 4.95 (0.52) | 5.57 (1.55) | 5.89 (1.77) | 7.33 (1.35) | 4.94 (0.33) | 4.81 (0.86) | 6.67 (1.66) |
| IQR | 0.33 | 2.50 | 0.75 | 1.17 | 0.58 | 1.17 | 0.67 |
| min - max | 4.00 - 5.67 | 4.33 - 7.67 | 4.33 - 9.33 | 4.67 - 8.67 | 4.67 - 5.33 | 3.67 - 6.00 | 3.00 - 7.67 |

### Hypothesis test

Patient Specific Functional Scale (PSFS) Total Score

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | 1.857 | -2.095 | -2.119 | -0.786 |
| 2-03 | 1.294 | -1.667 | -0.762 | -0.378 |
| 2-04 | 0.238 | -0.603 | 0.190 | -0.058 |
| 2-05 | -3.095 | -1.667 | -0.238 | -1.667 |
| 2-06 | -0.667 | -0.429 | -0.905 | -0.667 |
| 2-07 | 0.095 | -0.131 | -0.095 | -0.044 |
| 3-002 | 0.619 | 0.571 | -0.905 | 0.095 |
| 3-004 | -1.857 | -0.714 | 0.714 | -0.619 |
| 3-008 | -0.317 | 2.389 | -1.857 | 0.072 |

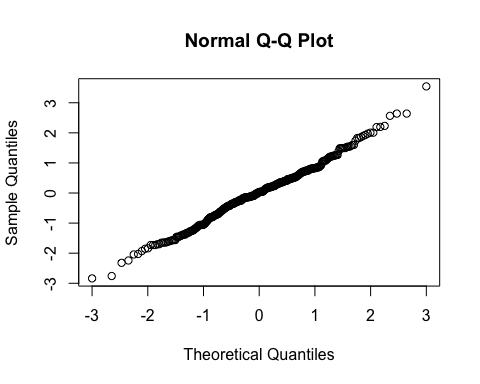
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.075.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
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## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.660 | 0.187 | 0.000 | -1.027 | -0.292 |
| 2-03 | -0.434 | 0.187 | 0.021 | -0.801 | -0.067 |
| 2-04 | -0.166 | 0.187 | 0.376 | -0.533 | 0.201 |
| 2-05 | -1.297 | 0.187 | 0.000 | -1.665 | -0.930 |
| 2-06 | -0.602 | 0.187 | 0.001 | -0.970 | -0.235 |
| 2-07 | -0.171 | 0.187 | 0.363 | -0.538 | 0.197 |
| 3-002 | -0.073 | 0.187 | 0.698 | -0.440 | 0.295 |
| 3-004 | -0.569 | 0.187 | 0.002 | -0.937 | -0.202 |
| 3-008 | -0.129 | 0.187 | 0.493 | -0.496 | 0.239 |

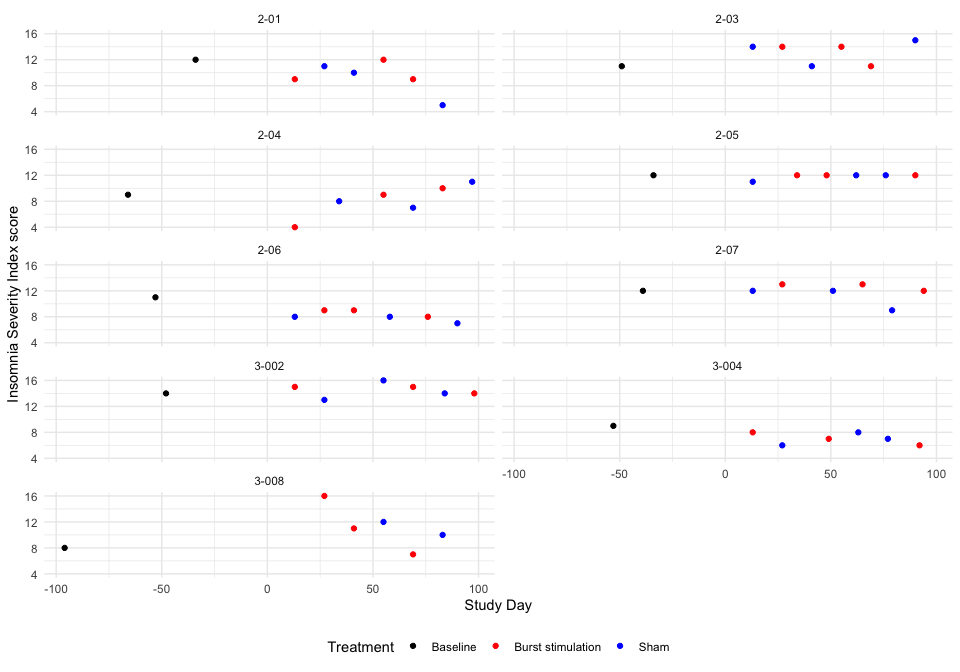
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.807 | 0.325 | 0 | 5.171 | 6.444 |
| Burst stimulation | 5.348 | 0.325 | 0 | 4.711 | 5.984 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.46 | 0.187 | 0.014 | -0.827 | -0.093 |

## Secondary endpoint: Insomnia Severity Index questionnaire total score

### Plot

 ### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Insomnia Severity Index score | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
|  | 12 | 9 | 11 | 12 | 10 | 9 | 5 |
| **2-03** |  |  |  |  |  |  |  |
|  | 11 | 14 | 14 | 14 | 11 | 11 | 15 |
| **2-04** |  |  |  |  |  |  |  |
|  | 9 | 4 | 8 | 9 | 7 | 10 | 11 |
| **2-05** |  |  |  |  |  |  |  |
|  | 12 | 12 | 11 | 12 | 12 | 12 | 12 |
| **2-06** |  |  |  |  |  |  |  |
|  | 11 | 9 | 8 | 9 | 8 | 8 | 7 |
| **2-07** |  |  |  |  |  |  |  |
|  | 12 | 13 | 12 | 13 | 12 | 12 | 9 |
| **3-002** |  |  |  |  |  |  |  |
|  | 14 | 15 | 13 | 15 | 16 | 14 | 14 |
| **3-004** |  |  |  |  |  |  |  |
|  | 9 | 8 | 6 | 7 | 8 | 6 | 7 |
| **3-008** |  |  |  |  |  |  |  |
|  | 8 | 16 | NA | 11 | 12 | 7 | 10 |

### Hypothesis test

Insomnia Severity Index score

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -2 | 2 | 4 | 1.333 |
| 2-03 | 0 | 3 | -4 | -0.333 |
| 2-04 | -4 | 2 | -1 | -1.000 |
| 2-05 | 1 | 0 | 0 | 0.333 |
| 2-06 | 1 | 1 | 1 | 1.000 |
| 2-07 | 1 | 1 | 3 | 1.667 |
| 3-002 | 2 | -1 | 0 | 0.333 |
| 3-004 | 2 | -1 | -1 | 0.000 |
| 3-008 | NaN | -1 | -3 | -2.000 |

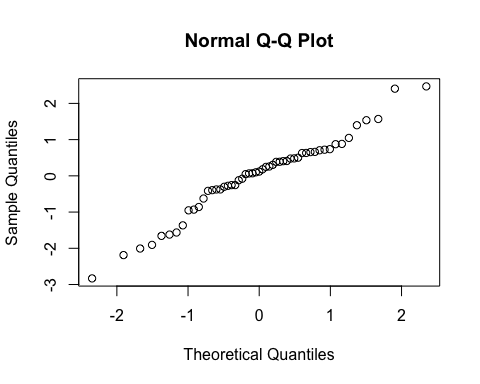
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.57.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
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## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.157 | 1.019 | 0.256 | -0.841 | 3.155 |
| 2-03 | -0.227 | 1.019 | 0.824 | -2.224 | 1.771 |
| 2-04 | -0.780 | 1.019 | 0.444 | -2.778 | 1.217 |
| 2-05 | 0.327 | 1.019 | 0.749 | -1.671 | 2.324 |
| 2-06 | 0.880 | 1.019 | 0.388 | -1.117 | 2.878 |
| 2-07 | 1.434 | 1.019 | 0.160 | -0.564 | 3.431 |
| 3-002 | 0.327 | 1.019 | 0.749 | -1.671 | 2.324 |
| 3-004 | 0.050 | 1.019 | 0.961 | -1.948 | 2.048 |
| 3-008 | -0.517 | 1.019 | 0.612 | -2.514 | 1.481 |

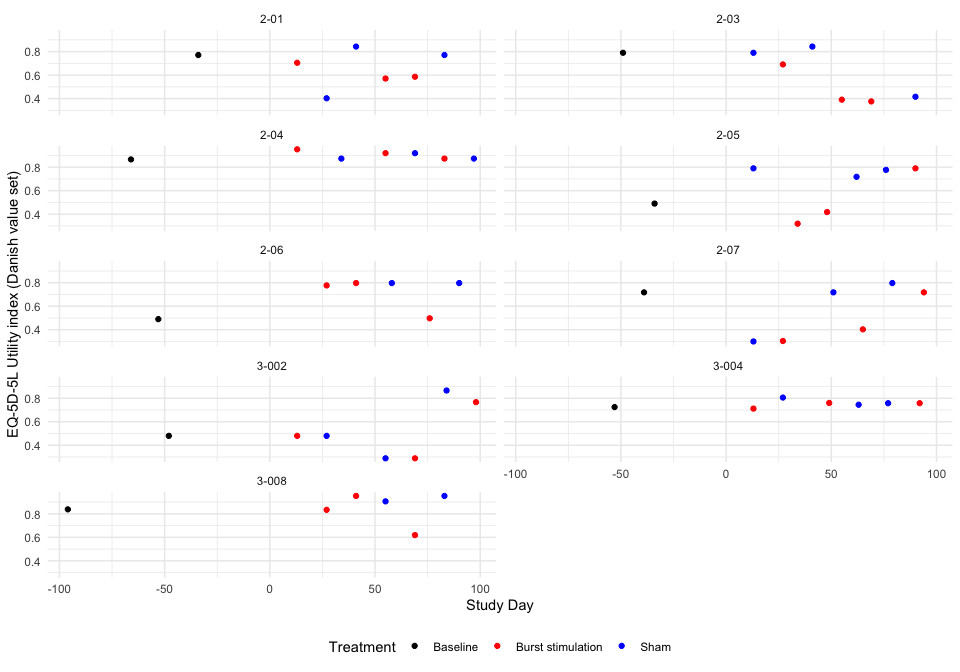
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 10.416 | 0.774 | 0 | 8.898 | 11.934 |
| Burst stimulation | 10.726 | 0.770 | 0 | 9.216 | 12.236 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.31 | 1.019 | 0.761 | -1.688 | 2.307 |

## Secondary endpoint: EQ-5D-5L Utility Index

### Plot

 ### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| EQ-5D-5L Utility index (Danish value set) | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
|  | 0.771 | 0.705 | 0.403 | 0.571 | 0.843 | 0.586 | 0.771 |
| **2-03** |  |  |  |  |  |  |  |
|  | 0.79 | 0.691 | 0.79 | 0.391 | 0.843 | 0.376 | 0.416 |
| **2-04** |  |  |  |  |  |  |  |
|  | 0.866 | 0.952 | 0.873 | 0.919 | 0.919 | 0.873 | 0.873 |
| **2-05** |  |  |  |  |  |  |  |
|  | 0.49 | 0.319 | 0.79 | 0.418 | 0.718 | 0.79 | 0.777 |
| **2-06** |  |  |  |  |  |  |  |
|  | 0.49 | 0.777 | NA | 0.797 | 0.797 | 0.497 | 0.797 |
| **2-07** |  |  |  |  |  |  |  |
|  | 0.718 | 0.304 | 0.3 | 0.403 | 0.718 | 0.718 | 0.797 |
| **3-002** |  |  |  |  |  |  |  |
|  | 0.48 | 0.48 | 0.48 | 0.289 | 0.289 | 0.767 | 0.866 |
| **3-004** |  |  |  |  |  |  |  |
|  | 0.725 | 0.712 | 0.806 | 0.76 | 0.745 | 0.758 | 0.758 |
| **3-008** |  |  |  |  |  |  |  |
|  | 0.838 | 0.834 | NA | 0.952 | 0.906 | 0.619 | 0.952 |

### Hypothesis test

EQ-5D-5L Utility index (Danish value set)

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | 0.302 | -0.272 | -0.185 | -0.052 |
| 2-03 | -0.099 | -0.452 | -0.040 | -0.197 |
| 2-04 | 0.079 | 0.000 | 0.000 | 0.026 |
| 2-05 | -0.471 | -0.300 | 0.013 | -0.253 |
| 2-06 | NaN | 0.000 | -0.300 | -0.150 |
| 2-07 | 0.004 | -0.315 | -0.079 | -0.130 |
| 3-002 | 0.000 | 0.000 | -0.099 | -0.033 |
| 3-004 | -0.094 | 0.015 | 0.000 | -0.026 |
| 3-008 | NaN | 0.046 | -0.333 | -0.144 |

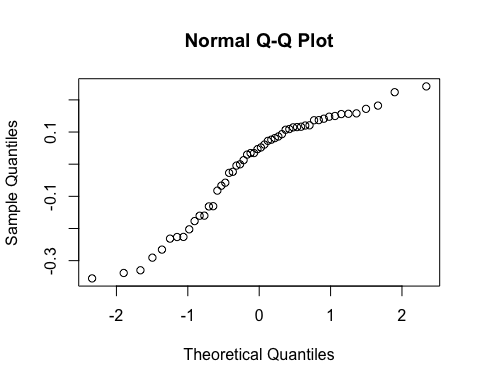
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.0091.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
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## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.073 | 0.067 | 0.275 | -0.204 | 0.058 |
| 2-03 | -0.138 | 0.067 | 0.038 | -0.269 | -0.007 |
| 2-04 | -0.038 | 0.067 | 0.571 | -0.169 | 0.093 |
| 2-05 | -0.163 | 0.067 | 0.014 | -0.294 | -0.033 |
| 2-06 | -0.085 | 0.067 | 0.203 | -0.216 | 0.046 |
| 2-07 | -0.108 | 0.067 | 0.105 | -0.239 | 0.023 |
| 3-002 | -0.065 | 0.067 | 0.334 | -0.195 | 0.066 |
| 3-004 | -0.062 | 0.067 | 0.357 | -0.192 | 0.069 |
| 3-008 | -0.081 | 0.067 | 0.223 | -0.212 | 0.049 |

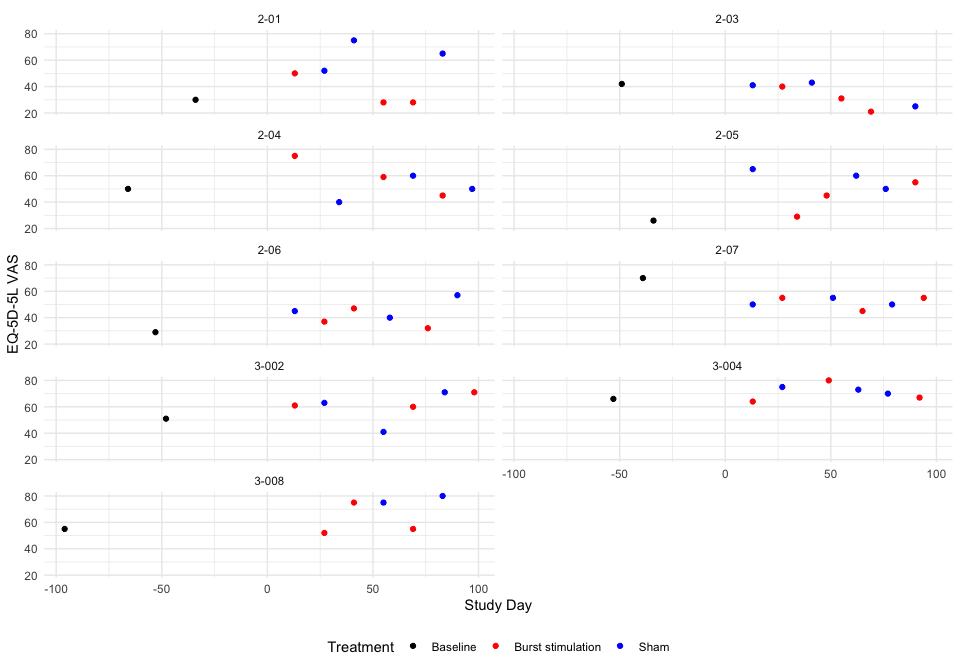
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 0.729 | 0.048 | 0 | 0.636 | 0.823 |
| Burst stimulation | 0.639 | 0.047 | 0 | 0.547 | 0.730 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.091 | 0.067 | 0.175 | -0.222 | 0.04 |

## Secondary endpoint: EQ-5D-5L self-rated health (VAS)

### Plot

 ### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| EQ-5D-5L VAS | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
|  | 30 | 50 | 52 | 28 | 75 | 28 | 65 |
| **2-03** |  |  |  |  |  |  |  |
|  | 42 | 40 | 41 | 31 | 43 | 21 | 25 |
| **2-04** |  |  |  |  |  |  |  |
|  | 50 | 75 | 40 | 59 | 60 | 45 | 50 |
| **2-05** |  |  |  |  |  |  |  |
|  | 26 | 29 | 65 | 45 | 60 | 55 | 50 |
| **2-06** |  |  |  |  |  |  |  |
|  | 29 | 37 | 45 | 47 | 40 | 32 | 57 |
| **2-07** |  |  |  |  |  |  |  |
|  | 70 | 55 | 50 | 45 | 55 | 55 | 50 |
| **3-002** |  |  |  |  |  |  |  |
|  | 51 | 61 | 63 | 60 | 41 | 71 | 71 |
| **3-004** |  |  |  |  |  |  |  |
|  | 66 | 64 | 75 | 80 | 73 | 67 | 70 |
| **3-008** |  |  |  |  |  |  |  |
|  | 55 | 52 | NA | 75 | 75 | 55 | 80 |

### Hypothesis test

EQ-5D-5L VAS

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | -2 | -47 | -37 | -28.667 |
| 2-03 | -1 | -12 | -4 | -5.667 |
| 2-04 | 35 | -1 | -5 | 9.667 |
| 2-05 | -36 | -15 | 5 | -15.333 |
| 2-06 | -8 | 7 | -25 | -8.667 |
| 2-07 | 5 | -10 | 5 | 0.000 |
| 3-002 | -2 | 19 | 0 | 5.667 |
| 3-004 | -11 | 7 | -3 | -2.333 |
| 3-008 | NaN | 0 | -25 | -12.500 |

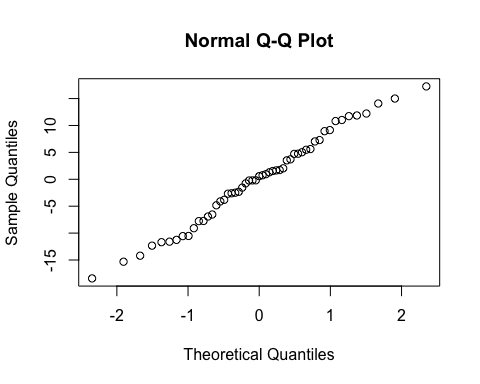
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.082.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
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## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -24.391 | 6.299 | 0.000 | -36.737 | -12.045 |
| 2-03 | -5.868 | 6.299 | 0.352 | -18.214 | 6.478 |
| 2-04 | 6.481 | 6.299 | 0.304 | -5.865 | 18.827 |
| 2-05 | -13.653 | 6.299 | 0.030 | -25.999 | -1.307 |
| 2-06 | -8.284 | 6.299 | 0.188 | -20.630 | 4.062 |
| 2-07 | -1.304 | 6.299 | 0.836 | -13.650 | 11.042 |
| 3-002 | 3.260 | 6.299 | 0.605 | -9.086 | 15.606 |
| 3-004 | -3.183 | 6.299 | 0.613 | -15.529 | 9.163 |
| 3-008 | -13.358 | 6.299 | 0.034 | -25.704 | -1.012 |

By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 56.866 | 4.465 | 0 | 48.115 | 65.617 |
| Burst stimulation | 50.292 | 4.443 | 0 | 41.584 | 58.999 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -6.574 | 6.299 | 0.297 | -18.92 | 5.772 |

## Secondary endpoint: Patient Global Impression of Change

### Descriptive table

| Full analysis set | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Patient Global Impression of Change | | | | | | |
|  | **Baseline - Burst stimulation** | **Baseline - Sham** | **Burst stimulation - Burst stimulation** | **Burst stimulation - Sham** | **Sham - Burst stimulation** | **Sham - Sham** |
| Veldig mye bedre | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Mye bedre | 2 (50.00%) | 1 (25.00%) | 3 (60.00%) | 8 (44.44%) | 3 (16.67%) | 1 (25.00%) |
| Minimalt bedre | 1 (25.00%) | 1 (25.00%) | 0 (0.00%) | 1 (5.56%) | 4 (22.22%) | 0 (0.00%) |
| Ingen endring | 0 (0.00%) | 1 (25.00%) | 1 (20.00%) | 4 (22.22%) | 1 (5.56%) | 1 (25.00%) |
| Minimalt verre | 1 (25.00%) | 0 (0.00%) | 0 (0.00%) | 2 (11.11%) | 1 (5.56%) | 1 (25.00%) |
| Mye verre | 0 (0.00%) | 1 (25.00%) | 1 (20.00%) | 2 (11.11%) | 9 (50.00%) | 1 (25.00%) |
| Veldig mye verre | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (5.56%) | 0 (0.00%) | 0 (0.00%) |

### Hypothesis test and treatment effect estimates

|  | Mean | SD |
| --- | --- | --- |
| Burst stimulation - Sham | 3.555556 | 1.688098 |
| Sham - Burst stimulation | 4.500000 | 1.689065 |

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.

| contrast | estimate | std.error | p.value | s.value | conf.low | conf.high |
| --- | --- | --- | --- | --- | --- | --- |
| Sham - Burst stimulation - Burst stimulation - Sham | 0.95 | 0.558 | 0.089 | 3.494 | -0.144 | 2.045 |

## Secondary outcome: Patient blinding question

### Descriptive table by participant

| Full analysis set | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Patient blinding question | | | | | | |
|  | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |
| Slått på | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) | 1 (11.11%) |
| Slått av | 0 (0.00%) | 1 (12.50%) | 1 (11.11%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| **2-03** |  |  |  |  |  |  |
| Slått på | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 1 (11.11%) | 0 (0.00%) |
| Slått av | 0 (0.00%) | 1 (12.50%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) |
| **2-04** |  |  |  |  |  |  |
| Slått på | 1 (11.11%) | 0 (0.00%) | 1 (11.11%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) |
| Slått av | 0 (0.00%) | 1 (12.50%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 1 (11.11%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| **2-05** |  |  |  |  |  |  |
| Slått på | 0 (0.00%) | 1 (12.50%) | 0 (0.00%) | 1 (11.11%) | 1 (11.11%) | 1 (11.11%) |
| Slått av | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| **2-06** |  |  |  |  |  |  |
| Slått på | 0 (0.00%) | 1 (12.50%) | 1 (11.11%) | 1 (11.11%) | 0 (0.00%) | 1 (11.11%) |
| Slått av | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| **2-07** |  |  |  |  |  |  |
| Slått på | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) | 1 (11.11%) |
| Slått av | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 1 (12.50%) | 1 (11.11%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) |
| **3-002** |  |  |  |  |  |  |
| Slått på | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) |
| Slått av | 0 (0.00%) | 1 (12.50%) | 1 (11.11%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) |
| **3-004** |  |  |  |  |  |  |
| Slått på | 0 (0.00%) | 1 (12.50%) | 1 (11.11%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) |
| Slått av | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) |
| **3-008** |  |  |  |  |  |  |
| Slått på | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) |
| Slått av | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 1 (11.11%) | 0 (0.00%) |
| Vet ikke | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |

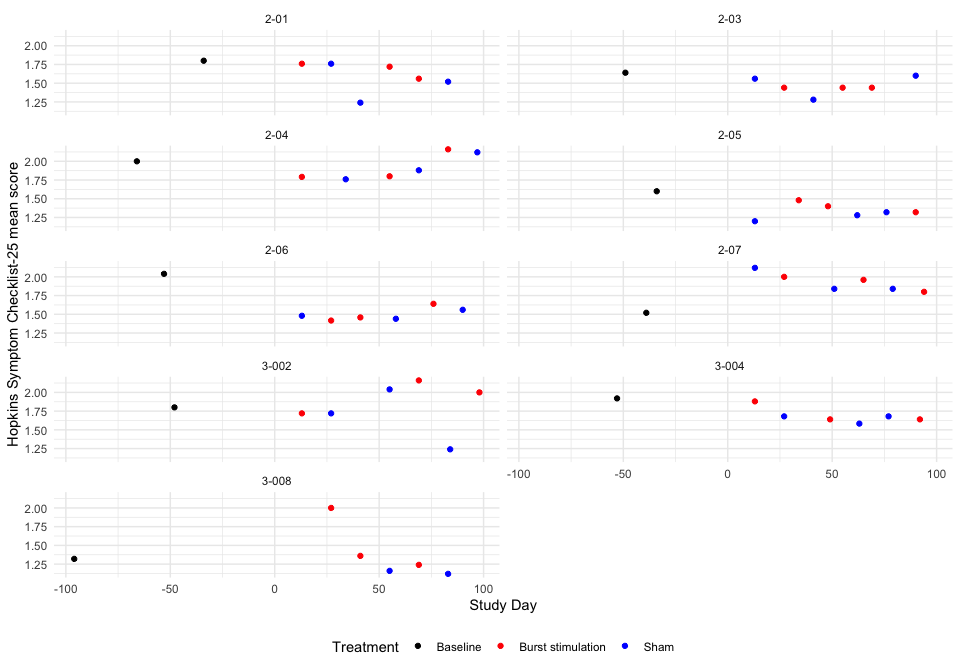
| Full analysis set | | |
| --- | --- | --- |
| Patient Blinding Quesiton | | |
|  | **Burst stimulation** | **Sham** |
| Slått på | 11 (40.74%) | 16 (61.54%) |
| Slått av | 10 (37.04%) | 8 (30.77%) |
| Vet ikke | 6 (22.22%) | 2 (7.69%) |

P-value of the null hypothesis chi-squared test: 0.21.

P-value of the null hypothesis Fisher test: 0.21.

## Secondary endpoint: Hopkins Symptom Checklist-25 mean score

### Plot

 ### Descriptive table

| Full analysis set | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hopkins Symptom Checklist-25 mean score | | | | | | | |
|  | **Baseline** | **Pair 1** | | **Pair 2** | | **Pair 3** | |
|  | **Baseline** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** | **Burst stimulation** | **Sham** |
| **2-01** |  |  |  |  |  |  |  |
|  | 1.8 | 1.76 | 1.76 | 1.72 | 1.24 | 1.56 | 1.52 |
| **2-03** |  |  |  |  |  |  |  |
|  | 1.64 | 1.44 | 1.56 | 1.44 | 1.28 | 1.44 | 1.6 |
| **2-04** |  |  |  |  |  |  |  |
|  | 2 | 1.79166666666667 | 1.76 | 1.8 | 1.88 | 2.16 | 2.12 |
| **2-05** |  |  |  |  |  |  |  |
|  | 1.6 | 1.48 | 1.2 | 1.4 | 1.28 | 1.32 | 1.32 |
| **2-06** |  |  |  |  |  |  |  |
|  | 2.04 | 1.41666666666667 | 1.48 | 1.45833333333333 | 1.44 | 1.64 | 1.56 |
| **2-07** |  |  |  |  |  |  |  |
|  | 1.52 | 2 | 2.12 | 1.96 | 1.84 | 1.8 | 1.84 |
| **3-002** |  |  |  |  |  |  |  |
|  | 1.8 | 1.72 | 1.72 | 2.16 | 2.04 | 2 | 1.24 |
| **3-004** |  |  |  |  |  |  |  |
|  | 1.92 | 1.88 | 1.68 | 1.64 | 1.58333333333333 | 1.64 | 1.68 |
| **3-008** |  |  |  |  |  |  |  |
|  | 1.32 | 2 | NA | 1.36 | 1.16 | 1.24 | 1.12 |

### Hypothesis test

Hopkins Symptom Checklist-25 mean score

| Subject ID | Difference Pair 1 | Difference Pair 2 | Difference Pair 3 | Overall difference |
| --- | --- | --- | --- | --- |
| 2-01 | 0.000 | 0.480 | 0.04 | 0.173 |
| 2-03 | -0.120 | 0.160 | -0.16 | -0.040 |
| 2-04 | 0.032 | -0.080 | 0.04 | -0.003 |
| 2-05 | 0.280 | 0.120 | 0.00 | 0.133 |
| 2-06 | -0.063 | 0.018 | 0.08 | 0.012 |
| 2-07 | -0.120 | 0.120 | -0.04 | -0.013 |
| 3-002 | 0.000 | 0.120 | 0.76 | 0.293 |
| 3-004 | 0.200 | 0.057 | -0.04 | 0.072 |
| 3-008 | NaN | 0.200 | 0.12 | 0.160 |

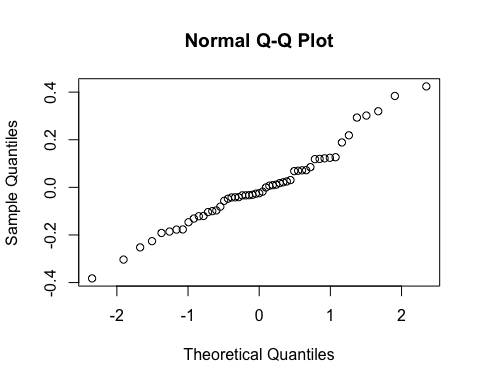
Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.036.

### Treatment effect estimates

QQ-plot

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.



By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 0.158 | 0.112 | 0.158 | -0.062 | 0.378 |
| 2-03 | -0.007 | 0.112 | 0.951 | -0.227 | 0.213 |
| 2-04 | 0.022 | 0.112 | 0.845 | -0.198 | 0.242 |
| 2-05 | 0.127 | 0.112 | 0.257 | -0.093 | 0.347 |
| 2-06 | 0.033 | 0.112 | 0.768 | -0.187 | 0.253 |
| 2-07 | 0.014 | 0.112 | 0.903 | -0.206 | 0.233 |
| 3-002 | 0.251 | 0.112 | 0.025 | 0.031 | 0.471 |
| 3-004 | 0.080 | 0.112 | 0.476 | -0.140 | 0.300 |
| 3-008 | 0.277 | 0.112 | 0.014 | 0.057 | 0.497 |

By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 1.573 | 0.079 | 0 | 1.418 | 1.729 |
| Burst stimulation | 1.676 | 0.079 | 0 | 1.521 | 1.831 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.103 | 0.112 | 0.359 | -0.117 | 0.323 |

## Carry over effect

First fit the model:

## Linear mixed model fit by REML ['lmerMod']  
## Formula:   
## painleg3 ~ rantrt + pair + prevtrt + prevtrt:rantrt + (1 | subjectid) +   
## (1 | subjectid:pair) + (1 | subjectid:rantrt)  
## Data: data  
##   
## REML criterion at convergence: 1233.7  
##   
## Scaled residuals:   
## Min 1Q Median 3Q Max   
## -3.5267 -0.5314 -0.0363 0.5708 3.0218   
##   
## Random effects:  
## Groups Name Variance Std.Dev.  
## subjectid:pair (Intercept) 0.6485 0.8053   
## subjectid:rantrt (Intercept) 0.3284 0.5731   
## subjectid (Intercept) 0.4838 0.6956   
## Residual 1.3256 1.1514   
## Number of obs: 370, groups:   
## subjectid:pair, 27; subjectid:rantrt, 18; subjectid, 9  
##   
## Fixed effects:  
## Estimate Std. Error t value  
## (Intercept) 4.24918 0.52934 8.027  
## rantrtSham -0.25410 0.39355 -0.646  
## pairPair 2 -0.55315 0.41566 -1.331  
## pairPair 3 -0.05001 0.41263 -0.121  
## prevtrtSham 0.25622 0.34113 0.751  
## rantrtSham:prevtrtSham -0.06868 0.35044 -0.196  
##   
## Correlation of Fixed Effects:  
## (Intr) rntrtS parPr2 parPr3 prvtrS  
## rantrtSham -0.577   
## pairPair 2 -0.489 0.091   
## pairPair 3 -0.462 0.058 0.516   
## prevtrtSham -0.606 0.625 0.179 0.131   
## rntrtShm:pS 0.384 -0.587 -0.054 -0.018 -0.693

Then plot the expected outcome by current and previous treatment:

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.

Outcome by tretment and previous treatment

| prevtrt | rantrt | estimate | std.error | statistic | p.value | s.value | conf.low | conf.high | term |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sham | Sham | 3.983 | 0.393 | 10.138 | 0 | 77.813 | 3.213 | 4.753 | Sham Sham |
| Burst stimulation | Sham | 3.795 | 0.360 | 10.547 | 0 | 83.982 | 3.090 | 4.501 | Burst stimulation Sham |
| Sham | Burst stimulation | 4.311 | 0.354 | 12.173 | 0 | 110.833 | 3.617 | 5.005 | Sham Burst stimulation |
| Burst stimulation | Burst stimulation | 4.055 | 0.446 | 9.091 | 0 | 63.143 | 3.180 | 4.929 | Burst stimulation Burst stimulation |

Then compute the treatment effect estimate by previous treatment:

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.

| contrast | prevtrt | estimate | std.error | p.value | s.value | conf.low | conf.high |
| --- | --- | --- | --- | --- | --- | --- | --- |
| mean(Sham) - mean(Burst stimulation) | Burst stimulation | -0.259 | 0.394 | 0.510 | 0.972 | -1.031 | 0.512 |
| mean(Sham) - mean(Burst stimulation) | Sham | -0.328 | 0.340 | 0.335 | 1.579 | -0.995 | 0.339 |

Finally see if there is a difference:

## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.  
## Warning: For this model type, `marginaleffects` only takes into account the  
## uncertainty in fixed-effect parameters. You can use the `re.form=NA`  
## argument to acknowledge this explicitly and silence this warning.

| estimate | std.error | p.value | s.value | conf.low | conf.high |
| --- | --- | --- | --- | --- | --- |
| 0.069 | 0.35 | 0.845 | 0.244 | -0.618 | 0.756 |

# Safety Analysis

| Site name | Subject Id | Date of informed consent | Gender | Alder | Date of first randomisation |  | Full Analysis Set? | Dato for oppstått komplikasjon | Beskrivelse av komplikasjon | Annet |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OUS | 2-01 | 2021-02-18 | Female | 66 | 2021-03-25 | TRUE | TRUE | 2021-04-22 | Tråkket over 14.5, ankelbrudd høyre (Weber A), behandles konservativt, ikke brukt analgetika, oppfattes ikke relatert til ryggmargsstimulering. Hun er deltaker i studien pga. smerter i venstre underekstremitet. | Oppfattes ikke studierelatert |
| OUS | 2-03 | 2021-03-18 | Male | 38 | 2021-05-06 | TRUE | TRUE | 2021-05-06 | Moderate smerter over IPG som ikke påvirker funksjon. Fikk Versatisplaster. | NA |
| OUS | 2-07 | 2021-09-30 | Female | 50 | 2021-11-26 | TRUE | TRUE | 2021-11-12 | Smerter i relasjon til IPG, dette påvirker hennes funksjonsskåringer, utsetter derfor oppstart av burst/sham i to uker | NA |
| OUS | 2-08 | 2022-02-03 | Female | 49 | NA | FALSE | FALSE | 2022-03-17 | Signifikant elektrode-dislokasjon | Signifikant elektrode-dislokasjon, må ekskluderes fra studien |
| Akademiska | 3-003 | 2022-05-10 | Female | 56 | 2022-07-04 | TRUE | FALSE | 2022-07-04 | Ved Kontroll 1 ser man att elektroden har migrerat 2 hela segment kranielt, så att den nu ligger med spetsen/pol 1 vid kraniella delen av Th7. Ingen elektrod över Th9/10, således exklusion. | Elektrod-migration. |
| Akademiska | 3-004 | 2022-05-11 | Male | 55 | 2022-07-04 | TRUE | TRUE | 2022-07-19 | COVID konstaterad 19/7. Lindriga symtom i 3 dagar. | Lindrig COVID 19-21/7. |
| Akademiska | 3-007 | 2022-10-18 | Female | 57 | 2023-01-03 | TRUE | FALSE | 2023-01-03 | Elektrodmigration, ej möjligt att stimulera målområde Th9/10. Således eksklusion. | Elektrodemigration. |

# Parathesia Coverage

| Site | Subject ID | Parathesia Coverage Leg | Parathesia Coverage Back |
| --- | --- | --- | --- |
| OUS | 2-01 | 100% | 0% |
| OUS | 2-03 | 1-24% | 0% |
| OUS | 2-04 | 100% | 25-49% |
| OUS | 2-05 | 100% | 75-99% |
| OUS | 2-06 | 100% | Ikke relevant |
| OUS | 2-07 | 100% | 0% |
| Akademiska | 3-002 | 100% | 0% |
| Akademiska | 3-004 | 75-99% | 0% |
| Akademiska | 3-008 | 100% | 1-24% |

# Listings

## Analgetica

| Subject | Studyday | Treatment | Period | Pair | Changed analgetica since last control? | Specify | Changed analgetica last 7 days | Specify | Any other use of analgetica last 7 days? | Specify |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2-01 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-01 | 28 days | Sham | 2 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-01 | 42 days | Sham | 3 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-01 | 56 days | Burst stimulation | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-01 | 70 days | Burst stimulation | 5 | Pair 3 | Nei | NA | Nei | NA | Ja | Nobligan 50 mg, men ikke i måleperioden |
| 2-01 | 84 days | Sham | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-03 | 14 days | Sham | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-03 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-03 | 42 days | Sham | 3 | Pair 2 | Nei | NA | Nei | NA | Ja | Ibux pga hodepine 14/6 |
| 2-03 | 56 days | Burst stimulation | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-03 | 77 days | Burst stimulation | 5 | Pair 3 | Nei | NA | Nei | NA | Ja | Ibux x3 én dag for hodepine under spørreskjemautfylling |
| 2-03 | 92 days | Sham | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-04 | 21 days | Burst stimulation | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-04 | 42 days | Sham | 2 | Pair 1 | Nei | NA | Nei | NA | Ja | Typisk 1 Pinex forte noen dager under måle perioden. |
| 2-04 | 56 days | Burst stimulation | 3 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-04 | 70 days | Sham | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-04 | 84 days | Burst stimulation | 5 | Pair 3 | Nei | NA | Nei | NA | Ja | Pinex Forte, ettermidag kveld 3 av måletidspunkter |
| 2-04 | 105 days | Sham | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-05 | 21 days | Sham | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-05 | 35 days | Burst stimulation | 2 | Pair 1 | Nei | NA | Nei | NA | Ja | 1 g paracetamol ekstra på kvelden halvparten av siste 7 måledager |
| 2-05 | 49 days | Burst stimulation | 3 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-05 | 63 days | Sham | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-05 | 77 days | Sham | 5 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-05 | 91 days | Burst stimulation | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-06 | 14 days | Sham | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-06 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-06 | 45 days | Burst stimulation | 3 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-06 | 63 days | Sham | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 2-06 | 77 days | Burst stimulation | 5 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-06 | 91 days | Sham | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-07 | 14 days | Sham | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-07 | 38 days | Burst stimulation | 2 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 2-07 | 52 days | Sham | 3 | Pair 2 | Nei | NA | Nei | NA | Ja | Paracet 1gx2 siste tre dager |
| 2-07 | 66 days | Burst stimulation | 4 | Pair 2 | Nei | NA | Nei | NA | Ja | Tramadol fredag 28/1 og lørdag 29/1, Tramadol 50mg |
| 2-07 | 81 days | Sham | 5 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 2-07 | 97 days | Burst stimulation | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 3-002 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 3-002 | 42 days | Sham | 2 | Pair 1 | Nei | NA | Nei | NA | Ja | Paracetamol fulldos i v 5 pga av smärta och infektion (COVID). |
| 3-002 | 56 days | Sham | 3 | Pair 2 | Nei | NA | Nei | NA | Ja | Alvedon till kvällen och enstaka Ipren. |
| 3-002 | 71 days | Burst stimulation | 4 | Pair 2 | Nei | NA | Nei | NA | Ja | Ipren og paracetamol daglig. |
| 3-002 | 85 days | Sham | 5 | Pair 3 | Nei | NA | Nei | NA | Ja | Paracetamol x 2 under de senaste 14 dagar, |
| 3-002 | 99 days | Burst stimulation | 6 | Pair 3 | Nei | NA | Nei | NA | Ja | Naproxen 1x2, Alvedon 2x2, 9/4 pga av huvudvärk. |
| 3-004 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA | Nei | NA | Ja | Tar som tidigare 2-3 citodon per dag. |
| 3-004 | 36 days | Sham | 2 | Pair 1 | Nei | NA | Ja | Halverat från 4 till ca 2 Citodon per dygn. | Ja | Citodon 2/dag. |
| 3-004 | 50 days | Burst stimulation | 3 | Pair 2 | Nei | NA | Nei | NA | Ja | (1 tablett Citodon + 1 tablett Alvedon 500 mg) x 2 per dag i genomsnitt under senaste 7 dagar. |
| 3-004 | 64 days | Sham | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 3-004 | 79 days | Sham | 5 | Pair 3 | Nei | NA | Nei | NA | Ja | Citodon 1,5 g och Alvedon 1,5 g per dag senaste 2 veckor. |
| 3-004 | 94 days | Burst stimulation | 6 | Pair 3 | Nei | NA | Nei | NA | Ja | Citodon upp till 1,5 g/dygn |
| 3-008 | 14 days | Sham | 1 | Pair 1 | Nei | NA | Nei | NA | Ja | Paracetamol vid två tillfällen senaset 14 dagar. |
| 3-008 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA | Nei | NA | Ja | Alvedon vb vid två tillfällen. |
| 3-008 | 42 days | Burst stimulation | 3 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 3-008 | 56 days | Sham | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 3-008 | 70 days | Burst stimulation | 5 | Pair 3 | Nei | NA | Nei | NA | Ja | Paracetamol 1g vid två tillfällen senaste 7 dagar. |
| 3-008 | 84 days | Sham | 6 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |

## Adverse reactions to the stimulation

| Subject | Studyday | Treatment | Period | Pair | Any adverse reactions last 14 days? | Specify |
| --- | --- | --- | --- | --- | --- | --- |
| 2-01 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 2-01 | 28 days | Sham | 2 | Pair 1 | Nei | NA |
| 2-01 | 42 days | Sham | 3 | Pair 2 | Nei | NA |
| 2-01 | 56 days | Burst stimulation | 4 | Pair 2 | Ja | Ny sensasjon . Endret kuldefølelse i beinet. |
| 2-01 | 70 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-01 | 84 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-03 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-03 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-03 | 42 days | Sham | 3 | Pair 2 | Nei | NA |
| 2-03 | 56 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 2-03 | 77 days | Burst stimulation | 5 | Pair 3 | Ja | Kløe over ene hjørnet av IPG, nedre hjørne, medialt. Ingen infeksjonstegn |
| 2-03 | 92 days | Sham | 6 | Pair 3 | Ja | kløe rundt generator |
| 2-04 | 21 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 2-04 | 42 days | Sham | 2 | Pair 1 | Nei | NA |
| 2-04 | 56 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 2-04 | 70 days | Sham | 4 | Pair 2 | Nei | NA |
| 2-04 | 84 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-04 | 105 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-05 | 21 days | Sham | 1 | Pair 1 | Ja | Stikker litt over kanten av IPGen |
| 2-05 | 35 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-05 | 49 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 2-05 | 63 days | Sham | 4 | Pair 2 | Nei | NA |
| 2-05 | 77 days | Sham | 5 | Pair 3 | Nei | NA |
| 2-05 | 91 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 2-06 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-06 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-06 | 45 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 2-06 | 63 days | Sham | 4 | Pair 2 | Nei | NA |
| 2-06 | 77 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-06 | 91 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-07 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-07 | 38 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-07 | 52 days | Sham | 3 | Pair 2 | Nei | NA |
| 2-07 | 66 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 2-07 | 81 days | Sham | 5 | Pair 3 | Nei | NA |
| 2-07 | 97 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 3-002 | 14 days | Burst stimulation | 1 | Pair 1 | Ja | Obehag över dosfickan i ett par dagar (för ca 7 dagar sedan, |
| 3-002 | 42 days | Sham | 2 | Pair 1 | Nei | NA |
| 3-002 | 56 days | Sham | 3 | Pair 2 | Nei | NA |
| 3-002 | 71 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 3-002 | 85 days | Sham | 5 | Pair 3 | Nei | NA |
| 3-002 | 99 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 3-004 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 3-004 | 36 days | Sham | 2 | Pair 1 | Ja | Lätt sveda över IPG-fickan. |
| 3-004 | 50 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 3-004 | 64 days | Sham | 4 | Pair 2 | Ja | Möjligt att kramper är relaterat till stimulering? Viss ömhet över IPG fortfarande. |
| 3-004 | 79 days | Sham | 5 | Pair 3 | Nei | NA |
| 3-004 | 94 days | Burst stimulation | 6 | Pair 3 | Ja | Smärta/obehag vid beröring av IPG. |
| 3-008 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 3-008 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 3-008 | 42 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 3-008 | 56 days | Sham | 4 | Pair 2 | Nei | NA |
| 3-008 | 70 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 3-008 | 84 days | Sham | 6 | Pair 3 | Nei | NA |

## Technical problems

| Subject | Studyday | Treatment | Period | Pair | Any technical problems last 14 days? | Specify |
| --- | --- | --- | --- | --- | --- | --- |
| 2-01 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 2-01 | 28 days | Sham | 2 | Pair 1 | Nei | NA |
| 2-01 | 42 days | Sham | 3 | Pair 2 | Nei | NA |
| 2-01 | 56 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 2-01 | 70 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-01 | 84 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-03 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-03 | 28 days | Burst stimulation | 2 | Pair 1 | Ja | Butikkalarm gikk av én gang, ikke andre ganger. |
| 2-03 | 42 days | Sham | 3 | Pair 2 | Ja | Kom borti strømgjere ved et uhell, kjente ekstra sterk støt. Lurer på om det kan ha hatt noe med stimulatoren å gjøre |
| 2-03 | 56 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 2-03 | 77 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-03 | 92 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-04 | 21 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 2-04 | 42 days | Sham | 2 | Pair 1 | Nei | NA |
| 2-04 | 56 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 2-04 | 70 days | Sham | 4 | Pair 2 | Nei | NA |
| 2-04 | 84 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-04 | 105 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-05 | 21 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-05 | 35 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-05 | 49 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 2-05 | 63 days | Sham | 4 | Pair 2 | Nei | NA |
| 2-05 | 77 days | Sham | 5 | Pair 3 | Nei | NA |
| 2-05 | 91 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 2-06 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-06 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-06 | 45 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 2-06 | 63 days | Sham | 4 | Pair 2 | Nei | NA |
| 2-06 | 77 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 2-06 | 91 days | Sham | 6 | Pair 3 | Nei | NA |
| 2-07 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 2-07 | 38 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 2-07 | 52 days | Sham | 3 | Pair 2 | Nei | NA |
| 2-07 | 66 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 2-07 | 81 days | Sham | 5 | Pair 3 | Nei | NA |
| 2-07 | 97 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 3-002 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 3-002 | 42 days | Sham | 2 | Pair 1 | Nei | NA |
| 3-002 | 56 days | Sham | 3 | Pair 2 | Nei | NA |
| 3-002 | 71 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 3-002 | 85 days | Sham | 5 | Pair 3 | Nei | NA |
| 3-002 | 99 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 3-004 | 14 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 3-004 | 36 days | Sham | 2 | Pair 1 | Nei | NA |
| 3-004 | 50 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 3-004 | 64 days | Sham | 4 | Pair 2 | Nei | NA |
| 3-004 | 79 days | Sham | 5 | Pair 3 | Nei | NA |
| 3-004 | 94 days | Burst stimulation | 6 | Pair 3 | Nei | NA |
| 3-008 | 14 days | Sham | 1 | Pair 1 | Nei | NA |
| 3-008 | 28 days | Burst stimulation | 2 | Pair 1 | Nei | NA |
| 3-008 | 42 days | Burst stimulation | 3 | Pair 2 | Nei | NA |
| 3-008 | 56 days | Sham | 4 | Pair 2 | Nei | NA |
| 3-008 | 70 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 3-008 | 84 days | Sham | 6 | Pair 3 | Nei | NA |

# Suppementary Materials

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