BURST Statistical Final Report

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10 November, 2023

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# Introduction

This is the report for the first interim analysis of the BURST trial. 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 13 included patients of which 10 were randomised and included in the full analysis set.

# Demographics

## All randomised

| All included | |
| --- | --- |
| Demographics and baseline characteristics | |
|  | all obs |
|  | (N=13) |
| Site name |  |
| Akademiska | 6 (46.15%) |
| OUS | 7 (53.85%) |
| Gender |  |
| Male | 3 (23.08%) |
| Female | 10 (76.92%) |
| Age (years) |  |
| n | 13 |
| Mean (sd) | 52.90 (6.91) |
| IQR | 7.50 |
| min - max | 38.90 - 66.70 |
| Marital status |  |
| Married | 5 (38.46%) |
| Single | 1 (7.69%) |
| Divorsed | 1 (7.69%) |
| Cohabitant | 5 (38.46%) |
| Partner | 1 (7.69%) |
| Number of children |  |
| n | 13 |
| Mean (sd) | 1.54 (1.05) |
| IQR | 1.00 |
| min - max | 0.00 - 4.00 |
| Working? |  |
| Yes | 8 (61.54%) |
| No | 5 (38.46%) |
| Working hours per week |  |
| n | 8 |
| Mean (sd) | 31.62 (14.48) |
| IQR | 8.75 |
| 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 (7.69%) |
| Sykepenger delvis (er delvis sykmeldt) | 1 (7.69%) |
| Arbeidsavklaringspenger (AAP) | 4 (30.77%) |
| Uføreytelse/pensjon, hel | 1 (7.69%) |
| Uføreytelse/pensjon, delvis | 1 (7.69%) |
| Mottar ingen stønad, får lønn fra arbeidsgiver | 5 (38.46%) |
| PCS Total score |  |
| n | 13 |
| Mean (sd) | 18.54 (6.89) |
| IQR | 12.00 |
| min - max | 8.00 - 28.00 |
| PCS Rumination |  |
| n | 13 |
| Mean (sd) | 7.85 (3.26) |
| IQR | 4.00 |
| min - max | 3.00 - 14.00 |
| PCS Magnification |  |
| n | 13 |
| Mean (sd) | 2.54 (1.66) |
| IQR | 3.00 |
| min - max | 0.00 - 5.00 |
| PCS Helplessness |  |
| n | 13 |
| Mean (sd) | 8.15 (3.34) |
| IQR | 5.00 |
| min - max | 4.00 - 14.00 |
| Treatment for neuropatic pain? |  |
| No | 8 (61.54%) |
| Yes | 5 (38.46%) |
| Amitriptyline |  |
| No | 11 (84.62%) |
| Yes | 2 (15.38%) |
| Gabapentin |  |
| No | 10 (76.92%) |
| Yes | 3 (23.08%) |
| Pregabalin |  |
| No | 11 (84.62%) |
| Yes | 2 (15.38%) |
| Duloxetine |  |
| No | 13 (100.00%) |
| Treatment with other non-opoids? |  |
| No | 3 (23.08%) |
| Yes | 10 (76.92%) |
| Paracetamol |  |
| No | 5 (38.46%) |
| Yes | 8 (61.54%) |
| NSAIDs |  |
| No | 9 (69.23%) |
| Yes | 4 (30.77%) |
| Antidepressiva |  |
| No | 13 (100.00%) |
| Treatmetn with opoids? |  |
| No | 8 (61.54%) |
| Yes | 5 (38.46%) |
| 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 | 13 (100.00%) |
| Previous chiropractor? |  |
| No | 6 (46.15%) |
| Yes | 7 (53.85%) |
| Previous psychologist? |  |
| No | 11 (84.62%) |
| Yes | 2 (15.38%) |
| Previous TENS? |  |
| No | 3 (23.08%) |
| Yes | 10 (76.92%) |
| Other previous treatment? |  |
| No | 10 (76.92%) |
| Yes | 3 (23.08%) |
| 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 (69.23%) |
| Yes | 4 (30.77%) |
| Current chiropractor? |  |
| No | 13 (100.00%) |
| Current psychologist? |  |
| No | 13 (100.00%) |
| Current TENS |  |
| No | 9 (69.23%) |
| Yes | 4 (30.77%) |
| Other current treatment? |  |
| No | 12 (92.31%) |
| Yes | 1 (7.69%) |
| Other current treatment, specify |  |
| Följer sjukgymnast-program hemma. | 1 |
| Current back pain? |  |
| No | 3 (23.08%) |
| Yes | 10 (76.92%) |
| Duration of pain (years) |  |
| n | 13 |
| Mean (sd) | 6.91 (9.90) |
| IQR | 8.30 |
| min - max | 0.40 - 36.00 |
| Duration of current pain level (years) |  |
| n | 13 |
| Mean (sd) | 2.63 (3.51) |
| IQR | 1.75 |
| min - max | 0.25 - 10.00 |

## Excluded from FAS

| Excluded before randomisation | |
| --- | --- |
| Demographics and baseline characteristics | |
|  | 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%) |
| 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 |
| 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 |

## Full analysis set

| Full analysis set (randomised) | |
| --- | --- |
| Demographics and baseline characteristics | |
|  | all obs |
|  | (N=10) |
| Site name |  |
| Akademiska | 4 (40.00%) |
| OUS | 6 (60.00%) |
| Gender |  |
| Male | 3 (30.00%) |
| Female | 7 (70.00%) |
| Age (years) |  |
| n | 10 |
| Mean (sd) | 52.45 (7.63) |
| IQR | 7.27 |
| min - max | 38.90 - 66.70 |
| Marital status |  |
| Married | 5 (50.00%) |
| Single | 1 (10.00%) |
| Divorsed | 0 (0.00%) |
| Cohabitant | 3 (30.00%) |
| Partner | 1 (10.00%) |
| Number of children |  |
| n | 10 |
| Mean (sd) | 1.80 (1.03) |
| IQR | 0.75 |
| min - max | 0.00 - 4.00 |
| Working? |  |
| Yes | 6 (60.00%) |
| No | 4 (40.00%) |
| Working hours per week |  |
| n | 6 |
| Mean (sd) | 28.83 (16.01) |
| IQR | 15.75 |
| 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 (10.00%) |
| Sykepenger delvis (er delvis sykmeldt) | 0 (0.00%) |
| Arbeidsavklaringspenger (AAP) | 3 (30.00%) |
| Uføreytelse/pensjon, hel | 1 (10.00%) |
| Uføreytelse/pensjon, delvis | 1 (10.00%) |
| Mottar ingen stønad, får lønn fra arbeidsgiver | 4 (40.00%) |
| PCS Total score |  |
| n | 10 |
| Mean (sd) | 16.80 (6.83) |
| IQR | 9.50 |
| min - max | 8.00 - 28.00 |
| PCS Rumination |  |
| n | 10 |
| Mean (sd) | 7.30 (3.50) |
| IQR | 3.75 |
| min - max | 3.00 - 14.00 |
| PCS Magnification |  |
| n | 10 |
| Mean (sd) | 2.10 (1.60) |
| IQR | 2.00 |
| min - max | 0.00 - 5.00 |
| PCS Helplessness |  |
| n | 10 |
| Mean (sd) | 7.40 (3.13) |
| IQR | 3.75 |
| min - max | 4.00 - 14.00 |
| Treatment for neuropatic pain? |  |
| No | 6 (60.00%) |
| Yes | 4 (40.00%) |
| Amitriptyline |  |
| No | 8 (80.00%) |
| Yes | 2 (20.00%) |
| Gabapentin |  |
| No | 8 (80.00%) |
| Yes | 2 (20.00%) |
| Pregabalin |  |
| No | 8 (80.00%) |
| Yes | 2 (20.00%) |
| Duloxetine |  |
| No | 10 (100.00%) |
| Treatment with other non-opoids? |  |
| No | 3 (30.00%) |
| Yes | 7 (70.00%) |
| Paracetamol |  |
| No | 5 (50.00%) |
| Yes | 5 (50.00%) |
| NSAIDs |  |
| No | 7 (70.00%) |
| Yes | 3 (30.00%) |
| Antidepressiva |  |
| No | 10 (100.00%) |
| Treatmetn with opoids? |  |
| No | 7 (70.00%) |
| Yes | 3 (30.00%) |
| 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 | 10 (100.00%) |
| Previous chiropractor? |  |
| No | 4 (40.00%) |
| Yes | 6 (60.00%) |
| Previous psychologist? |  |
| No | 8 (80.00%) |
| Yes | 2 (20.00%) |
| Previous TENS? |  |
| No | 2 (20.00%) |
| Yes | 8 (80.00%) |
| Other previous treatment? |  |
| No | 7 (70.00%) |
| Yes | 3 (30.00%) |
| 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 | 8 (80.00%) |
| Yes | 2 (20.00%) |
| Current chiropractor? |  |
| No | 10 (100.00%) |
| Current psychologist? |  |
| No | 10 (100.00%) |
| Current TENS |  |
| No | 6 (60.00%) |
| Yes | 4 (40.00%) |
| Other current treatment? |  |
| No | 9 (90.00%) |
| Yes | 1 (10.00%) |
| Other current treatment, specify |  |
| Följer sjukgymnast-program hemma. | 1 |
| Current back pain? |  |
| No | 3 (30.00%) |
| Yes | 7 (70.00%) |
| Duration of pain (years) |  |
| n | 10 |
| Mean (sd) | 8.69 (10.74) |
| IQR | 7.53 |
| min - max | 1.00 - 36.00 |
| Duration of current pain level (years) |  |
| n | 10 |
| Mean (sd) | 3.26 (3.81) |
| IQR | 3.27 |
| min - max | 0.25 - 10.00 |

## Pain etc at baseline

| Full analysis set (randomised) | |
| --- | --- |
| Mean pain etc at baseline | |
|  | all obs |
|  | (N=10) |
| Strongest pain in leg |  |
| n | 10 |
| Mean (sd) | 6.21 (1.30) |
| IQR | 1.46 |
| min - max | 3.57 - 8.00 |
| Weakest pain in leg |  |
| n | 10 |
| Mean (sd) | 3.81 (1.26) |
| IQR | 1.46 |
| min - max | 2.43 - 6.57 |
| Most common pain in leg |  |
| n | 10 |
| Mean (sd) | 4.94 (1.05) |
| IQR | 1.46 |
| min - max | 3.29 - 6.71 |
| Pain now in leg |  |
| n | 10 |
| Mean (sd) | 5.13 (1.08) |
| IQR | 1.16 |
| min - max | 3.43 - 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 | 10 |
| Mean (sd) | 4.38 (1.34) |
| IQR | 1.89 |
| min - max | 2.00 - 6.29 |
| Ability to do first activity (higher is better) |  |
| n | 10 |
| Mean (sd) | 4.29 (0.98) |
| IQR | 0.64 |
| min - max | 1.86 - 5.14 |
| Ability to do second activity (higher is better) |  |
| n | 10 |
| Mean (sd) | 4.27 (1.13) |
| IQR | 1.07 |
| min - max | 1.71 - 5.86 |
| Ability to do third activity (higher is better) |  |
| n | 10 |
| Mean (sd) | 4.21 (1.26) |
| IQR | 0.64 |
| min - max | 1.14 - 5.83 |
| EQ-5D-5L Utility index (Danish value set) |  |
| n | 10 |
| Mean (sd) | 0.71 (0.16) |
| IQR | 0.28 |
| min - max | 0.48 - 0.91 |
| EQ-5D-5L VAS |  |
| n | 10 |
| Mean (sd) | 49.80 (18.27) |
| IQR | 30.25 |
| min - max | 26.00 - 79.00 |
| Hopkins Symptom Checklist-25 mean score |  |
| n | 10 |
| Mean (sd) | 1.71 (0.24) |
| IQR | 0.35 |
| min - max | 1.32 - 2.04 |
| Insomnia Severity Index score |  |
| n | 10 |
| Mean (sd) | 11.10 (1.91) |
| IQR | 2.50 |
| min - max | 8.00 - 14.00 |

# Treatment information

## Amplitude for sensory threshod

| Amplitude for sensory treshold | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
| Period | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |
|  | 0.7 | 0.65 | 1 | 0.8 | 1 | 1 |

## Impedance

| Impedance | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
| Period | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |
|  | 287 | 362 | 300 | 362 | 287 | 325 |

## 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 |
| 3-009 |  |  |  |  |  |  |  |
|  | 0 | 0.4 | 0 | 0.45 | 0 | 0.6 | 0 |

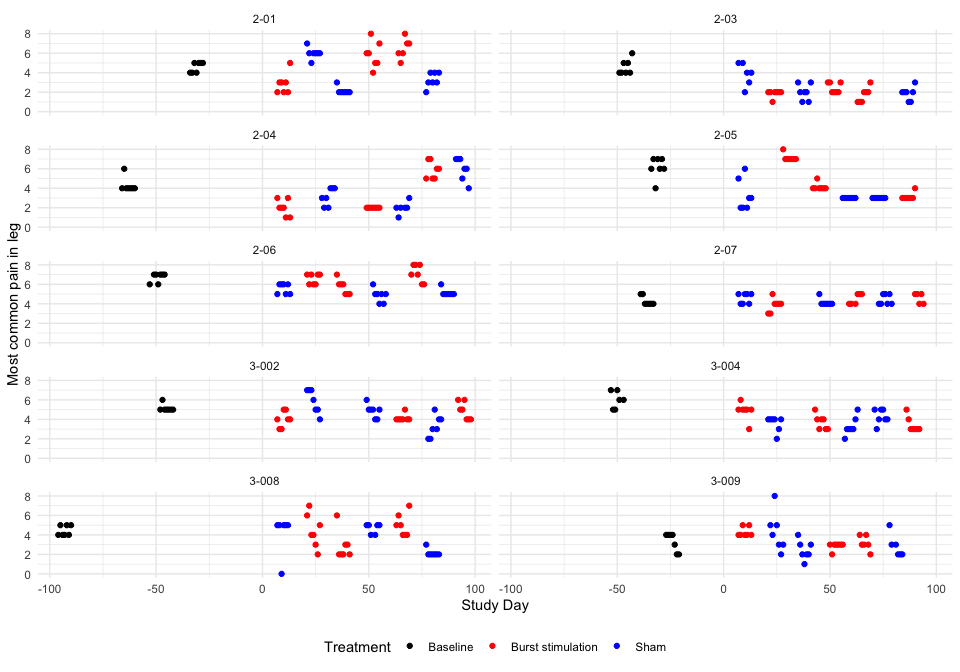
## Stimulation amplitude as registered after treatment period

| Stimulation Amplitude from previous period | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |
|  | 0.4 | 0 | 0.45 | 0 | 0.6 | 0 |

# Analysis

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

### Plot



### Descriptive table

| Most common pain in leg | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 3.29 (0.95) | 4.29 (0.49) | 4.29 (1.98) | 2.86 (0.38) | 2.43 (0.98) | 3.17 (0.75) | 2.83 (1.17) |
| IQR | 1.50 | 0.50 | 2.00 | 0.00 | 1.00 | 0.75 | 1.00 |
| min - max | 2.00 - 4.00 | 4.00 - 5.00 | 2.00 - 8.00 | 2.00 - 3.00 | 1.00 - 4.00 | 2.00 - 4.00 | 2.00 - 5.00 |

### Hypothesis test

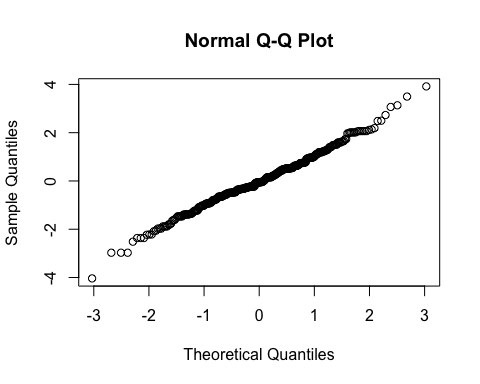
Most common pain in leg

| 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 |
| 3-009 | 0.000 | 0.429 | 0.333 | 0.254 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.21.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.039 | 0.249 | 0.000 | 0.550 | 1.527 |
| 2-03 | -0.340 | 0.249 | 0.172 | -0.829 | 0.149 |
| 2-04 | -0.277 | 0.249 | 0.267 | -0.766 | 0.212 |
| 2-05 | 1.447 | 0.249 | 0.000 | 0.958 | 1.936 |
| 2-06 | 1.104 | 0.249 | 0.000 | 0.616 | 1.593 |
| 2-07 | 0.009 | 0.249 | 0.970 | -0.480 | 0.498 |
| 3-002 | -0.189 | 0.249 | 0.450 | -0.677 | 0.300 |
| 3-004 | 0.306 | 0.249 | 0.220 | -0.183 | 0.795 |
| 3-008 | 0.479 | 0.249 | 0.055 | -0.010 | 0.968 |
| 3-009 | 0.278 | 0.249 | 0.264 | -0.210 | 0.767 |

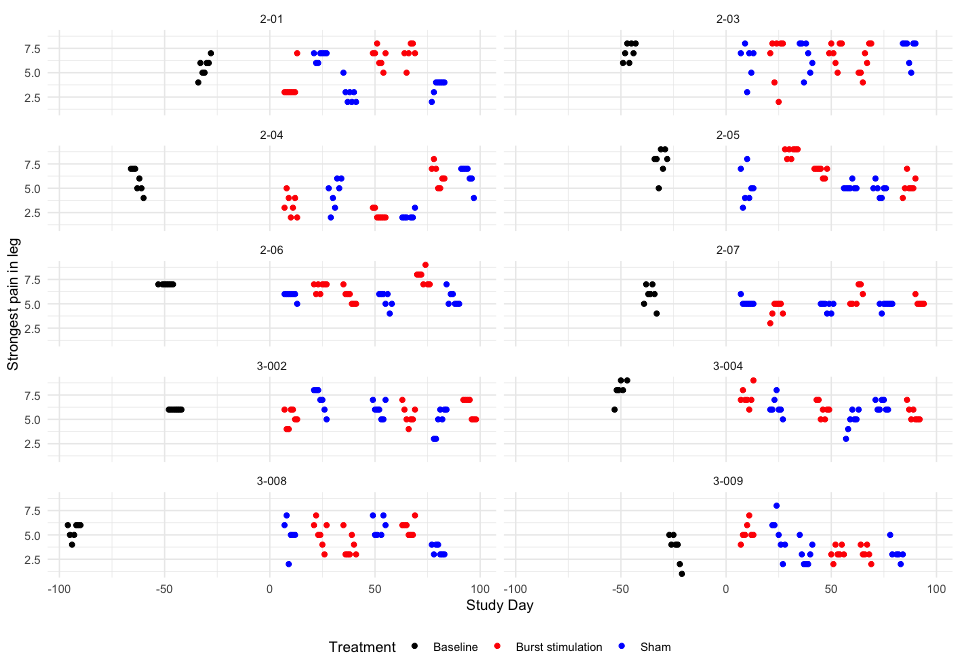
Overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.794 | 0.318 | 0 | 3.171 | 4.416 |
| Burst stimulation | 4.184 | 0.318 | 0 | 3.561 | 4.807 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.39 | 0.249 | 0.118 | -0.099 | 0.879 |

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

### Plot



### Descriptive table

| Strongest pain in leg | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 3.57 (1.51) | 5.29 (0.95) | 5.00 (1.91) | 3.14 (0.69) | 3.00 (1.15) | 3.17 (0.75) | 3.17 (0.98) |
| IQR | 1.50 | 0.50 | 2.00 | 0.50 | 1.50 | 0.75 | 0.00 |
| min - max | 1.00 - 5.00 | 4.00 - 7.00 | 2.00 - 8.00 | 2.00 - 4.00 | 2.00 - 5.00 | 2.00 - 4.00 | 2.00 - 5.00 |

### Hypothesis test

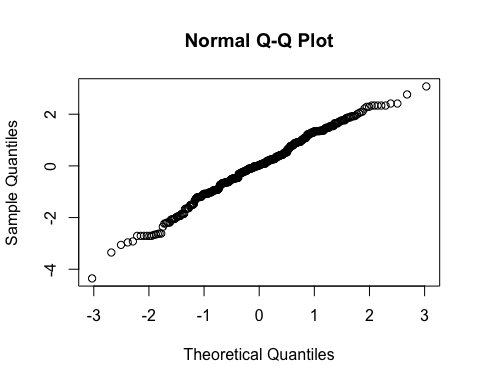
Strongest pain in leg

| 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 |
| 3-009 | 0.286 | 0.143 | 0.000 | 0.143 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.14.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.043 | 0.237 | 0.000 | 0.578 | 1.508 |
| 2-03 | 0.002 | 0.237 | 0.992 | -0.463 | 0.467 |
| 2-04 | -0.146 | 0.237 | 0.539 | -0.611 | 0.319 |
| 2-05 | 1.469 | 0.237 | 0.000 | 1.004 | 1.933 |
| 2-06 | 0.915 | 0.237 | 0.000 | 0.450 | 1.380 |
| 2-07 | 0.280 | 0.237 | 0.237 | -0.185 | 0.745 |
| 3-002 | -0.159 | 0.237 | 0.504 | -0.623 | 0.306 |
| 3-004 | 0.430 | 0.237 | 0.070 | -0.035 | 0.895 |
| 3-008 | 0.273 | 0.237 | 0.251 | -0.192 | 0.737 |
| 3-009 | 0.230 | 0.237 | 0.332 | -0.235 | 0.695 |

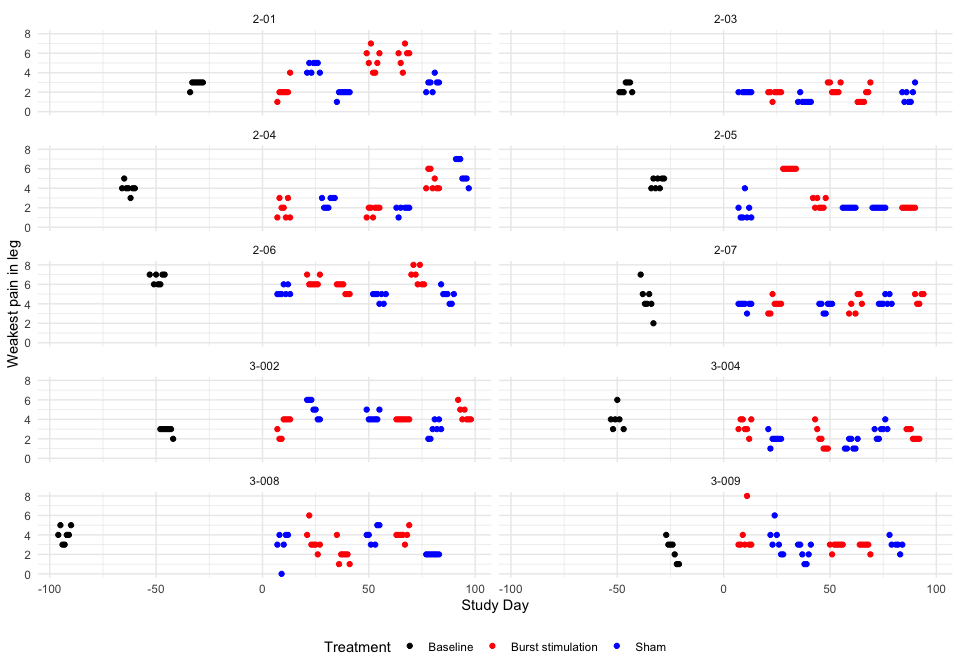
By treatment and Overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.134 | 0.316 | 0 | 4.514 | 5.754 |
| Burst stimulation | 5.572 | 0.316 | 0 | 4.952 | 6.192 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.438 | 0.237 | 0.065 | -0.027 | 0.903 |

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

### Plot



### Descriptive table

| Weakest pain in leg | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 2.43 (1.13) | 3.86 (1.86) | 3.43 (1.40) | 2.86 (0.38) | 2.14 (0.90) | 2.83 (0.41) | 3.00 (0.63) |
| IQR | 1.50 | 0.50 | 1.50 | 0.00 | 1.50 | 0.00 | 0.00 |
| min - max | 1.00 - 4.00 | 3.00 - 8.00 | 2.00 - 6.00 | 2.00 - 3.00 | 1.00 - 3.00 | 2.00 - 3.00 | 2.00 - 4.00 |

### Hypothesis test

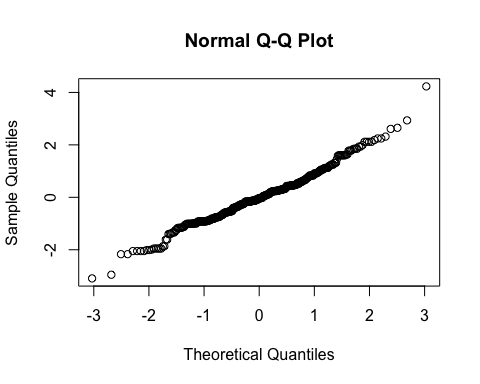
Weakest pain in leg

| 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 |
| 3-009 | 0.429 | 0.714 | -0.167 | 0.325 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.086.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.071 | 0.219 | 0.000 | 0.642 | 1.500 |
| 2-03 | 0.373 | 0.219 | 0.088 | -0.056 | 0.802 |
| 2-04 | -0.398 | 0.219 | 0.069 | -0.827 | 0.031 |
| 2-05 | 1.348 | 0.219 | 0.000 | 0.919 | 1.777 |
| 2-06 | 1.121 | 0.219 | 0.000 | 0.692 | 1.550 |
| 2-07 | 0.250 | 0.219 | 0.254 | -0.179 | 0.678 |
| 3-002 | -0.052 | 0.219 | 0.811 | -0.481 | 0.377 |
| 3-004 | 0.477 | 0.219 | 0.029 | 0.049 | 0.906 |
| 3-008 | 0.256 | 0.219 | 0.242 | -0.173 | 0.685 |
| 3-009 | 0.378 | 0.219 | 0.084 | -0.051 | 0.807 |

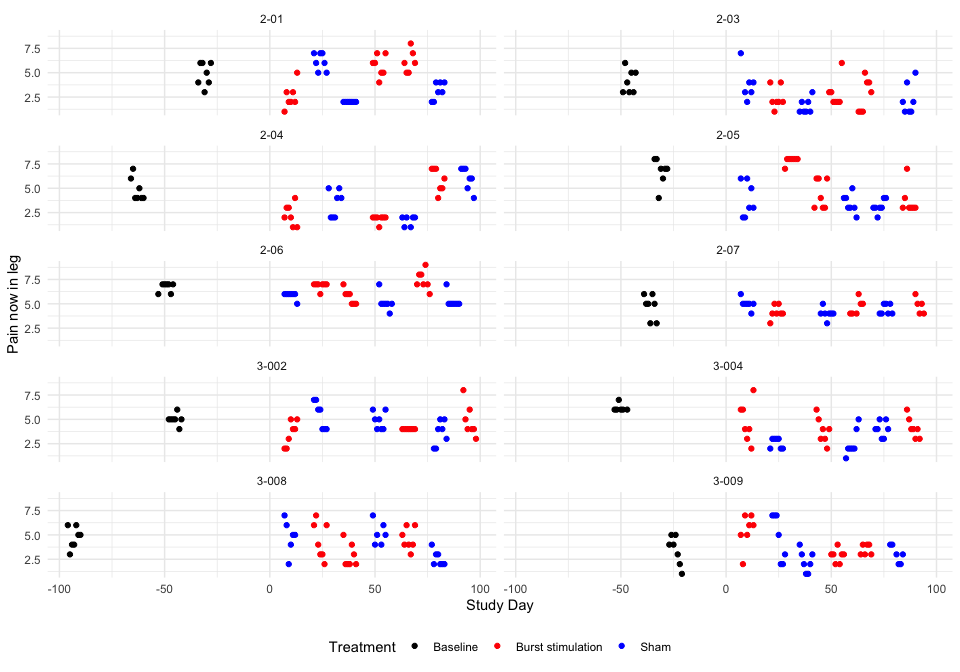
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.092 | 0.356 | 0 | 2.394 | 3.791 |
| Burst stimulation | 3.579 | 0.356 | 0 | 2.880 | 4.278 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.487 | 0.219 | 0.026 | 0.058 | 0.916 |

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

### Plot



### Descriptive table

| Pain now in leg | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 3.43 (1.51) | 5.43 (1.72) | 4.71 (2.36) | 2.86 (0.69) | 2.29 (1.11) | 3.50 (0.55) | 3.00 (0.89) |
| IQR | 2.00 | 1.50 | 4.50 | 0.50 | 1.50 | 1.00 | 1.50 |
| min - max | 1.00 - 5.00 | 2.00 - 7.00 | 2.00 - 7.00 | 2.00 - 4.00 | 1.00 - 4.00 | 3.00 - 4.00 | 2.00 - 4.00 |

### Hypothesis test

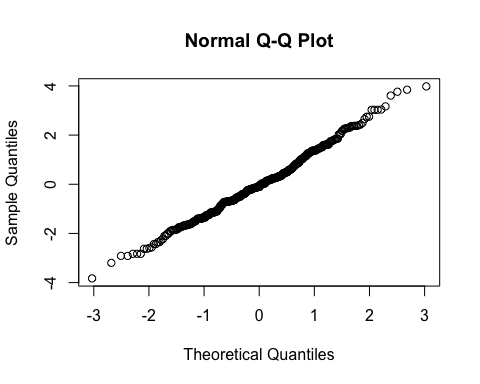
Pain now in leg

| 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 |
| 3-009 | 0.714 | 0.571 | 0.500 | 0.595 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.11.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 0.858 | 0.252 | 0.001 | 0.363 | 1.353 |
| 2-03 | 0.244 | 0.252 | 0.333 | -0.250 | 0.739 |
| 2-04 | -0.134 | 0.252 | 0.594 | -0.629 | 0.360 |
| 2-05 | 1.474 | 0.252 | 0.000 | 0.979 | 1.968 |
| 2-06 | 1.030 | 0.252 | 0.000 | 0.535 | 1.525 |
| 2-07 | 0.164 | 0.252 | 0.516 | -0.331 | 0.659 |
| 3-002 | -0.199 | 0.252 | 0.430 | -0.694 | 0.296 |
| 3-004 | 0.996 | 0.252 | 0.000 | 0.501 | 1.491 |
| 3-008 | 0.026 | 0.252 | 0.917 | -0.468 | 0.521 |
| 3-009 | 0.572 | 0.252 | 0.024 | 0.077 | 1.066 |

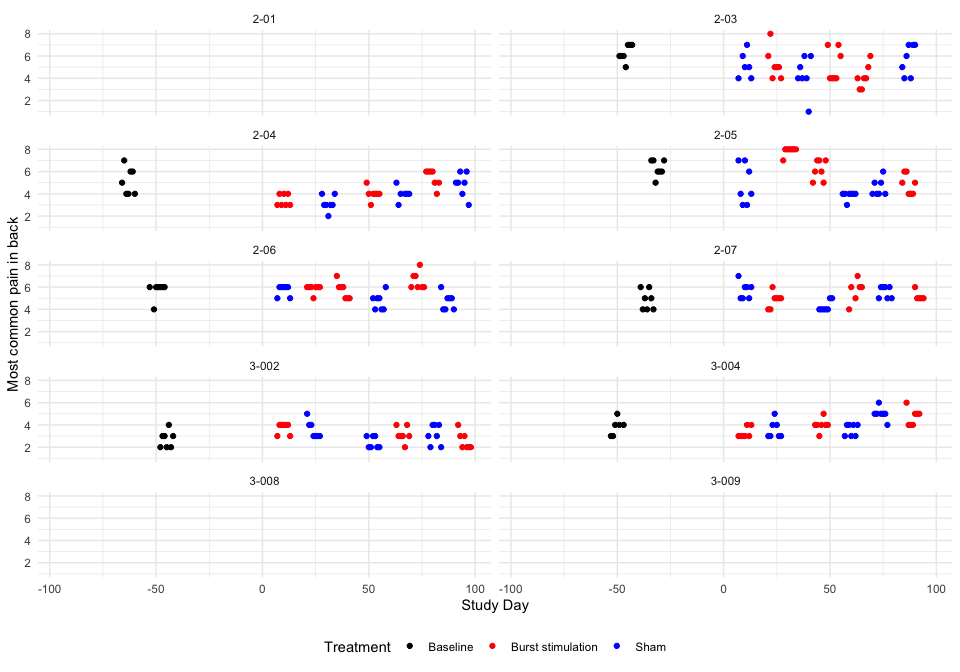
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.854 | 0.309 | 0 | 3.248 | 4.461 |
| Burst stimulation | 4.363 | 0.309 | 0 | 3.757 | 4.970 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.509 | 0.252 | 0.044 | 0.014 | 1.003 |

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

### Plot



### Descriptive table

| Most common pain in back | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| 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

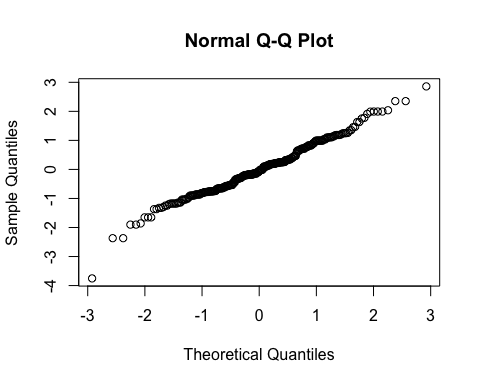
Most common pain in back

| 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 |
| 3-009 | NaN | NaN | NaN | NaN |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.075.

### Treatment effect estimates

QQ-plot 

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 |

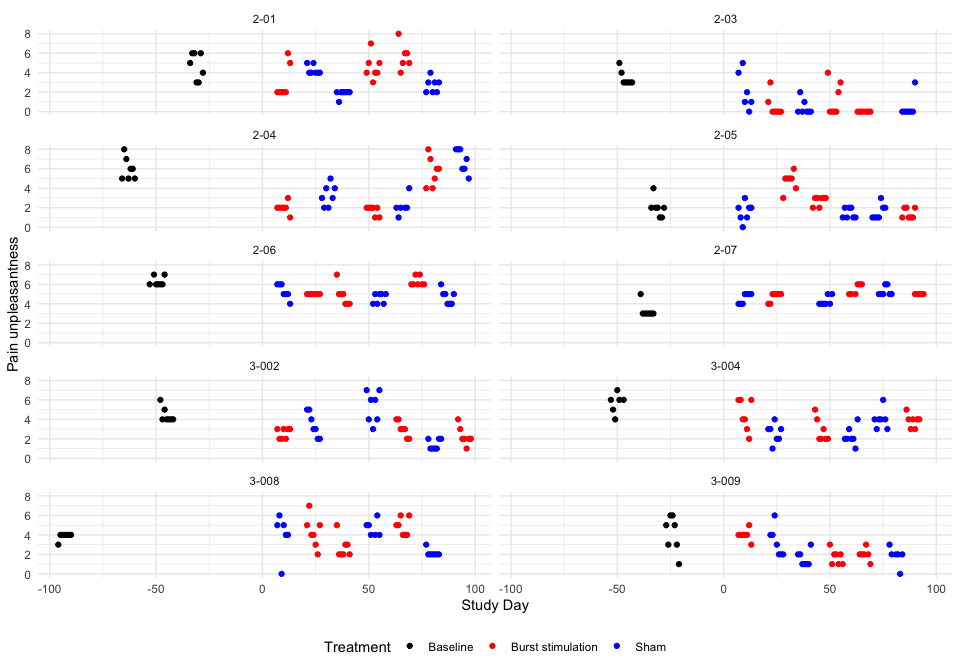
By treatment and overall

| 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

| Pain unpleasantness | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 4.14 (1.86) | 4.00 (0.58) | 3.29 (1.50) | 1.71 (0.76) | 1.57 (0.79) | 2.00 (0.63) | 1.83 (0.98) |
| IQR | 2.50 | 0.00 | 2.00 | 1.00 | 1.00 | 0.00 | 0.00 |
| min - max | 1.00 - 6.00 | 3.00 - 5.00 | 2.00 - 6.00 | 1.00 - 3.00 | 1.00 - 3.00 | 1.00 - 3.00 | 0.00 - 3.00 |

### Hypothesis test

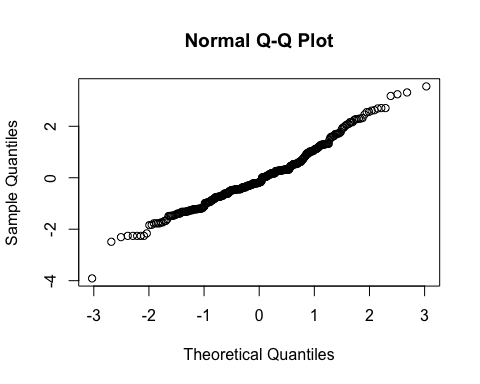
Pain unpleasantness

| 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 |
| 3-009 | 0.714 | 0.143 | 0.167 | 0.341 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.24.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.207 | 0.259 | 0.000 | 0.700 | 1.715 |
| 2-03 | -0.228 | 0.259 | 0.378 | -0.736 | 0.279 |
| 2-04 | -0.731 | 0.259 | 0.005 | -1.238 | -0.223 |
| 2-05 | 1.219 | 0.259 | 0.000 | 0.712 | 1.727 |
| 2-06 | 0.485 | 0.259 | 0.061 | -0.023 | 0.992 |
| 2-07 | 0.354 | 0.259 | 0.172 | -0.154 | 0.861 |
| 3-002 | -0.559 | 0.259 | 0.031 | -1.066 | -0.052 |
| 3-004 | 0.678 | 0.259 | 0.009 | 0.171 | 1.186 |
| 3-008 | 0.396 | 0.259 | 0.126 | -0.111 | 0.904 |
| 3-009 | 0.343 | 0.259 | 0.185 | -0.164 | 0.851 |

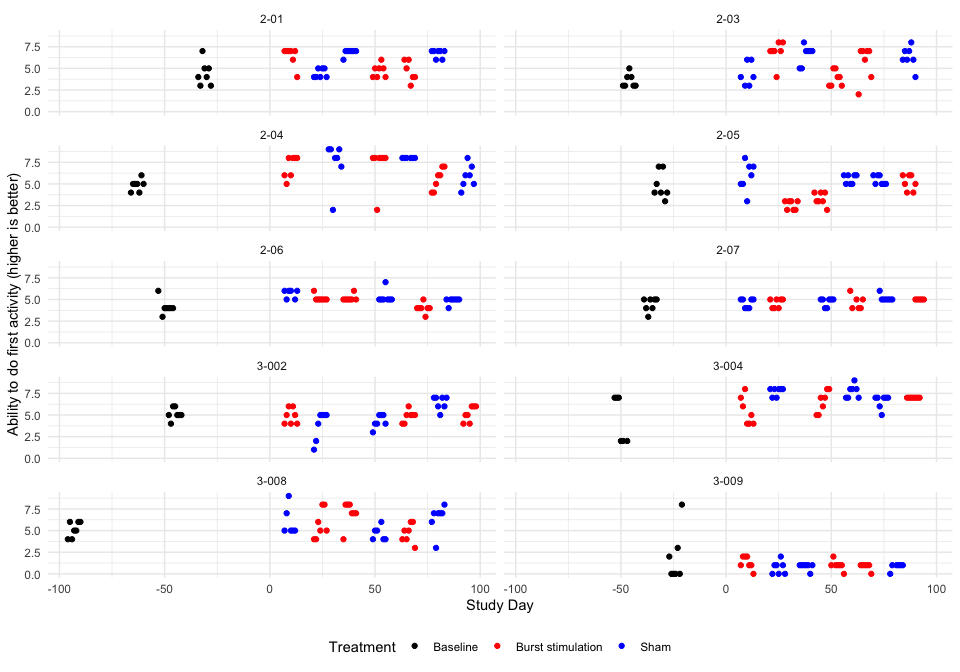
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 3.120 | 0.423 | 0 | 2.291 | 3.949 |
| Burst stimulation | 3.437 | 0.423 | 0 | 2.608 | 4.266 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.317 | 0.259 | 0.22 | -0.19 | 0.825 |

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

### Plot



### Descriptive table

| Ability to do first activity (higher is better) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 1.86 (2.97) | 1.29 (0.76) | 0.71 (0.76) | 1.00 (0.58) | 0.86 (0.38) | 0.83 (0.41) | 0.83 (0.41) |
| IQR | 2.50 | 1.00 | 1.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| min - max | 0.00 - 8.00 | 0.00 - 2.00 | 0.00 - 2.00 | 0.00 - 2.00 | 0.00 - 1.00 | 0.00 - 1.00 | 0.00 - 1.00 |

### Hypothesis test

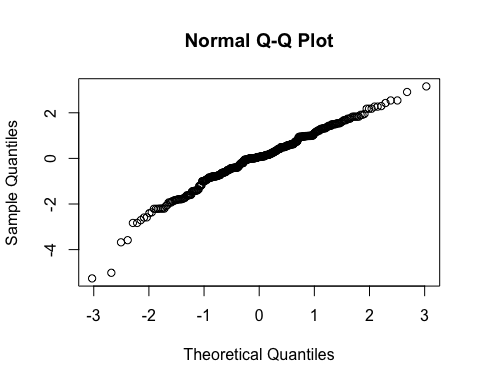
Ability to do first activity (higher is better)

| 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 |
| 3-009 | 0.571 | 0.143 | 0.000 | 0.238 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.084.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.620 | 0.208 | 0.003 | -1.027 | -0.213 |
| 2-03 | -0.371 | 0.208 | 0.074 | -0.778 | 0.035 |
| 2-04 | -0.489 | 0.208 | 0.019 | -0.896 | -0.082 |
| 2-05 | -1.465 | 0.208 | 0.000 | -1.872 | -1.058 |
| 2-06 | -0.488 | 0.208 | 0.019 | -0.895 | -0.081 |
| 2-07 | -0.206 | 0.208 | 0.322 | -0.613 | 0.201 |
| 3-002 | -0.089 | 0.208 | 0.669 | -0.496 | 0.318 |
| 3-004 | -0.825 | 0.208 | 0.000 | -1.232 | -0.418 |
| 3-008 | -0.114 | 0.208 | 0.584 | -0.521 | 0.293 |
| 3-009 | 0.007 | 0.208 | 0.972 | -0.399 | 0.414 |

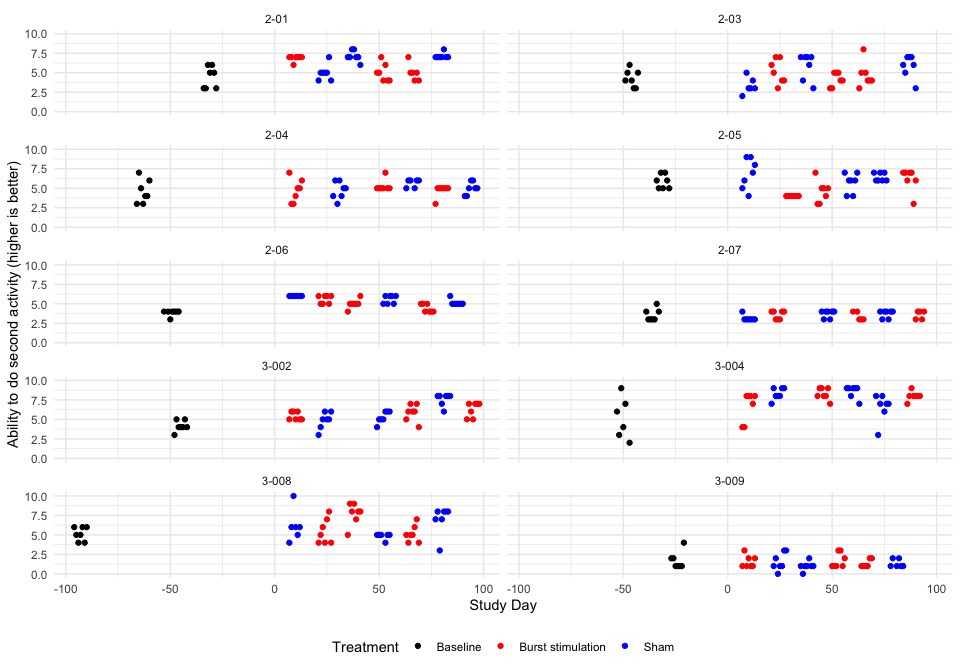
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.344 | 0.535 | 0 | 4.294 | 6.393 |
| Burst stimulation | 4.872 | 0.535 | 0 | 3.823 | 5.922 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.472 | 0.208 | 0.023 | -0.878 | -0.065 |

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

### Plot



### Descriptive table

| Ability to do second activity (higher is better) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 1.71 (1.11) | 1.57 (0.79) | 1.57 (1.13) | 1.71 (0.95) | 1.00 (0.58) | 1.33 (0.52) | 1.33 (0.52) |
| IQR | 1.00 | 1.00 | 1.50 | 1.50 | 0.00 | 0.75 | 0.75 |
| min - max | 1.00 - 4.00 | 1.00 - 3.00 | 0.00 - 3.00 | 1.00 - 3.00 | 0.00 - 2.00 | 1.00 - 2.00 | 1.00 - 2.00 |

### Hypothesis test

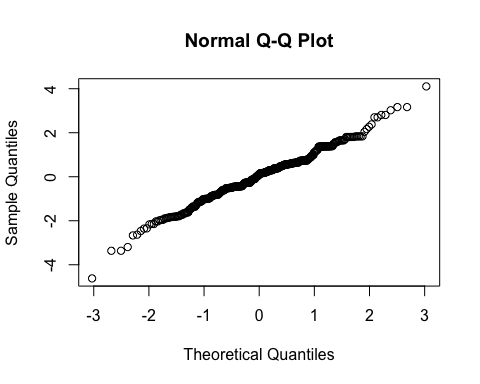
Ability to do second activity (higher is better)

| 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 |
| 3-009 | 0.000 | 0.714 | 0.000 | 0.238 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.18.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.528 | 0.157 | 0.001 | -0.837 | -0.219 |
| 2-03 | -0.368 | 0.157 | 0.020 | -0.676 | -0.059 |
| 2-04 | -0.277 | 0.157 | 0.079 | -0.585 | 0.032 |
| 2-05 | -0.826 | 0.157 | 0.000 | -1.135 | -0.518 |
| 2-06 | -0.439 | 0.157 | 0.005 | -0.748 | -0.131 |
| 2-07 | -0.177 | 0.157 | 0.261 | -0.486 | 0.132 |
| 3-002 | -0.203 | 0.157 | 0.198 | -0.511 | 0.106 |
| 3-004 | -0.246 | 0.157 | 0.119 | -0.554 | 0.063 |
| 3-008 | -0.165 | 0.157 | 0.294 | -0.474 | 0.143 |
| 3-009 | -0.075 | 0.157 | 0.632 | -0.384 | 0.233 |

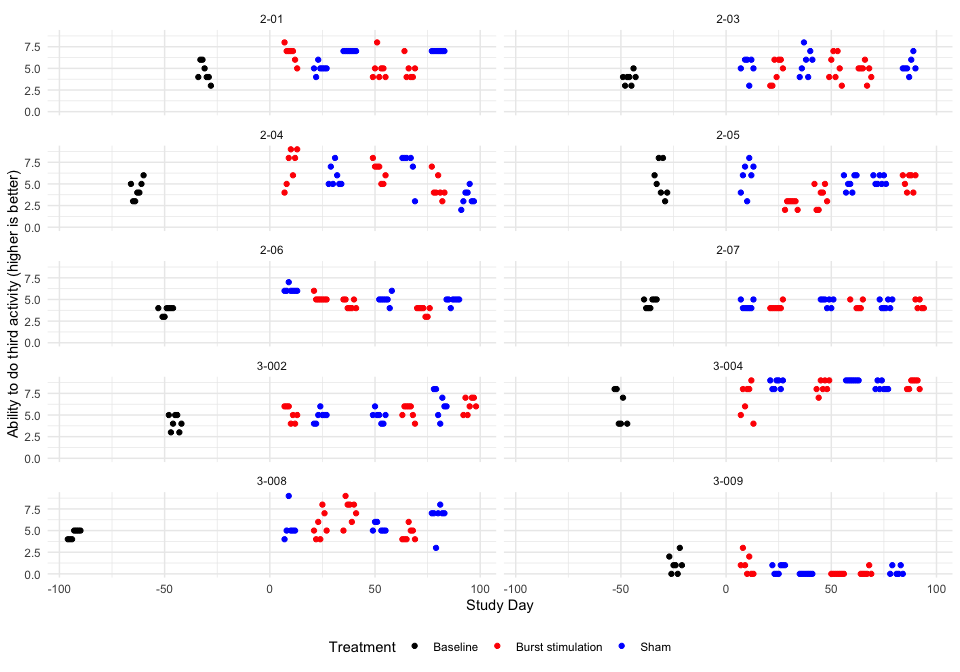
By treatment group and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.342 | 0.54 | 0 | 4.283 | 6.402 |
| Burst stimulation | 5.009 | 0.54 | 0 | 3.950 | 6.068 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.333 | 0.157 | 0.034 | -0.642 | -0.025 |

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

### Plot



### Descriptive table

| Ability to do third activity (higher is better) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
| n | 7 | 7 | 7 | 7 | 7 | 6 | 6 |
| Mean (sd) | 1.14 (1.07) | 1.00 (1.15) | 0.57 (0.53) | 0.00 (0.00) | 0.00 (0.00) | 0.17 (0.41) | 0.33 (0.52) |
| IQR | 1.00 | 1.50 | 1.00 | 0.00 | 0.00 | 0.00 | 0.75 |
| min - max | 0.00 - 3.00 | 0.00 - 3.00 | 0.00 - 1.00 | 0.00 - 0.00 | 0.00 - 0.00 | 0.00 - 1.00 | 0.00 - 1.00 |

### Hypothesis test

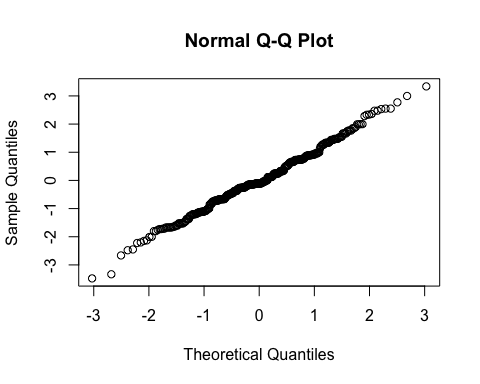
Ability to do third activity (higher is better)

| 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 |
| 3-009 | 0.429 | 0.000 | -0.167 | 0.087 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.076.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.675 | 0.208 | 0.001 | -1.082 | -0.267 |
| 2-03 | -0.494 | 0.208 | 0.018 | -0.902 | -0.086 |
| 2-04 | 0.339 | 0.208 | 0.103 | -0.069 | 0.747 |
| 2-05 | -1.289 | 0.208 | 0.000 | -1.696 | -0.881 |
| 2-06 | -0.765 | 0.208 | 0.000 | -1.173 | -0.358 |
| 2-07 | -0.227 | 0.208 | 0.274 | -0.635 | 0.180 |
| 3-002 | 0.072 | 0.208 | 0.730 | -0.336 | 0.479 |
| 3-004 | -0.626 | 0.208 | 0.003 | -1.034 | -0.218 |
| 3-008 | -0.139 | 0.208 | 0.505 | -0.546 | 0.269 |
| 3-009 | -0.034 | 0.208 | 0.870 | -0.442 | 0.374 |

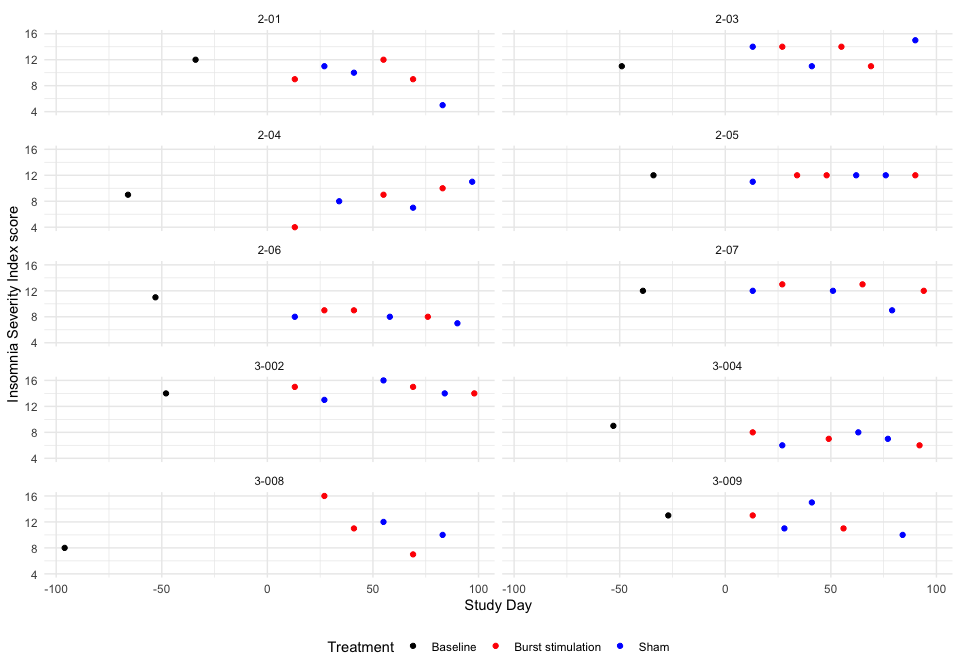
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 5.274 | 0.633 | 0 | 4.034 | 6.514 |
| Burst stimulation | 4.885 | 0.633 | 0 | 3.645 | 6.125 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.389 | 0.208 | 0.062 | -0.797 | 0.019 |

## Secondary endpoint: Insomnia Severity Index questionnaire total score

### Plot

 ### Descriptive table

| Insomnia Severity Index score | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
|  | 13 | 13 | 11 | 11 | 15 | NA | 10 |

### Hypothesis test

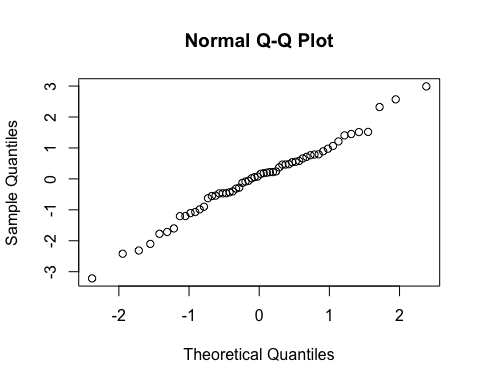
Insomnia Severity Index score

| 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 |
| 3-009 | 2 | -4 | NaN | -1.000 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.73.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 1.119 | 0.976 | 0.251 | -0.794 | 3.033 |
| 2-03 | -0.226 | 0.976 | 0.817 | -2.139 | 1.688 |
| 2-04 | -0.764 | 0.976 | 0.434 | -2.677 | 1.150 |
| 2-05 | 0.312 | 0.976 | 0.749 | -1.601 | 2.226 |
| 2-06 | 0.850 | 0.976 | 0.384 | -1.063 | 2.764 |
| 2-07 | 1.389 | 0.976 | 0.155 | -0.525 | 3.302 |
| 3-002 | 0.312 | 0.976 | 0.749 | -1.601 | 2.226 |
| 3-004 | 0.043 | 0.976 | 0.965 | -1.870 | 1.957 |
| 3-008 | -0.313 | 0.976 | 0.749 | -2.226 | 1.601 |
| 3-009 | -0.477 | 0.976 | 0.625 | -2.391 | 1.436 |

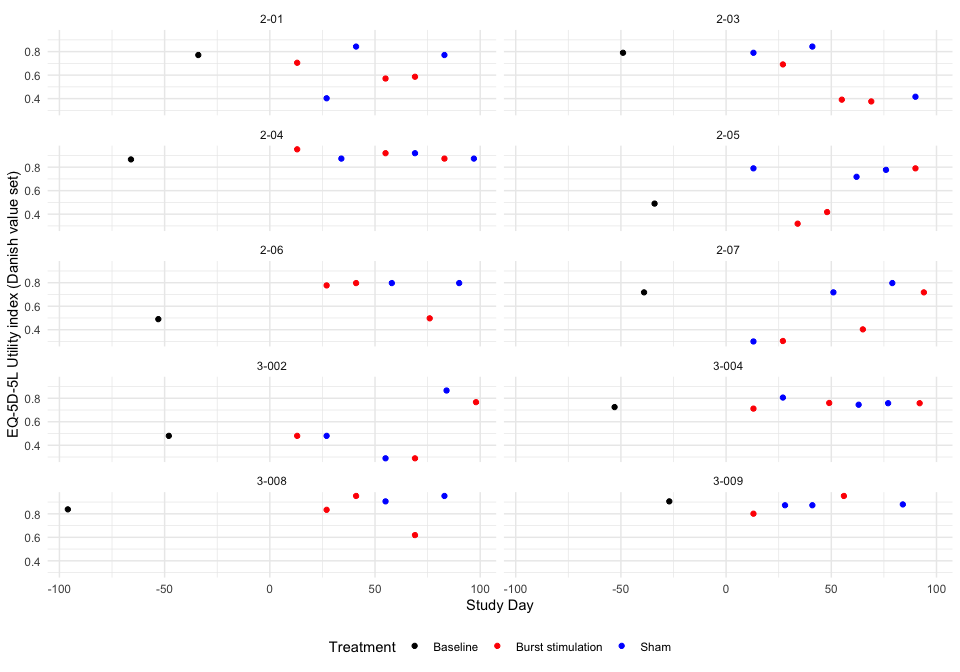
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 10.565 | 0.724 | 0 | 9.145 | 11.985 |
| Burst stimulation | 10.811 | 0.724 | 0 | 9.391 | 12.231 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.246 | 0.976 | 0.801 | -1.667 | 2.159 |

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

### Plot

 ### Descriptive table

| EQ-5D-5L Utility index (Danish value set) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis 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 |
| 3-009 |  |  |  |  |  |  |  |
|  | 0.906 | 0.801 | 0.873 | 0.952 | 0.873 | NA | 0.88 |

### Hypothesis test

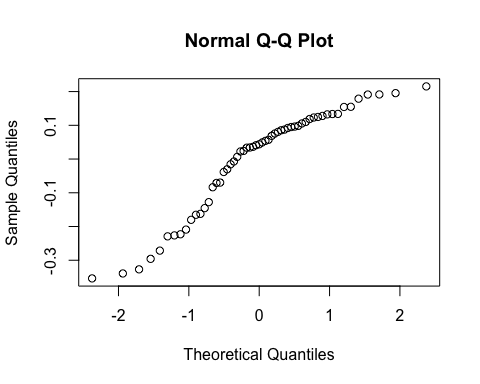
EQ-5D-5L Utility index (Danish value set)

| 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 |
| 3-009 | -0.072 | 0.079 | NaN | 0.004 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.01.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -0.068 | 0.066 | 0.303 | -0.197 | 0.061 |
| 2-03 | -0.144 | 0.066 | 0.029 | -0.273 | -0.015 |
| 2-04 | -0.027 | 0.066 | 0.683 | -0.156 | 0.102 |
| 2-05 | -0.173 | 0.066 | 0.008 | -0.302 | -0.044 |
| 2-06 | -0.084 | 0.066 | 0.199 | -0.213 | 0.044 |
| 2-07 | -0.109 | 0.066 | 0.098 | -0.238 | 0.020 |
| 3-002 | -0.058 | 0.066 | 0.378 | -0.187 | 0.071 |
| 3-004 | -0.054 | 0.066 | 0.407 | -0.183 | 0.074 |
| 3-008 | -0.082 | 0.066 | 0.212 | -0.211 | 0.047 |
| 3-009 | -0.055 | 0.066 | 0.399 | -0.184 | 0.073 |

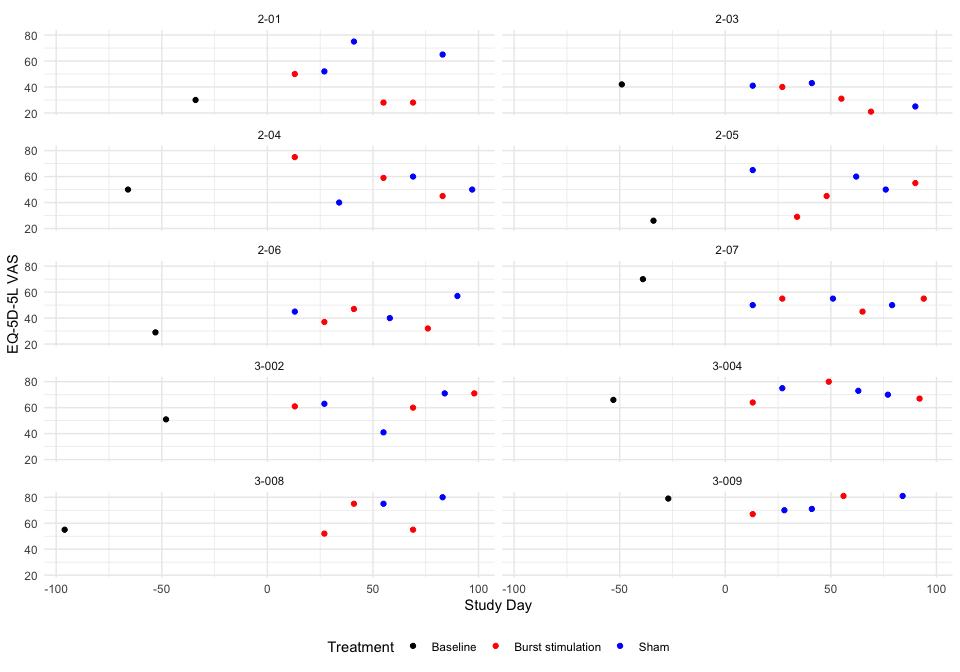
By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 0.743 | 0.047 | 0 | 0.652 | 0.835 |
| Burst stimulation | 0.657 | 0.046 | 0 | 0.567 | 0.748 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -0.086 | 0.066 | 0.19 | -0.215 | 0.043 |

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

### Plot

 ### Descriptive table

| EQ-5D-5L VAS | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
|  | 79 | 67 | 70 | 81 | 71 | NA | 81 |

### Hypothesis test

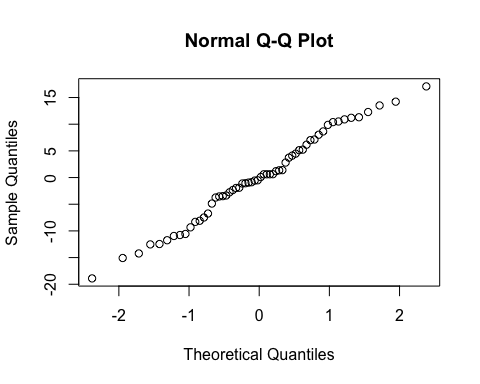
EQ-5D-5L VAS

| 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 |
| 3-009 | -3 | 10 | NaN | 3.500 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.1.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | -24.858 | 6.29 | 0.000 | -37.186 | -12.529 |
| 2-03 | -5.767 | 6.29 | 0.359 | -18.096 | 6.562 |
| 2-04 | 6.960 | 6.29 | 0.269 | -5.368 | 19.289 |
| 2-05 | -13.790 | 6.29 | 0.028 | -26.119 | -1.462 |
| 2-06 | -8.257 | 6.29 | 0.189 | -20.586 | 4.072 |
| 2-07 | -1.063 | 6.29 | 0.866 | -13.392 | 11.265 |
| 3-002 | 3.640 | 6.29 | 0.563 | -8.689 | 15.969 |
| 3-004 | -3.000 | 6.29 | 0.633 | -15.329 | 9.329 |
| 3-008 | -13.613 | 6.29 | 0.030 | -25.941 | -1.284 |
| 3-009 | -2.812 | 6.29 | 0.655 | -15.141 | 9.516 |

By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 58.411 | 4.447 | 0 | 49.695 | 67.128 |
| Burst stimulation | 52.223 | 4.447 | 0 | 43.507 | 60.939 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| -6.188 | 6.29 | 0.325 | -18.517 | 6.14 |

## Secondary endpoint: Patient Global Impression of Change

### Descriptive table

| Patient Global Impression of Change | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
|  | 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 (40.00%) | 1 (25.00%) | 3 (60.00%) | 8 (40.00%) | 3 (15.79%) | 1 (20.00%) |
| Minimalt bedre | 1 (20.00%) | 1 (25.00%) | 0 (0.00%) | 1 (5.00%) | 4 (21.05%) | 0 (0.00%) |
| Ingen endring | 1 (20.00%) | 1 (25.00%) | 1 (20.00%) | 6 (30.00%) | 2 (10.53%) | 2 (40.00%) |
| Minimalt verre | 1 (20.00%) | 0 (0.00%) | 0 (0.00%) | 2 (10.00%) | 1 (5.26%) | 1 (20.00%) |
| Mye verre | 0 (0.00%) | 1 (25.00%) | 1 (20.00%) | 2 (10.00%) | 9 (47.37%) | 1 (20.00%) |
| Veldig mye verre | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (5.00%) | 0 (0.00%) | 0 (0.00%) |

### Hypothesis test and treatment effect estimates

|  | Mean | SD |
| --- | --- | --- |
| Burst stimulation - Sham | 3.600000 | 1.602629 |
| Sham - Burst stimulation | 4.473684 | 1.645479 |

| contrast | estimate | std.error | p.value | conf.low | conf.high |
| --- | --- | --- | --- | --- | --- |
| Sham - Burst stimulation - Burst stimulation - Sham | 0.878 | 0.517 | 0.09 | -0.137 | 1.892 |

## Secondary outcome: Patient blinding question

### Descriptive table by participant

| Patient blinding question | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | |
|  | Pair 1 | | Pair 2 | | Pair 3 | |
|  | Burst stimulation | Sham | Burst stimulation | Sham | Burst stimulation | Sham |
| 2-01 |  |  |  |  |  |  |
| Slått på | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) | 0 (0.00%) | 1 (10.00%) |
| Slått av | 0 (0.00%) | 1 (11.11%) | 1 (10.00%) | 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%) |
| 2-03 |  |  |  |  |  |  |
| Slått på | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) | 1 (11.11%) | 0 (0.00%) |
| Slått av | 0 (0.00%) | 1 (11.11%) | 1 (10.00%) | 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 (10.00%) |
| 2-04 |  |  |  |  |  |  |
| Slått på | 1 (10.00%) | 0 (0.00%) | 1 (10.00%) | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) |
| Slått av | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) | 0 (0.00%) | 1 (11.11%) | 1 (10.00%) |
| 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 (11.11%) | 0 (0.00%) | 1 (10.00%) | 1 (11.11%) | 1 (10.00%) |
| Slått av | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Vet ikke | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| 2-06 |  |  |  |  |  |  |
| Slått på | 0 (0.00%) | 1 (11.11%) | 1 (10.00%) | 1 (10.00%) | 0 (0.00%) | 1 (10.00%) |
| Slått av | 1 (10.00%) | 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 (10.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) | 0 (0.00%) | 1 (10.00%) |
| 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 (11.11%) | 1 (10.00%) | 0 (0.00%) | 1 (11.11%) | 0 (0.00%) |
| 3-002 |  |  |  |  |  |  |
| Slått på | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) |
| Slått av | 0 (0.00%) | 1 (11.11%) | 1 (10.00%) | 1 (10.00%) | 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 (11.11%) | 1 (10.00%) | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) |
| Slått av | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) |
| 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 (10.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) |
| Slått av | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) | 1 (11.11%) | 0 (0.00%) |
| Vet ikke | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| 3-009 |  |  |  |  |  |  |
| Slått på | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (10.00%) | 0 (0.00%) | 0 (0.00%) |
| Slått av | 1 (10.00%) | 1 (11.11%) | 1 (10.00%) | 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 (10.00%) |

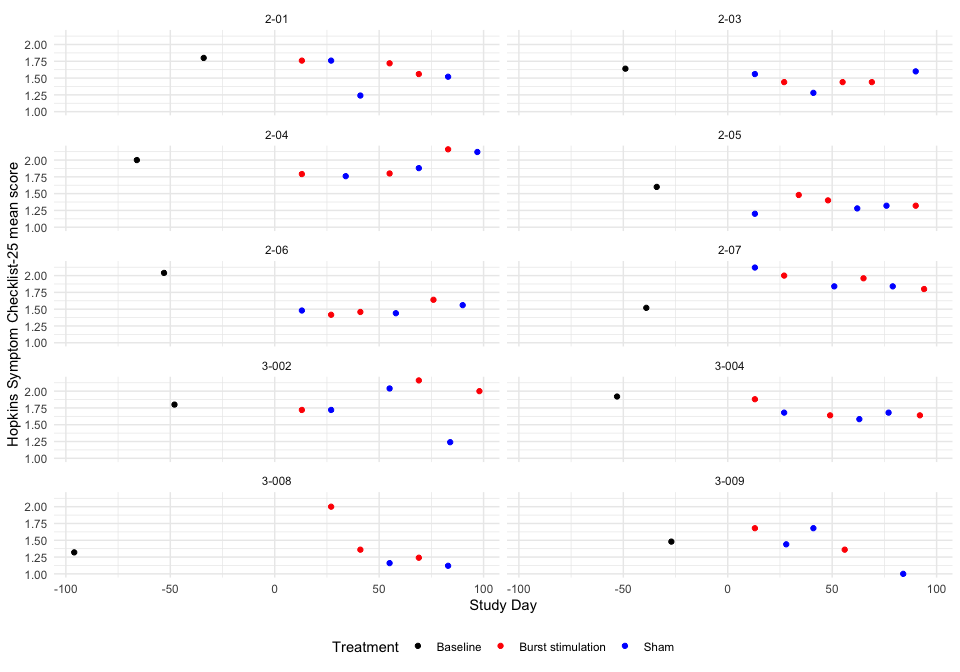
| Patient Blinding Quesiton | | |
| --- | --- | --- |
| Full analysis set | | |
|  | Burst stimulation | Sham |
| Slått på | 11 (37.93%) | 17 (58.62%) |
| Slått av | 12 (41.38%) | 9 (31.03%) |
| Vet ikke | 6 (20.69%) | 3 (10.34%) |

P-value of the null hypothesis chi-squared test: 0.26.

P-value of the null hypothesis Fisher test: 0.27.

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

### Plot

 ### Descriptive table

| Hopkins Symptom Checklist-25 mean score | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Full analysis set | | | | | | | |
|  | 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 |
| 3-009 |  |  |  |  |  |  |  |
|  | 1.48 | 1.68 | 1.44 | 1.36 | 1.68 | NA | 1 |

### Hypothesis test

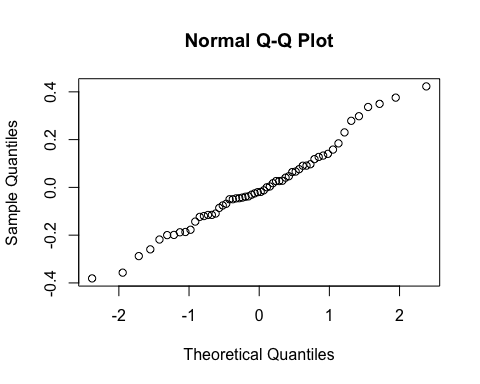
Hopkins Symptom Checklist-25 mean score

| 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 |
| 3-009 | 0.240 | -0.320 | NaN | -0.040 |

Values are Burst stimulation - Sham.

P-value of the null hypothesis test: 0.06.

### Treatment effect estimates

QQ-plot 

By subject

| Subject ID | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| 2-01 | 0.156 | 0.104 | 0.132 | -0.047 | 0.360 |
| 2-03 | -0.001 | 0.104 | 0.995 | -0.204 | 0.203 |
| 2-04 | 0.027 | 0.104 | 0.796 | -0.177 | 0.230 |
| 2-05 | 0.127 | 0.104 | 0.221 | -0.076 | 0.330 |
| 2-06 | 0.037 | 0.104 | 0.718 | -0.166 | 0.241 |
| 2-07 | 0.019 | 0.104 | 0.854 | -0.184 | 0.222 |
| 3-002 | 0.245 | 0.104 | 0.018 | 0.041 | 0.448 |
| 3-004 | 0.082 | 0.104 | 0.429 | -0.121 | 0.285 |
| 3-008 | 0.264 | 0.104 | 0.011 | 0.061 | 0.468 |
| 3-009 | 0.136 | 0.104 | 0.190 | -0.067 | 0.340 |

By treatment and overall

| Treatment | Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- | --- |
| Sham | 1.556 | 0.073 | 0 | 1.412 | 1.700 |
| Burst stimulation | 1.663 | 0.073 | 0 | 1.519 | 1.806 |

| Estimate | Std. Err. | p-value | Lower CL | Upper CL |
| --- | --- | --- | --- | --- |
| 0.106 | 0.104 | 0.306 | -0.097 | 0.31 |

## 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: 1361.3  
##   
## Scaled residuals:   
## Min 1Q Median 3Q Max   
## -3.5354 -0.5623 -0.0413 0.5410 3.4583   
##   
## Random effects:  
## Groups Name Variance Std.Dev.  
## subjectid:pair (Intercept) 0.6074 0.7793   
## subjectid:rantrt (Intercept) 0.2719 0.5214   
## subjectid (Intercept) 0.4813 0.6938   
## Residual 1.3109 1.1449   
## Number of obs: 410, groups:   
## subjectid:pair, 30; subjectid:rantrt, 20; subjectid, 10  
##   
## Fixed effects:  
## Estimate Std. Error t value  
## (Intercept) 4.32389 0.48083 8.993  
## rantrtSham -0.27496 0.34855 -0.789  
## pairPair 2 -0.69209 0.37976 -1.822  
## pairPair 3 -0.18468 0.38140 -0.484  
## prevtrtSham 0.17862 0.30937 0.577  
## rantrtSham:prevtrtSham -0.07987 0.32264 -0.248  
##   
## Correlation of Fixed Effects:  
## (Intr) rntrtS parPr2 parPr3 prvtrS  
## rantrtSham -0.566   
## pairPair 2 -0.475 0.080   
## pairPair 3 -0.478 0.075 0.513   
## prevtrtSham -0.596 0.629 0.148 0.155   
## rntrtShm:pS 0.380 -0.595 -0.059 -0.039 -0.683

Then plot the expected outcome by current and previous treatment:

Outcome by tretment and previous treatment

| prevtrt | rantrt | estimate | std.error | statistic | p.value | conf.low | conf.high |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Sham | Sham | 3.859 | 0.361 | 10.691 | 0 | 3.152 | 4.567 |
| Burst stimulation | Sham | 3.761 | 0.330 | 11.393 | 0 | 3.114 | 4.407 |
| Sham | Burst stimulation | 4.219 | 0.325 | 12.976 | 0 | 3.582 | 4.856 |
| Burst stimulation | Burst stimulation | 4.040 | 0.405 | 9.986 | 0 | 3.247 | 4.833 |

Then compute the treatment effect estimate by previous treatment:

| contrast | prevtrt | estimate | std.error | p.value | conf.low | conf.high |
| --- | --- | --- | --- | --- | --- | --- |
| mean(Sham) - mean(Burst stimulation) | Sham | -0.36 | 0.303 | 0.235 | -0.953 | 0.234 |
| mean(Sham) - mean(Burst stimulation) | Burst stimulation | -0.28 | 0.349 | 0.422 | -0.963 | 0.403 |

Finally see if there is a difference:

| estimate | std.error | p.value | conf.low | conf.high |
| --- | --- | --- | --- | --- |
| -0.08 | 0.323 | 0.804 | -0.712 | 0.553 |

# 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. |
| Akademiska | 3-009 | 2023-02-28 | Male | 45 | 2023-03-28 | TRUE | TRUE | 2023-04-04 | Serom, som spontant går i regress på 3 dager. | Serom |

# 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% |
| Akademiska | 3-009 | 100% | 0% |

# 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 |
| 3-009 | 15 days | Burst stimulation | 1 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 3-009 | 28 days | Sham | 2 | Pair 1 | Nei | NA | Nei | NA | Nei | NA |
| 3-009 | 43 days | Sham | 3 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 3-009 | 57 days | Burst stimulation | 4 | Pair 2 | Nei | NA | Nei | NA | Nei | NA |
| 3-009 | 71 days | Burst stimulation | 5 | Pair 3 | Nei | NA | Nei | NA | Nei | NA |
| 3-009 | 86 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 |
| 3-009 | 15 days | Burst stimulation | 1 | Pair 1 | Ja | Kortvarig icke-infektiös svullnad över dosficka och ankare för 10 dagar sedan. |
| 3-009 | 28 days | Sham | 2 | Pair 1 | Nei | NA |
| 3-009 | 43 days | Sham | 3 | Pair 2 | Nei | NA |
| 3-009 | 57 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 3-009 | 71 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 3-009 | 86 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 |
| 3-009 | 15 days | Burst stimulation | 1 | Pair 1 | Nei | NA |
| 3-009 | 28 days | Sham | 2 | Pair 1 | Nei | NA |
| 3-009 | 43 days | Sham | 3 | Pair 2 | Nei | NA |
| 3-009 | 57 days | Burst stimulation | 4 | Pair 2 | Nei | NA |
| 3-009 | 71 days | Burst stimulation | 5 | Pair 3 | Nei | NA |
| 3-009 | 86 days | Sham | 6 | Pair 3 | Nei | NA |

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