

# NOR-SOLIDARITY First Interim Report

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## Contents

<b>Introduction</b>	<b>1</b>
<b>Demographics</b>	<b>1</b>
All randomised . . . . .	1
Excluded from FAS . . . . .	1
Full analysis set . . . . .	4
<b>Analysis</b>	<b>7</b>
Primary analysis . . . . .	7

## 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 2023-07-04 system time stamped “\_20230704\_090943”.

While the results are based on real data, the treatment allocation has been drawn randomly for this report. Thus, this is a mock-up report intended to show how the final report will look like, without showing the actual results of the trial and the treatment differences.

There were 13 included patients of which 10 are included in the full analysis set.

## Demographics

### All randomised

### Excluded from FAS

```
## Demographics and baseline characteristics
## Excluded
##
## -----
##                                     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%)
##	Divorced	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%)
##	Sykepenges helt (er helt sykmeldt)	0 (0.00%)
##	Sykepenges 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-opioids?	
## 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 opioids?	
## 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

```

## Demographics and baseline characteristics
## Full analysis set
## -----
## 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%)
## Divorced 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-opioids?	
## 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%)
## Treatment with opioids?	
## 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%)

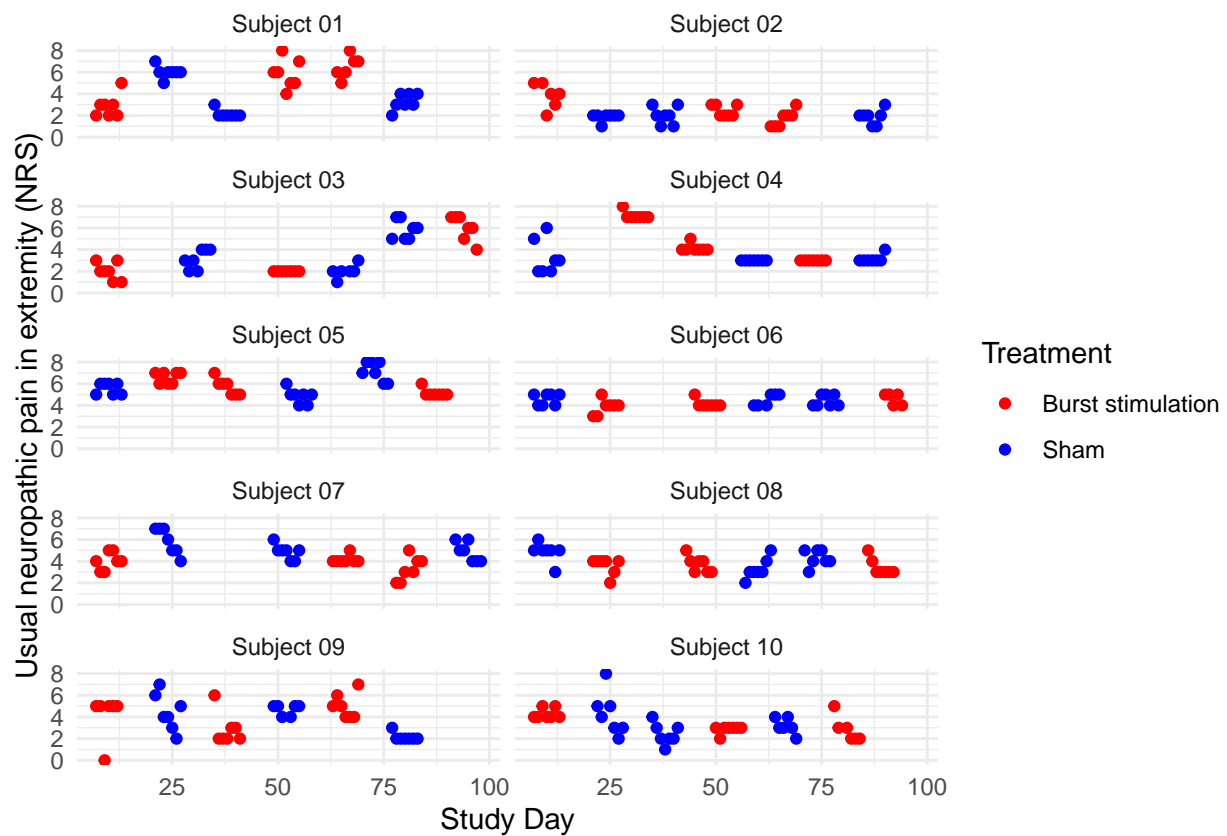
```
## Other current treatment, specify
##   Följer sjukgymnast-program hemma. 1
## Current back pain?
##   No 3 (30.00%)
##   Yes 7 (70.00%)
## Duration of pain (years)
##   n 10
##   Mean (sd) 8.69 (10.74)
##   IQR 7.53
##   min - max 1.00 - 36.00
## Duration of current pain level (years)
##   n 10
##   Mean (sd) 3.26 (3.81)
##   IQR 3.27
##   min - max 0.25 - 10.00
```

## Analysis

### Primary analysis

#### Plot

```
## Don't know how to automatically pick scale for object of type <difftime>.
## Defaulting to continuous.
```



# Descriptive table

## Descriptive table

## Full analysis set

##

##		Baseline	Pair 1	Pair 2		
##		Baseline	Burst stimulation	Sham	Burst stimulation	Sham
##						
## 2-01						
## n	8	7	7	7	7	6
## Mean (sd)	4.88 (0.99)	2.86 (1.07)	6.00 (0.58)	5.86 (1.35)	2.14 (0.38)	6.00 (0.58)
## IQR	1.00	1.00	0.00	1.50	0.00	1.00
## min - max	4.00 - 7.00	2.00 - 5.00	5.00 - 7.00	4.00 - 8.00	2.00 - 3.00	5.00 - 7.00
## 2-03						
## n	8	6	7	7	7	1
## Mean (sd)	4.50 (0.76)	3.83 (1.17)	1.86 (0.38)	2.43 (0.53)	2.00 (0.82)	1.86 (0.38)
## IQR	1.00	1.50	0.00	1.00	1.00	1.00
## min - max	4.00 - 6.00	2.00 - 5.00	1.00 - 2.00	2.00 - 3.00	1.00 - 3.00	1.00 - 2.00
## 2-04						
## n	7	7	7	7	6	6
## Mean (sd)	4.29 (0.76)	2.00 (0.82)	3.14 (0.90)	2.00 (0.00)	2.00 (0.63)	3.14 (0.90)
## IQR	0.00	1.00	1.50	0.00	0.00	1.00
## min - max	4.00 - 6.00	1.00 - 3.00	2.00 - 4.00	2.00 - 2.00	1.00 - 3.00	4.00 - 6.00
## 2-05						
## n	8	7	7	7	7	3
## Mean (sd)	6.25 (1.04)	7.14 (0.38)	3.29 (1.60)	4.14 (0.38)	3.00 (0.00)	7.14 (0.38)
## IQR	1.00	0.00	2.00	0.00	0.00	1.00
## min - max	4.00 - 7.00	7.00 - 8.00	2.00 - 6.00	4.00 - 5.00	3.00 - 3.00	7.00 - 8.00
## 2-06						
## n	8	7	7	7	7	5
## Mean (sd)	6.75 (0.46)	6.57 (0.53)	5.57 (0.53)	5.71 (0.76)	4.86 (0.69)	6.57 (0.53)
## IQR	0.25	1.00	1.00	1.00	0.50	1.00
## min - max	6.00 - 7.00	6.00 - 7.00	5.00 - 6.00	5.00 - 7.00	4.00 - 6.00	6.00 - 7.00
## 2-07						
## n	8	7	7	7	6	4
## Mean (sd)	4.25 (0.46)	3.86 (0.69)	4.57 (0.53)	4.14 (0.38)	4.50 (0.55)	3.86 (0.69)
## IQR	0.25	0.50	1.00	0.00	1.00	0.50
## min - max	4.00 - 5.00	3.00 - 5.00	4.00 - 5.00	4.00 - 5.00	4.00 - 5.00	3.00 - 5.00
## 3-002						
## n	7	7	7	7	7	3
## Mean (sd)	5.14 (0.38)	4.00 (0.82)	5.86 (1.21)	4.14 (0.38)	4.86 (0.69)	4.00 (0.82)
## IQR	0.00	1.00	2.00	0.00	0.50	1.00
## min - max	5.00 - 6.00	3.00 - 5.00	4.00 - 7.00	4.00 - 5.00	4.00 - 6.00	2.00 - 5.00
## 3-004						
## n	7	7	7	7	7	3
## Mean (sd)	6.00 (0.82)	3.57 (0.79)	4.86 (0.90)	3.71 (0.76)	3.29 (0.95)	3.57 (0.79)
## IQR	1.00	0.50	0.00	1.00	0.50	1.00
## min - max	5.00 - 7.00	2.00 - 4.00	3.00 - 6.00	3.00 - 5.00	2.00 - 5.00	3.00 - 6.00
## 3-008						
## n	7	6	7	7	6	5
## Mean (sd)	4.43 (0.53)	4.17 (2.04)	4.43 (1.72)	2.86 (1.46)	4.67 (0.52)	4.17 (2.04)
## IQR	1.00	0.00	2.00	1.00	0.75	1.00
## min - max	4.00 - 5.00	0.00 - 5.00	2.00 - 7.00	2.00 - 6.00	4.00 - 5.00	0.00 - 5.00



```
## 3-009
##      n              8              7              6              7              8
## Mean (sd)  3.38 (0.92)  4.29 (0.49)  4.50 (2.07)  2.86 (0.38)  2.50 (0.93)
## IQR        1.25         0.50         1.75         0.00         1.00
## min - max  2.00 - 4.00  4.00 - 5.00  2.00 - 8.00  2.00 - 3.00  1.00 - 4.00
```

subjectid	Pair 1	Pair 2	Pair 3	Overall
2-01	-3.14	3.71	3.21	1.26
2-03	1.98	0.43	-0.14	0.76
2-04	-1.14	0.00	0.14	-0.33
2-05	3.86	1.14	-0.14	1.62
2-06	1.00	0.86	-2.00	-0.05
2-07	-0.71	-0.36	0.17	-0.30
3-002	-1.86	-0.71	-1.57	-1.38
3-004	-1.29	0.43	-0.86	-0.57
3-008	-0.26	-1.81	2.86	0.26
3-009	-0.21	0.36	-0.33	-0.06

Values are Burst stimulation - Sham.

```
## [1] 0.6994537

## Linear mixed model fit by REML ['lmerMod']
## Formula: painleg3 ~ rantrt + pair + (1 | subjectid) + (1 | subjectid:pair) +
##          (1 | subjectid:rantrt)
## Data: data
##
## REML criterion at convergence: 1360
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -3.9059 -0.5630 -0.0399  0.5780  3.2344
##
## Random effects:
##   Groups             Name             Variance Std.Dev.
## subjectid:pair      (Intercept)  0.6062     0.7786
## subjectid:rantrt    (Intercept)  0.3298     0.5742
## subjectid           (Intercept)  0.4479     0.6693
## Residual                1.3001     1.1402
## Number of obs: 410, groups:
## subjectid:pair, 30; subjectid:rantrt, 20; subjectid, 10
##
## Fixed effects:
##              Estimate Std. Error t value
## (Intercept)   4.3725     0.3887  11.248
## rantrtSham   -0.1178     0.2805  -0.420
## pairPair 2   -0.7388     0.3744  -1.973
## pairPair 3   -0.2414     0.3747  -0.644
##
## Correlation of Fixed Effects:
##              (Intr) rntrtS parPr2
## rantrtSham  -0.361
## pairPair 2  -0.482  0.001
## pairPair 3  -0.481 -0.001  0.500
```

```

##
##      Term                                Contrast subjectid Estimate Std. Error
## rantrt mean(Burst stimulation) - mean(Sham)      2-01   1.03150      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      2-03   0.62581      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      2-04  -0.27487      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      2-05   1.38175      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      2-06  -0.02148      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      2-07  -0.25050      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      3-002 -1.14405      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      3-004 -0.46249      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      3-008   0.29725      0.28
## rantrt mean(Burst stimulation) - mean(Sham)      3-009 -0.00512      0.28
##      z Pr(>|z|)    2.5 % 97.5 %
##    3.6776 <0.001  0.4818 1.5812
##    2.2312  0.0257  0.0761 1.1755
##   -0.9800  0.3271 -0.8246 0.2749
##    4.9264 <0.001  0.8320 1.9315
##   -0.0766  0.9390 -0.5712 0.5283
##   -0.8931  0.3718 -0.8002 0.2992
##   -4.0790 <0.001 -1.6938 -0.5943
##   -1.6489  0.0992 -1.0122 0.0872
##    1.0598  0.2892 -0.2525 0.8470
##   -0.0183  0.9854 -0.5548 0.5446
##
## Columns: term, contrast, subjectid, estimate, std.error, statistic, p.value, conf.low, conf.high, pr
##
##      Term                                Contrast Estimate Std. Error    z Pr(>|z|)  2.5 %
## rantrt Burst stimulation - Sham      0.118      0.28 0.42    0.675 -0.432
## 97.5 %
##    0.667
##
## Columns: term, contrast, estimate, std.error, statistic, p.value, conf.low, conf.high
## # A tibble: 10 x 2
##   subjectid mean
##   <fct>      <dbl>
## 1 2-01      1.26
## 2 2-03      0.754
## 3 2-04     -0.333
## 4 2-05      1.62
## 5 2-06     -0.0476
## 6 2-07     -0.3
## 7 3-002    -1.38
## 8 3-004    -0.571
## 9 3-008     0.262
## 10 3-009   -0.0635

```