Supplementary Figure 1. Details of the trial schedule

Item		Clinical trial period							Clinical trial period (continuous trial)					Follow-up period
		Pre-evaluation period	Evaluation period						Continuous-evaluation period					
		2 weeks before intervention	1st day		2nd day	3rd day	4th day	5th day or abortion		1st week	2nd week	3rd week	4th week	4 weeks after completion of intervention
Informed consent		+												
Eligibility evaluation (VAS, MMSE, BDI-II)		+												
Final eligibility test (Compliance test)			+											
Definitive registration and assignment			+											
Eligibility evaluation for continuous trial									+					
Informed consent for continuous trial									+					
Intervention	Active or sham stimulation			+	+	+	+	+						
	Active stimulation									+	+	+	+	
VAS	Immediately before intervention			+	+	+	+	+		+	+	+	+	
	Immediately after intervention			+	+	+	+	+		+	+	+	+	
SF-MPQ2	Immediately before intervention			+	+	+	+	+		+	+	+	+	
	Immediately after intervention			+	+	+	+	+		+	+	+	+	
PGIC[a]	After intervention							+					+[b]	
BDI-II[a], EQ-5D-5L[a]				+[c]				+[d]					+[e]	
Final evaluation (VAS, SF-MPQ2, MMSE, BDI-II)														+
Adverse events and malfunction of devices				+	+	+	+	+		+	+	+	+	+
Evaluation of blindness[a]	After intervention			+				+						

The schedule of evaluations is shown. Evaluations during the continuous trial were performed on the day of the intervention (at least once weekly).

Abbreviations: VAS, visual analogue scale; MMSE, Mini mental state examination; BDI-II, Beck Depression Inventory second version; SF-MPQ2, short-form McGill pain questionnaire 2; PGIC, Patient Global Impression of Change; EQ-5D-5L, European Quality of Life-5 Dimensions 5-level.

[a] Performed on the day of treatment termination or the day after treatment termination in cases of study withdrawal.

[b] Evaluated on the final day of intervention. [c] Evaluated before the intervention.

[d] Evaluated after the intervention. [e] Evaluated after the final intervention.

Supplementary Table 1. Evaluation of blinding

	Active	Sham
First day, No. (%)	**n=72**	**n=70**
Thought that they received active	21 (29)	20 (29)
Thought that they received sham	11 (15)	11 (16)
Cannot tell	40 (56)	39 (56)
Fifth day, No. (%)	**n=71**	**n=68**
Thought that they received active	22 (31)	27 (40)
Thought that they received sham	13 (18)	14 (21)
Cannot tell	36 (51)	27 (40)

Among the active stimulation group, 21 patients (29%) correctly guessed their intervention on the first day and 22 (31%) on the fifth day. Among the sham group, 11 patients (16%) guessed correctly on the first day and 14 (21%) on the fifth day.

Supplementary Table 2. Secondary outcomes of five daily interventions (change rate)

	Active n=72	Sham n=70	Mean difference or odds ratio (95% CI)	*p* value
VAS				
Decrease rate, mean (SD), %	12.1 (19.0)	13.5 (19.4)	-1.4 (-7.8 to 4.9)	0.66
≥15% decrease, No. (%)	26 (36)	28 (40)	0.8 (0.4 to 1.7)	0.73
≥30% decrease, No. (%)	10 (14)	12 (17)	0.8 (0.3 to 1.9)	0.65
Short-term decrease rate, mean (SD), %	6.3 (11.9)	6.0 (15.2)	0.3 (-4.2 to 4.8)	0.89
SF-MPQ2, mean (SD), %				
Decrease rate	33.4 (30.3)	29.1 (28.8)	4.3 (-5.5 to 14.1)	0.39
Short-term decrease rate	14.2 (16.4)	14.1 (15.9)	0.1 (-5.2 to 5.4)	0.98
EQ-5D-5L, mean (SD), %				
Index value rate of increase	14.7 (45.1)	10.6 (27.2)	4.0 (-8.5 to 16.6)	0.52
$VAS_{EQ\text{-}5D}$ rate of increase	8.0 (37.7)	7.3 (55.3)	0.7 (-15.1 to 16.5)	0.93
BDI-II, mean (SD), %				
Decrease rate[a]	-1.1 (63.9)	8.6 (120.4)	7.5 (-27.9 to 42.8)	0.67

Analyses were performed on the intention-to-treat population (active vs. sham, n=72 vs. 70), except for analysis on decrease rate of BDI-II.

Abbreviations: VAS, visual analogue scale; SF-MPQ2, short-form McGill pain questionnaire 2; EQ-5D-5L, European Quality of Life-5 Dimensions 5-level; BDI-II, Beck Depression Inventory second version.

[a] Analysis was performed in 57 (active) and 64 (sham) patients because excluded patients had a score of zero at baseline.

Supplementary Table 3. Results of the final evaluations at the last follow-up

	All patients				Patients enrolled in the continuous trial			
	Active n=70	Sham n=67	Mean difference (95% CI)	*p* value	Active n=16	Sham n=15	Mean difference (95% CI)	*p* value
VAS decrease, mean (SD)	6.9±18.4	7.3±13.6	-0.4 (-6.7 to 5.8)	0.90	24.7±22.6	21.4±23.5	3.3 (-13.6 to 20.2)	0.69
VAS decrease rate, mean (SD), %	10.8±29.6	10.3±31.2	0.5 (-9.7 to 10.8)	0.92	40.9±36.8	32.5±36.3	8.4 (-18.4 to 35.3)	0.53
SF-MPQ2 decrease, mean (SD)	13.1±32.9	8.0±30.4	5.1 (-5.6 to 15.8)	0.35	37.6±31.5	15.1±33.8	22.5 (-1.5 to 46.5)	0.07
SF-MPQ2 decrease rate, mean (SD), %	20.5±48.2	13.6±46.7	6.8 (-9.2 to 22.9)	0.40	57.4±43.8	30.0±58.6	31.4 (-6.4 to 69.3)	0.10
BDI-II decrease, mean (SD)[a]	0.4±5.3	0.9±5.9	-0.6 (-2.4 to 1.3)	0.56	1.1±5.1	0.9±4.6	-0.2 (-3.4 to 3.8)	0.91
BDI-II decrease rate, mean (SD), %[b]	1.5±86.9	-0.2±113.1	1.6 (-35.4 to 38.7)	0.93	15.9±73.8	-10.7±169.9	26.7 (-76.6 to 129.9)	0.60
MMSE increase, mean (SD)	0.1±1.7	0.1±1.8	-0.1 (-0.7 to 0.5)	0.80	-0.4±1.8	0.1±1.6	-0.6 (-1.8 to 0.7)	0.36
MMSE increase rate, mean (SD), %	0.3±6.0	0.6±6.6	-0.3 (-2.5 to 1.8)	0.78	-1.4±6.1	0.6±5.6	-2.0 (-6.3 to 2.3)	0.36

Abbreviations: VAS, visual analogue scale; SF-MPQ2, short-form McGill pain questionnaire 2; BDI-II, Beck Depression Inventory second version; MMSE, Mini mental state examination.

[a] Analysis was performed in 69 (active) and 67 (sham) patients for the all patients.

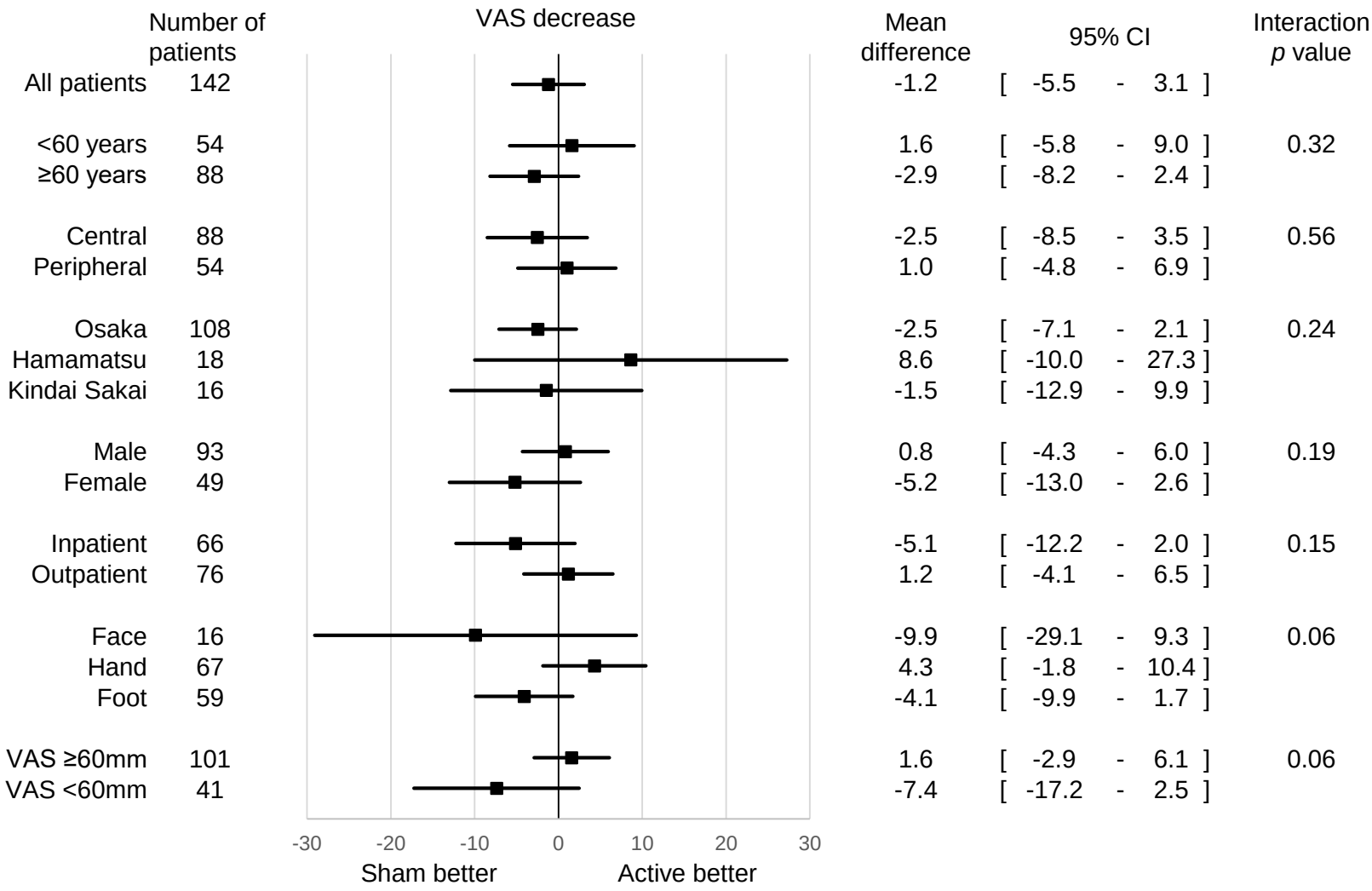
[b] Analysis was performed in 56 (active) and 62 (sham) patients for the all patients, and in 14 (active) and 12 (sham) patients for the patients enrolled in the continuous trial.

Supplementary Table 4. Post-hoc analyses of SF-MPQ2 during 5-daily intervention

	Active	Sham	Mean difference (95% CI)	*p* value
SF-MPQ2 Decrease (per-protocol)	22.3 (24.3)	15.3 (19.8)	7.0 (-0.6 to 14.6)	0.07
Decrease of SF-MPQ2 subscale scores (intention-to-treat)				
Continuous pain	7.9 (8.7)	4.8 (6.4)	3.1 (0.5 to 5.6)	0.02
Intermittent pain	5.1 (8.8)	3.9 (7.6)	1.2 (-1.6 to 3.9)	0.41
Neuropathic pain	5.0 (6.8)	4.0 (5.8)	1.0 (-1.1 to 3.1)	0.34
Affective descriptors	3.7 (5.2)	3.5 (5.1)	0.2 (-1.5 to 1.9)	0.81

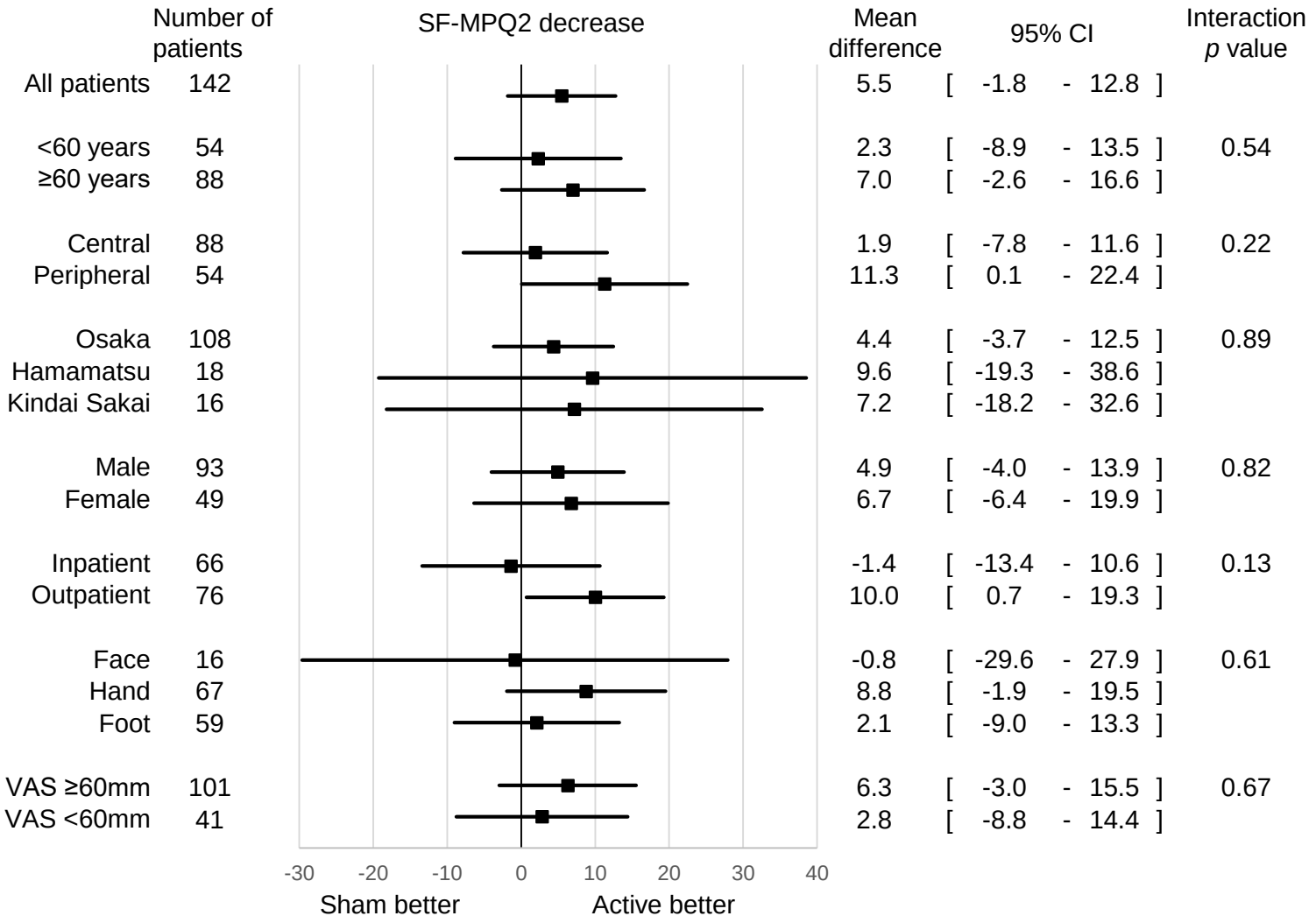
Data are mean (SD). Analyses were performed in the per-protocol population (active vs. sham, n=72 vs. 70) or the intention-to-treat population (n=69 vs. 65). SF-MPQ2 = short-form McGill pain questionnaire 2.

Supplementary Figure 2A. Subgroup analyses of VAS decrease during the evaluation period



Subgroup analyses of decrease in visual analogue scale (VAS) were performed to evaluate the influence of background factors (age, cause of pain, trial site, inpatient vs. outpatient, location with maximum pain [i.e. stimulation location], and VAS at baseline [≥60 vs. <60 mm]) in the intention-to-treat population. Analyses of maximum pain and VAS at baseline were performed as post-hoc analyses.
Abbreviations: Osaka, Osaka University Hospital; Hamamatsu, Hamamatsu University Hospital; Kindai Sakai, Kindai University Sakai Hospital.

Supplementary Figure 2B. Subgroup analyses of SF-MPQ2 decrease during the evaluation period



Subgroup analyses of decrease in short-form McGill pain questionnaire 2 (SF-MPQ2) were performed to evaluate the influence of background factors (age, cause of pain, trial site, inpatient vs. outpatient, location with maximum pain [i.e. stimulation location], and VAS at baseline [≥60 vs. <60 mm]) in the intention-to-treat population. Subgroup analyses of SF-MPQ2 decrease were performed as post-hoc analyses.
Abbreviations: Osaka, Osaka University Hospital; Hamamatsu, Hamamatsu University Hospital; Kindai Sakai, Kindai University Sakai Hospital.