

Efficacy of adding selective electrical muscle stimulation to usual physical therapy for Bell's palsy: immediate and six-month outcomes

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Abstract

Bell's palsy is the most common cause of facial paralysis, affecting one in every 60 people in their lifetime. Transcutaneously applied selective electrical muscle stimulation could potentially accelerate recovery from Bell's palsy but this intervention remains controversial. Studies have shown benefit, but concerns for lack of efficacy and potential for worsening synkinesis remain. We performed a prospective controlled trial comparing outcomes at initial recovery and six months later with selective electrical muscle stimulation and usual physical therapy versus usual physical therapy alone in adults with acute Bell's palsy. Outcomes were facial function assessed with the House Brackman and eFACE scales. Outcomes were evaluated at discharge and six months after discharge. Discharge occurred when participants were judged to be fully recovered by their treating therapist and supervisor. 38 adults participated in the study. Participants in the electrical stimulation group achieved maximal recovery twice as fast as the control group (2.5 weeks versus 5.2 weeks) with no significant differences in facial function or synkinesis between groups at any time point. This study is the first human trial of electrical stimulation in Bell's palsy to follow patients 6 months from recovery and supports that selective electrical muscle stimulation accelerates recovery and does not increase synkinesis.

Key Words: Bell's palsy; facial paralysis; synkinesis; long pulse electrical muscle stimulation; clinical trial.

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Bell's palsy, an idiopathic facial nerve palsy, is the most common cause of facial paralysis. One in 60 people experience Bell's palsy in their lifetime.^{1,2} The functional and psychological consequences of facial paralysis are substantial.

Affected patients cannot close their eyes for protection, and cannot control their lips to speak, smile, and retain food and saliva in their mouth. In Bell's palsy, the degree of paralysis ranges from mild weakness to complete paralysis. Onset of paralysis is relatively quick, reaching maximum severity within 72 hours from onset, and

resolution is slow, taking from a few weeks to up to 6 months.³ Most people recover full facial muscle strength. However 29% of patients develop synkinesis which involves involuntary ipsilateral facial muscle contractions, facial muscle spasms, and unintentional facial movement that occurs simultaneously with intentional movement.^{4,5}

Synkinesis also has substantial consequences including inability to smile, difficulty eating and speaking, difficulty with vision, and distorted facial appearance. Synkinesis is thought to be caused by aberrant muscle re-innervation by the facial nerve.⁶ Synkinesis typically

develops 6 months after onset of flaccid paralysis.⁷ Transcutaneously applied selective electrical stimulation can produce muscle contractions in paralyzed denervated muscles, including facial muscles affected by Bell's palsy.

Such selective electrical muscle stimulation could potentially shorten the duration of paralysis and reduce long-term sequelae of Bell's palsy by preventing muscle atrophy and improving selectivity of re-innervation. While electrical stimulation for recovery after musculoskeletal and central nervous system injury has been widely studied and shown to accelerate recovery,⁸⁻¹² the effectiveness of electrical stimulation for Bell's palsy remains controversial.¹³ Expert researchers and practicing clinicians are divided in their opinions on the use of electrical stimulation in this context; some assert it improves recovery, while other are concerned about adverse effects, particularly potentially increasing the risk for or severity of synkinesis.¹³⁻¹⁵

Previously published human clinical trials of electrical stimulation for Bell's palsy have substantial limitations.¹⁶⁻²³

The trials are not controlled (only one is randomized),²⁰ do not account for predictors of prognosis, use insensitive outcome measures, and do not follow patients for long enough to evaluate for synkinesis.

For example, complete paralysis is a significant predictor of sequelae, with 61% of patients with complete paralysis developing synkinesis.⁴

In the previously published clinical trials, the baseline degree of paralysis is not clearly reported. The most commonly used outcome measure has been the House Brackmann (HB) scale, which gives a global score for facial function ranging from I to VI. This scale has low inter-rater reliability and lacks precision in capturing differences in facial function.²⁴

Blinding to group allocation is uncommon in prior studies. We found only one study with blinded evaluators).²⁰ Furthermore, although synkinesis takes up to 6 months from initial recovery to develop, prior clinical trials only followed participants for up to 3 months. Additionally, the electrical stimulation parameters used in prior clinical trials for Bell's palsy have varied. Most used sufficient intensity to produce muscle contraction (one used subsensory stimulation),¹⁹ which is intended to prevent or delay muscle atrophy.^{25,26} Both monophasic and biphasic pulsed currents have been used.

Monophasic electrical currents may be most effective as they have been shown to promote tissue healing which could be beneficial in Bell's palsy.²⁷⁻³⁰

To more fully elucidate the impacts of selective electrical muscle stimulation in patients with Bell's palsy, we performed a prospective controlled trial comparing selective electrical muscle stimulation, using a monophasic pulsed exponential waveform together with usual physical therapy versus usual physical therapy alone in the treatment of adults with acute Bell's palsy.

The eFACE scale, a sensitive validated clinician-graded scale of facial paralysis with high interrater and intrarater reliability, with scores for static, dynamic, and synkinesis facial function, was used as the primary outcome measure.^{31,32} Evaluators were blinded to group allocation by using high quality video recordings of participants for the eFACE grading. Participants were followed for 6 months beyond their initial recovery to assess for eventual development of synkinesis.

Materials and Methods

Subjects and design

This was a single-blind, alternating allocation (active or control), controlled trial comparing usual physical therapy plus selective electrical muscle stimulation (active) to usual physical therapy (control) for treatment of acute Bell's palsy in adults. Evaluators were blinded to the intervention, while research subjects and treating therapists were aware of the treatment used. The study took place between February 2017 and December 2018 at the Kinesiology Department at the National University of the Northeast (Universidad Nacional del Nordeste (UNNE) in Argentina.

Inclusion criteria were diagnosis of acute (up to one month from onset of paralysis), incomplete, Bell's palsy. Potential participants were excluded if they had other causes of facial paralysis, or had hypertension, diabetes, or complete facial paralysis given the potential impact on outcome. Patients who had received prior facial physical therapy or muscle stimulation were also excluded. The diagnoses of Bell's palsy and comorbid conditions were made by the referring physician. Referrals came from primary care, neurology, and emergency physicians. Participants did not receive oral corticosteroids or antivirals.

The study was approved by the ethics committee of UNNE and all participants provided informed consent. After providing consent, participants were allocated alternately to the active or control condition. Data were captured from the first 20 participants who completed each allocation. The trial was registered at ISRCTN registry 14974687.

Usual physical therapy (control condition)

Usual physical therapy included neuromuscular reeducation (NMR) in front of a mirror and massage therapy. NMR focused on creating symmetric facial expressions by activating the affected side and avoiding over-activation of the unaffected side³³⁻³⁵. Participants performed the following 11 facial expressions: raise the eyebrows, frown, blink, close the eyes tightly, contract the nose, kiss, blow air, Mona Lisa smile (without teeth), large smile (with teeth), pout, and inflate the cheeks. Depending on the degree of dysfunction, the therapist aided the movement or helped suppress a movement. Participants performed 5 sets of movements, each repeated 5 times (approximate duration 12 minutes). Massage therapy was provided extending from the

Table 1. Clinicodemographic characteristics of the analyzed study participants in the control and selective electric stimulation group.

	All	Control group	Selective electric muscle stimulation group
Number of participants	38	18	20
Age, years: mean (sd)	38.0 (16.4)	36.8(15.6)	39.2 (16.8)
Sex, female: n (%)	17 (44.7)	10 (55.6)	7 (35.0)
Side of paralysis, right: n (%)	19 (50)	8 (44.4)	11 (55.0)
Days since onset of paralysis: mean (sd)	8.2 (6.4)	9.2 (8.2)	6.9 (3.8)
House-Brackman at presentation: median (IQR)	3.9 (1.0)	4 (3-5)	3.5 (3-4)

Note: SD= standard deviation,
IQR= interquartile range (25th and 75th percentile)

scapula and neck to the scalp and face. This usual physical therapy intervention lasted 15 to 20 minutes.

Selective electrical muscle stimulation (added to usual physical therapy for the active condition)

The active selective electrical muscle stimulation group received electrical stimulation in addition to the above-described usual physical therapy. Electrical stimulation was applied transcutaneously with an indirect digital technique with the positive electrode on the ipsilateral neck of the patient and the negative electrode on the dominant forearm of the treating physical therapist. Electrical contact of these electrodes was achieved with wet cotton gauze. Stimulation was then provided by the therapist's fingers being applied to the treatment locations on the patient's face, with gel for electrical contact between the fingers and the skin of the patient's face (Figure 1).

Stimulation was applied on the affected side to the following muscles: frontalis, orbicularis oculi, nasalis, zygomatic major, orbicularis oris, and mentalis. The current had a monophasic exponentially rising pulsed waveform, with pulse width of 30 to 200ms, no interpulse interval, and therefore a resulting frequency of 5 to 33.3 pulses per second. The pulse width and current amplitude were adjusted by the treating therapist to optimize comfort and muscle contraction strength and selectivity (Neuromatic 700, Meditea®, Buenos Aires, Argentina). Five maximal strength, patient tolerated, contractions per muscle group were performed³⁶. The selective electrical muscle stimulation added approximately an additional 20 minutes to the appointment length. All participants were treated daily, 5 days a week (Monday through Friday),

until discharge which was when they were judged to be fully recovered by their treating therapist. The physician supervising the physical therapists clinically evaluated recovery when the treating therapist judged the participant to be fully recovered. The supervising physician was blinded to treatment allocation and



Fig 1. Photo of the set up for selective electrical muscle stimulation. Stimulation was applied transcutaneously with a digital technique where the positive electrode was placed on the ipsilateral neck of the patient and the negative electrode was placed on the dominant forearm of the treating physical therapist. Stimulation was provided by the therapist's fingers being applied to treatment locations on the patient's face. The photo shows a co-author volunteering to demonstrate the setup (MC).

Table 2. Static, dynamic, and synkinesis eFACE scores at enrollment, discharge, and 6-month follow up for the control and selective electric stimulation group. There was no difference in the scores between the two groups..

		Control group	Selective electric muscle stimulation group	p-value*
Static [Mean (SD)]	Enrollment	75.2 (18.2)	80.5 (14.1)	0.12
	Discharge	90.5 (7.8)	93.0 (2.9)	0.34
	6-month follow up	92.4 (4.7)	95.1 (3.5)	0.66
Dynamic [Mean (SD)]	Enrollment	43.8 (18.4)	39.2 (19.6)	0.25
	Discharge	83.2 (17.4)	89.8 (7.3)	0.12
	6-month follow up	88.6 (12.5)	94.7 (3.9)	0.06
Synkinesis [Mean (SD)]	Enrollment	100 (0)	100 (0)	0.89
	Discharge	97.3 (4.1)	99.1 (2.5)	0.30
	6-month follow up	94.8 (7.9)	98.4 (2.3)	0.92

Note: SD= standard deviation, * p-value obtained from mixed effects linear regression model. See supplementary materials.

affected side of the face. If recovery was confirmed treatment was discontinued and the patient was discharged from physical therapy. If the patient was found to have residual weakness, physical therapy was continued until maximal recovery.

Assessments and outcomes

Baseline characteristics including age, gender, side of paralysis, and days from onset of paralysis to initiation of therapy were recorded on enrollment. Videos of participants performing the 11 facial expressions performed during physical therapy were recorded at enrollment, discharge from physical therapy, and at a follow-up visit 6 months after discharge from physical therapy. The video-recorded facial movements were rated by two independent, blinded reviewers using two scales, the House Brackman (HB) scale and the eFACE scale. HB scores each expression from I to VI, where I is normal and VI is complete paralysis.²⁴ eFACE rates on a scale from 0 to 100, where 100 is normal and lower scores indicated greater dysfunction. eFACE also provides subscores for static, dynamic and synkinesis on the same scale.³⁷

Statistical analysis

Results from participants who adhered to the entire assigned treatment protocol were analyzed to examine for differences between groups in improvements in HB and eFACE scores and in time to maximum improvement. Mixed effects linear regression models were built to characterize differences between groups in trajectory over time for static, dynamic, and synkinesis eFACE scores. Models included fixed effects for group assignment, days since onset of paralysis at enrollment,

evaluation (enrollment, discharge, or 6-months post-discharge), weeks elapsed at each outcome evaluation, and a random participant effect to account for within-participant correlations over repeated measurements. The difference between groups at each evaluation was characterized by the interaction between group and evaluation. (See Supplementary Materials: Regression Model Specification; Regression Model Output; Table S2; Table S3).

To test for between-group difference in time to recovery, a linear regression model, with adjustment for days from onset of paralysis, was used to compare the total number of treatment sessions between groups. Statistical analyses were conducted using Stata version 15.1 (StataCorp LLC, College Station, TX)³⁸ and R version 4.0.3 (R Core Team, Vienna, AT).³⁹ Visualizations were created in R using the ggplot2 package.⁴⁰

Results

There were initially 40 participants in the study, 20 in each group. Data from 38 (18 in the control group and 20 in the active experimental group) were analyzed. Data from 2 participants in the control group were excluded because, upon review, they did not meet inclusion criteria (one did not have Bell's palsy as the cause of their facial paralysis and the other one had complete rather than incomplete paralysis). The characteristics of the 38 participants are shown in Table 1.

The final HB score at discharge from treatment was 1 (IQR 1,2) for the control group and 1 (IQR 1,1) for the active group. The mean static, dynamic and synkinesis scores on the eFACE scale at enrollment, discharge, and 6 month follow up from discharge are shown in Table 2.

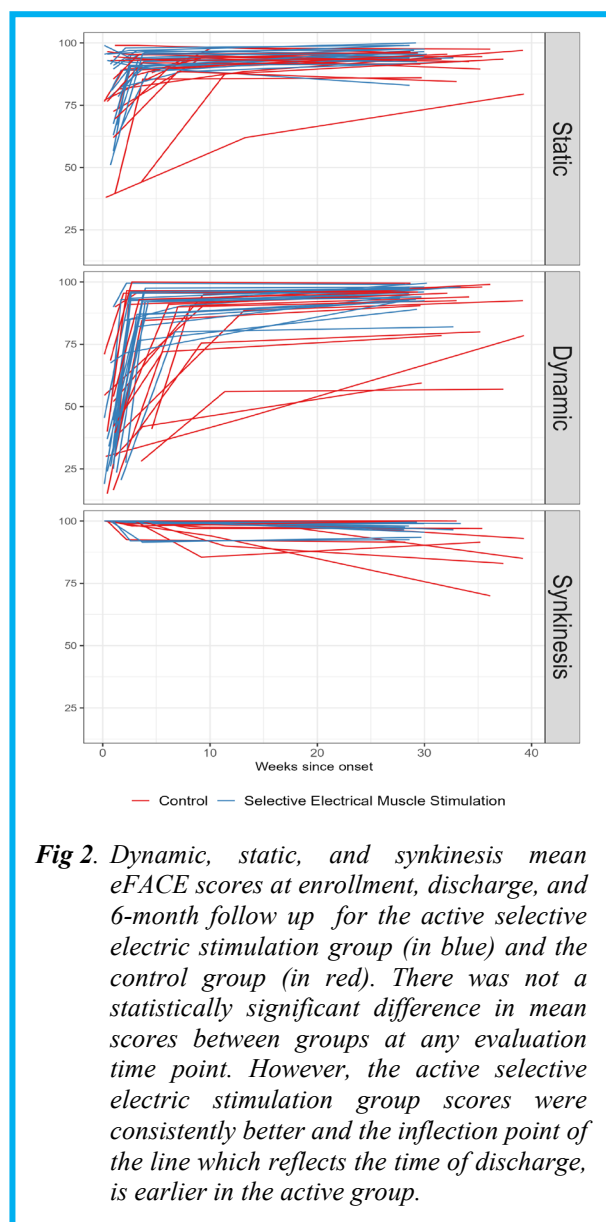


Fig 2. Dynamic, static, and synkinesis mean eFACE scores at enrollment, discharge, and 6-month follow up for the active selective electric stimulation group (in blue) and the control group (in red). There was not a statistically significant difference in mean scores between groups at any evaluation time point. However, the active selective electric stimulation group scores were consistently better and the inflection point of the line which reflects the time of discharge, is earlier in the active group.

After adjusting for time to evaluation, there were no statistically significant differences between groups in the static, dynamic, or synkinesis eFACE scores at any evaluation. Figure 1 shows individual static, dynamic and synkinesis eFACE scores over time.

Time to maximum improvement from flaccid paralysis was estimated from the time from starting to ending the intervention as the mean time from onset of symptoms to initiation of therapy was not different between groups and participants were discharged from the intervention when judged to be maximally recovered. Mean time from starting to ending the intervention was 5.2 weeks (SD 3.6) for the control group and 2.5 weeks (SD 1.2) for the active group. The control group took 2.7 weeks longer than the selective electric stimulation group to reach maximal improvement of flaccid paralysis. This difference was statistically significant by a two-tailed t test ($t(20.1) = 3.01, p=0.01$).

Discussion

This controlled trial supports that adding selective electrical muscle stimulation to the usual physical therapy intervention of exercise and massage in acute Bell's palsy is associated with significantly accelerated recovery from flaccid paralysis, and with a similar final outcome with regards to static facial expression, dynamic facial movement, and synkinesis.

Shortening the duration of Bell's palsy associated facial paralysis benefits patients by shortening the time they have poor eye closure and thus risk of eye damage, and by reducing the duration of the nutritional and psychosocial impacts of impaired eating, drinking, speech and non-verbal communication through facial expression. Knowing that this intervention does not increase the risk of developing synkinesis also increases its clinical value and appeal.

In our study, recovery from facial paralysis was achieved in approximately half the time in participants treated with selective electrical muscle stimulation plus usual physical therapy compared to participants treated with usual physical therapy alone (2.5 weeks versus 5.2 weeks). Upon recovery, static and dynamic facial function was similar with or without selective electrical muscle stimulation. Although the selective electrical muscle stimulation group had slightly better facial function scores, the difference was not statistically significant and the clinical relevance of this small difference is not known as the minimal clinically important difference for the eFACE scale has not been determined. Consistent with our findings, earlier, but similar, final recovery with electrical muscle stimulation has also been shown in the rehabilitation of other conditions associated with muscle weakness, such as after anterior cruciate ligament reconstruction.⁴¹⁻⁴³

One of the main reasons clinicians avoid using electrical stimulation in patients with Bell's palsy is fear of increasing the risk for synkinesis.¹³ However, reassuringly, we found no difference in synkinesis between groups, even 6 months after recovery from flaccid paralysis. Similarly, Puls *et al.* found no worsening in synkinesis one year after electrical stimulation in a small group of patients with facial nerve weakness after benign tumor removal.⁴⁴

This study has a number of strengths. The interventions were standardized and both the physical therapy and selective electrical muscle stimulation were provided by experienced physical therapists. The protocol for electrical stimulation, with a long pulse duration and long exponential rise, was ideal for denervated muscle.⁴⁵ The outcomes were based on recordings of facial expressions to allow for independent assessment, and were measured at baseline, on maximal recovery from paralysis, and 6 months later, to capture both recovery of facial strength and onset of synkinesis, and the outcome evaluators were blinded to treatment allocation. In addition to the HB scale, the eFACE scale provided more precise and complete assessment of the participants' facial function.

This study also had limitations. Certain aspects of the study, including alternating rather than random group allocation, differences in the duration of the control and active treatment sessions, and lack of blinding of patients and treating therapists to allocation may have introduced bias.

In addition, none of the participants received corticosteroids. Although this was consistent with usual practice in Argentina and enhanced sample uniformity, generalizability to patients who receive corticosteroids is uncertain. Most patients with Bell's palsy are prescribed oral corticosteroids because many evidence-based guidelines recommend oral corticosteroids be started within 72 hours of onset of paralysis in patients with Bell's palsy to shorten the duration of paralysis and improve recovery.⁴⁶⁻⁴⁸ Furthermore, lack of clear information on pulse duration and current intensity over the course of therapy, limits replication of the procedure. This study demonstrates that selective electrical stimulation accelerates recovery from Bell's palsy in patients who do not receive corticosteroids or do not receive them in a timely fashion. Based on proposed mechanisms of action, including slowing muscle atrophy and promoting nerve recovery, we expect electrical stimulation would have a similar, although possibly more muted, effect on recovery from Bell's palsy in those treated with corticosteroids. A future study, where participants are treated with corticosteroids, patients at high risk for poor outcome (e.g. with diabetes or complete paralysis) are included or selected for, with clear complete description of all treatment parameters and predetermined follow-up times, and an intent to treat analysis, would further improve our understanding of the optimal role and impacts of selective electrical muscle stimulation in the treatment of Bell's palsy.

In conclusion, this study supports the efficacy of selective electrical muscle stimulation in the treatment of acute Bell's palsy. The stimulation protocol used in the study accelerated recovery from flaccid paralysis, halving the recovery time, and resulted in similar excellent long-term outcomes with regards to static facial expression, dynamic facial movement and synkinesis.

List of acronyms

HB - House Brackmann
IQR - interquartile range
SD - standard deviation

Contributions of Authors

LLJ, AZC: Provided and cared for study participants and collected data, participated in interpreting data; ADP: Created the study protocol, supervised study, helped draft the manuscript; VC: Served as a scientific advisor for study protocol and study designed, aided in manuscript preparation; ML and MC: Participated as scientific advisors for data analysis and interpretation, prepared the manuscript; MC: volunteered to demonstrate the digital selective electrical muscle stimulation technique; CL and

CJ: Served as blinded raters for eFACE outcome; AH: Provided statistical analysis design and conducted the analysis and reviewed the final manuscript. All authors agree to be accountable for the work, critically reviewed for content and accuracy and gave final approval. All authors have read and approved the final edited typescript.

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Conflict of Interest

The authors declare no conflicts of interest.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Supplementary materials:

Regression Model Specification

Mixed effects linear regression models were built to characterize the between-group difference in trajectory over time for each of the static, dynamic, and synkinesis eFACE scores. These models included fixed effects for treatment group, days since onset of Bell's Palsy at baseline, visit, and weeks elapsed at each visit, and a random participant effect to account for within-participant correlations over repeated measurements. Between-group difference at each follow-up visit was characterized by the interaction between treatment group and visit. The hypothesis of interest was whether a group-by-visit interaction was present at either visit.

$$\begin{aligned}
 Y_{ij} &= \beta_0 + \beta_1(\text{treatment group})_i + \beta_2(\text{days since onset})_i + \beta_3(\text{visit 1})_{ij} + \beta_4(\text{visit 2})_{ij} \\
 &+ \beta_5(\text{visit 1} * \text{treatment group})_{ij} + \beta_6(\text{visit 2} * \text{treatment group})_{ij} \\
 &+ \beta_7(\text{visit 1} * \text{weeks elapsed})_{ij} + \beta_8(\text{visit 2} * \text{weeks elapsed})_{ij} + b_{ij} + \varepsilon_{ij}
 \end{aligned}$$

Where:

i = participant (1, 2, ..., 38)

j = visit (baseline, discharge, six-month follow up)

Y = eFACE score (static, dynamic, or synkinesis)

treatment group: 1 if treatment group = selective electric muscle stimulation, 0 otherwise

visit 1: 1 if visit = discharge, 0 otherwise

visit 2: 1 if visit = six-month follow up, 0 otherwise

b: participant random effect

ε : measurement error

To test whether there is a group effect at discharge, we test the hypothesis:

$$B_5 = 0 \text{ vs. } \beta_5 \neq 0$$

To test whether there is a group effect at six-month follow up, we test the hypothesis:

$$B_6 = 0 \text{ vs. } \beta_6 \neq 0$$

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Regression Model Output

Regression output for mixed effects linear regression of static, dynamic, and synkinetic eFACE scores. *Group* refers to the selective electric muscle stimulation group (control group as reference). In these analyses, we are most interested in between-group differences (group effect) at discharge and 6-month follow up (bolded).

Table S1: Regression output of static eFACE score

	Coefficient	Standard Error	95% Confidence Interval	p-value
Intercept (β_0)	75.58	3.00	69.70 – 81.46	<0.01
Group (β_1)	5.16	3.33	-1.37 – 11.69	0.12
Days since onset (β_2)	-0.04	0.20	-0.42 – 0.35	0.85
Change from baseline at:				
Discharge (β_3)	17.59	4.16	9.44 – 25.74	<0.01
6-month follow up (β_4)	7.82	18.98	-29.38 – 45.02	0.68
Group effect at:				
Discharge (β_5)	-3.95	4.14	-12.06 – 4.16	0.34
6-month follow up (β_6)	-1.81	4.14	-9.91 – 6.30	0.66
Weeks from baseline until:				
Discharge (β_7)	-0.44	0.60	-1.62 – 0.74	0.46
6-month follow up (β_8)	0.30	0.60	-0.88 – 1.48	0.50

Table S2: Regression output of dynamic eFACE score

	Coefficient	Standard Error	95% Confidence Interval	p-value
Intercept (β_0)	46.53	4.18	38.33 – 54.72	<0.01
Group (β_1)	-5.31	4.59	-14.31 – 3.69	0.25
Days since onset (β_2)	-0.29	0.28	-0.84 – 0.25	0.30
Change from baseline at:				
Discharge (β_3)	44.76	5.55	33.89 – 55.63	<0.01
6-month follow up (β_4)	48.91	25.53	-1.12 – 98.95	0.06
Group effect at:				
Discharge (β_5)	8.44	5.47	-2.28 – 19.16	0.12
6-month follow up (β_6)	10.41	5.47	-0.31 – 21.14	0.06
Weeks from baseline until:				
Discharge (β_7)	-1.07	0.81	-2.66 – 0.52	0.19
6-month follow up (β_8)	-0.13	0.81	-1.72 – 1.46	0.87

Table S3: Regression output of synkinetic eFACE score

	Coefficient	Standard Error	95% Confidence Interval	p-value
Intercept (β_0)	100.43	0.84	98.78 – 102.08	<0.01
Group (β_1)	0.14	1.07	-1.95 – 2.24	0.89
Days since onset (β_2)	-0.06	0.06	-0.18 – 0.06	0.30
Change from baseline at:				
Discharge (β_3)	-0.67	1.01	-2.64 – 1.30	0.51
6-month follow up (β_4)	34.94	5.70	23.77 – 46.11	<0.01
Group effect at:				
Discharge (β_5)	-1.44	1.39	-4.15 – 1.28	0.30
6-month follow up (β_6)	-0.15	1.39	-2.86 – 2.57	0.92
Weeks from baseline until:				
Discharge (β_7)	-0.11	0.20	-0.50 – 0.27	0.57
6-month follow up (β_8)	-1.28	0.20	-1.67 – -0.90	<0.01