Statistical analysis

Only research subjects who adhered to their entire assigned treatment protocol are included in this analysis. Data 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 the groups in trajectory over time for static, dynamic, and synkinesis eFACE scores (see below). 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) and R version 4.0.3 (R Core Team, Vienna, AT). Visualizations were created in R using the ggplot2 package.

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 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, and whether this interaction was present jointly over both follow-up visits.

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

Where:
i = participant (1, 2, … , 38)
j = visit (baseline, immediately post-intervention, six months post-intervention)
treatment group: 1 if treatment group = active, 0 otherwise
visit 1: 1 if visit = immediately post-intervention, 0 otherwise
visit 2: 1 if visit = six months post-intervention, 0 otherwise
ε: measurement error

To test whether there is a group effect immediately post-intervention, we test the hypothesis:
$\beta_7 = 0$ vs. $\beta_7 \neq 0$

To test whether there is a group effect at 6 months post-intervention, we test the hypothesis:
$B_8 = 0$ vs. $\beta_8 \neq 0$

To test whether there is a group effect over the entire follow up period, we test the hypothesis:
$\beta_7 = B_8 = 0$ vs. $\beta_7 \neq \beta_8 \neq 0$