Supplemental Mixed Effect Models

Results of mixed-effects model repeated measures analysis with maximum likelihood estimation that did not identify a statistically significant treatment by baseline interaction

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# Table S1. MMRM analyses of the ABC total

|  |  |
| --- | --- |
|  |  |
|  | **Models compared** | **BIC** |
| Model 1 | Time, treatment, time by treatment interaction | 3056.94 |
| Model 2 | Model 1 + baseline and all two-way interactions among time, treatment and baseline | 3052.76 |
| Model 3 | Model 2 + the three-way interaction of linear time by treatment by baseline | 3057.76 |
| Model 4 | Model 3 + the two-way and three-way interactions among quadratic time, treatment and baseline | 3067.39 |
| Model 5 | Model 1 adjusted for confounders | 3068.60 |
| Model 6 | Model 2 adjusted for confounders | 3064.39 |
| Model 7 | Model 3 adjusted for confounders | 3069.38 |
| Model 8 | Model 4 adjusted for confounders | 3079.00 |
|  | **Best-fitting model parameters** |
|  |  | **B** | **SE** | **P** |
|  | Intercept | -6.93 | 12.91 | 0.59 |
|  | Baseline | 0.22 | 0.14 | 0.11 |
|  | Treatment | -9.55 | 16.06 | 0.55 |
|  | Time | -0.57 | 1.51 | 0.71 |
|  | Baseline by treatment interaction | 0.21 | 0.17 | 0.22 |
|  | Baseline by time interaction | 0.01 | 0.02 | 0.34 |
|  | Treatment by time interaction | 2.48 | 0.73 | 0.00 |

Note. The lowest BIC is the best-fitting model and is underlined for clarity. The parameters of the best-fitting model are presented with statistically significant (p<.05) values are underlined for clarity.

# Table S2. MMRM analyses of the Hyperactivity subscale

|  |  |  |
| --- | --- | --- |
|  | **Models compared** | **BIC** |
| Model 1 | Time, treatment, time by treatment interaction | 2282.53 |
| Model 2 | Model 1 + baseline and all two-way interactions among time, treatment and baseline | 2281.59 |
| Model 3 | Model 2 + the three-way interaction of linear time by treatment by baseline | 2286.14 |
| Model 4 | Model 3 + the two-way and three-way interactions among quadratic time, treatment and baseline | 2298.34 |
| Model 5 | Model 1 adjusted for confounders | 2294.06 |
| Model 6 | Model 2 adjusted for confounders | 2293.05 |
| Model 7 | Model 3 adjusted for confounders | 2297.60 |
| Model 8 | Model 4 adjusted for confounders | 2309.80 |
|  | **Best-fitting model parameters** |
|  |  | **B** | **SE** | **P** |
|  | Intercept | 2.24 | 4.31 | 0.60 |
|  | Baseline | 0.08 | 0.13 | 0.53 |
|  | Treatment | -3.08 | 5.12 | 0.55 |
|  | Time | -0.54 | 0.50 | 0.28 |
|  | Baseline by treatment interaction | 0.21 | 0.15 | 0.16 |
|  | Baseline by time interaction | 0.02 | 0.01 | 0.11 |
|  | Treatment by time interaction | 0.83 | 0.26 | 0.00 |

Note. The lowest BIC is the best-fitting model and is underlined for clarity.

The parameters of the best-fitting model are presented with statistically significant (p<.05) values underlined for clarity.

# Table S3. MMRM analyses of the Inappropriate Behavior subscale

|  |  |  |
| --- | --- | --- |
|  | **Models compared** | **BIC** |
| Model 1 | Time, treatment, time by treatment interaction | 1586.61 |
| Model 2 | Model 1 + baseline and all two-way interactions among time, treatment and baseline | 1573.54 |
| Model 3 | Model 2 + the three-way interaction of linear time by treatment by baseline | 1579.19 |
| Model 4 | Model 3 + the two-way and three-way interactions among quadratic time, treatment and baseline | 1597.71 |
| Model 5 | Model 1 adjusted for confounders | 1595.27 |
| Model 6 | Model 2 adjusted for confounders | 1583.97 |
| Model 7 | Model 3 adjusted for confounders | 1589.64 |
| Model 8 | Model 4 adjusted for confounders | 1608.20 |
|  | **Best-fitting model parameters** |
|  |  | **B** | **SE** | **P** |
|  | Intercept | 0.04 | 0.77 | 0.96 |
|  | Baseline | 0.08 | 0.10 | 0.42 |
|  | Treatment | -1.54 | 0.86 | 0.08 |
|  | Time | -0.10 | 0.11 | 0.34 |
|  | Baseline by treatment interaction | 0.19 | 0.10 | 0.07 |
|  | Baseline by time interaction | 0.02 | 0.01 | 0.13 |
|  | Treatment by time interaction | 0.29 | 0.10 | 0.00 |

Note. The lowest BIC is the best-fitting model and is underlined for clarity.

The parameters of the best-fitting model are presented with statistically significant (p<.05) values underlined for clarity.

# Table S4. MMRM analyses of the Stereotypy subscale

|  |  |  |
| --- | --- | --- |
|  | **Models compared** | **BIC** |
| Model 1 | Time, treatment, time by treatment interaction | 1776.98 |
| Model 2 | Model 1 + baseline and all two-way interactions among time, treatment and baseline | 1770.32 |
| Model 3 | Model 2 + the three-way interaction of linear time by treatment by baseline | 1776.10 |
| Model 4 | Model 3 + the two-way and three-way interactions among quadratic time, treatment and baseline | 1787.10 |
| Model 5 | Model 1 adjusted for confounders | 1787.74 |
| Model 6 | Model 2 adjusted for confounders | 1780.20 |
| Model 7 | Model 3 adjusted for confounders | 1785.98 |
| Model 8 | Model 4 adjusted for confounders | 1796.92 |
|  | **Best-fitting model parameters** |
|  |  | **B** | **SE** | **P** |
|  | Intercept | -0.31 | 1.11 | 0.78 |
|  | Baseline | 0.25 | 0.11 | 0.02 |
|  | Treatment | 0.52 | 1.42 | 0.71 |
|  | Time | -0.09 | 0.16 | 0.60 |
|  | Baseline by treatment interaction | 0.02 | 0.12 | 0.88 |
|  | Baseline by time interaction | 0.01 | 0.01 | 0.38 |
|  | Treatment by time interaction | 0.22 | 0.14 | 0.10 |

Note. The lowest BIC is the best-fitting model and is underlined for clarity.

The parameters of the best-fitting model are presented with statistically significant (p<.05) values underlined for clarity.

# Table S5. MMRM analyses of the ABC clinician-rated irritability subscale

|  |  |  |
| --- | --- | --- |
|  | **Models compared** | **BIC** |
| Model 1 | Time, treatment, time by treatment interaction | 1328.24 |
| Model 2 | Model 1 + baseline and all two-way interactions among time, treatment and baseline | 1302.49 |
| Model 3 | Model 2 + the three-way interaction of linear time by treatment by baseline | 1306.05 |
| Model 4 | Model 3 + the two-way and three-way interactions among quadratic time, treatment and baseline | 1316.12 |
| Model 5 | Model 1 adjusted for confounders | 1338.67 |
| Model 6 | Model 2 adjusted for confounders | 1312.85 |
| Model 7 | Model 3 adjusted for confounders | 1316.41 |
| Model 8 | Model 4 adjusted for confounders | 1326.51 |
|  | **Best-fitting model parameters** |
|  |  | **B** | **SE** | **P** |
|  | Intercept | -3.19 | 5.79 | 0.58 |
|  | Baseline | 0.35 | 0.21 | 0.10 |
|  | Treatment | -4.42 | 5.85 | 0.45 |
|  | Time | -1.02 | 0.73 | 0.17 |
|  | Baseline by treatment interaction | 0.36 | 0.20 | 0.08 |
|  | Baseline by time interaction | 0.02 | 0.03 | 0.34 |
|  | Treatment by time interaction | 0.94 | 0.37 | 0.01 |

Note. The lowest BIC is the best-fitting model and is underlined for clarity.

The parameters of the best-fitting model are presented with statistically significant (p<.05) values underlined for clarity.

# Table S6. MMRM analyses of the CGI

|  |  |  |
| --- | --- | --- |
|  | **Models compared** | **BIC** |
| Model 1 | Time, treatment, time by treatment interaction | 1790.34 |
| Model 2 | Model 1 + baseline and all two-way interactions among time, treatment and baseline | 1728.13 |
| Model 3 | Model 2 + the three-way interaction of linear time by treatment by baseline | 1732.57 |
| Model 4 | Model 3 + the two-way and three-way interactions among quadratic time, treatment and baseline | 1721.91 |
| Model 5 | Model 1 adjusted for confounders | 1802.35 |
| Model 6 | Model 2 adjusted for confounders | 1739.04 |
| Model 7 | Model 3 adjusted for confounders | 1743.51 |
| Model 8 | Model 4 adjusted for confounders | 1732.8 |
|  | **Best-fitting model parameters** |
|  |  | **B** | **SE** | **P** |
|  | Intercept | -4.78 | 1.13 | 0.00 |
|  | Treatment | -0.07 | 1.56 | 0.96 |
|  | Baseline | 1.14 | 0.22 | 0.00 |
|  | Time | 0.36 | 0.52 | 0.50 |
|  | Quadratic time | -0.02 | 0.06 | 0.78 |
|  | Treatment by baseline | 0.10 | 0.30 | 0.75 |
|  | Treatment by time | 0.59 | 0.71 | 0.41 |
|  | Treatment by quadratic time | -0.09 | 0.08 | 0.22 |
|  | Baseline by time | -0.03 | 0.10 | 0.79 |
|  | Baseline by quadratic time | 0.00 | 0.01 | 0.88 |
|  | Treatment by baseline by time | -0.07 | 0.14 | 0.60 |
|   | Quadratic time by treatment by baseline | 0.02 | 0.01 | 0.27 |

Note. The lowest BIC is the best-fitting model and is underlined for clarity.

The parameters of the best-fitting model are presented with statistically significant (p<.05) values underlined for clarity.