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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Supplementary Table 1 Factors associated with change in agitation outcomes in placebo group (adjusted)** | | | | | | | | | | | | |
|  | NBRS-agitation\* | | | Cohen-Mansfield Agitation Inventory\* | | | CGIC agitation\*\* | | | NPI-agitation\* | | |
| Risk factor (at baseline) | Difference in slope\* | 95% CI | p-value | Difference in slope\* | 95% CI | p-value | OR\*\* | 95% CI | p-value | Difference in slope\* | 95% CI | p-value |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Age (years) |  |  |  |  |  |  |  |  |  |  |  |  |
| 47-75 | Ref |  | 0.60 | Ref |  | 0.26 | Ref |  | 0.66 | Ref |  | 0.79 |
| 76-82 | -0.02 | (-0.20, 0.16) | 0.21 | (-0.13, 0.54) | 0.59 | (0.16, 2.27) | 0.07 | (-0.14, 0.28) |
| 83-92 | -0.09 | (-0.27, 0.09) | -0.06 | (-0.39, 0.27) | 0.57 | (0.15, 2.17) | 0.04 | (-0.16, 0.24) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Sex |  |  |  |  |  |  |  |  |  |  |  |  |
| Women | Ref |  | 0.06 | Ref |  | 0.02 | Ref |  | 0.45 | Ref |  | 0.37 |
| Men | 0.14 | (0.00, 0.29) | 0.32 | (0.05, 0.59) | 0.67 | (0.24, 1.90) | -0.08 | (-0.24, 0.09) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Race |  |  |  |  |  |  |  |  |  |  |  |  |
| White, non-Hispanic | Ref |  | 0.03 | Ref |  | Macintosh HD:Users:prosenb9:Library:Caches:TemporaryItems:msoclip:0:clip_image001.png   |  | | --- | | 0.08 | | | Ref |  |  | Ref |  | 0.22 |
| Black, non-Hispanic | -0.16 | (-0.35, 0.04) | -0.38 | (-0.74, -0.02) | 2.66 | (0.67, 10.47) | 0.38 | -0.04 | (-0.26, 0.18) |
| Hispanic | -0.03 | (-0.24, 0.18) | 0.14 | (-0.25, 0.52) | 1.38 | (0.32, 5.98) | 0.04 | (-0.20, 0.27) |
| Other, non-Hispanic | -0.53 | (-0.91, -0.16) | -0.42 | (-1.12, 0.29) | -0.45 | (-0.88, -0.02) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Education (years) |  |  |  |  |  |  |  |  |  |  |  |  |
| High school or less | Ref |  | 0.08 | Ref |  | 0.43 | Ref |  | 0.16 | Ref |  | 0.74 |
| More than high school | 0.13 | (-0.01, 0.28) | 0.11 | (-0.16, 0.38) | 0.42 | (0.13, 1.41) | 0.03 | (-0.14, 0.19) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| NBRS agitation subscale tertiles |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-5 | Ref |  | <0.001 | Ref |  | 0.06 | Ref |  | <0.01 | Ref |  | 0.19 |
| Middle: 6-8 | -0.09 | (-0.28, 0.09) | -0.13 | (-0.49, 0.23) | 0.30 | (0.04, 2.33) | 0.16 | (-0.06, 0.39) |
| Highest (most agitated): 9+ | -0.40 | (-0.57, -0.23) | -0.38 | (-0.71, -0.05) | 4.46 | (1.04, 19.24) | 0.00 | (-0.21, 0.20) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| CMAI tertiles |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-24 | Ref |  | 0.75 | Ref |  | 0.01 | Ref |  | 0.59 | Ref |  | 0.29 |
| Middle: 25-30 | 0.05 | (-0.12, 0.22) | -0.19 | (-0.50, 0.13) | 1.00 | (0.26, 3.88) | 0.04 | (-0.16, 0.23) |
| Highest (most agitated): 31+ | -0.02 | (-0.20, 0.17) | -0.54 | (-0.87, -0.20) | 1.81 | (0.44, 7.36) | 0.16 | (-0.05, 0.37) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| NPI agitation tertiles |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-6 | Ref |  | 0.28 | Ref |  | 0.49 | Ref |  | 0.72 | Ref |  | 0.01 |
| Middle: 7-8 | -0.05 | (-0.21, 0.12) | 0.00 | (-0.31, 0.32) | 1.62 | (0.45, 5.79) | -0.16 | (-0.35, 0.03) |
| Highest (most agitated): 9+ | -0.15 | (-0.34, 0.03) | -0.19 | (-0.53, 0.15) | 1.57 | (0.39, 6.29) | -0.32 | (-0.52, -0.12) |
| NPI-Q-4-Agitation/Aggression |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-14 | Ref |  | 0.27 | Ref |  | 0.06 | Ref |  | 0.41 | Ref |  | 0.41 |
| Middle: 15-22 | -0.08 | (-0.25, 0.10) | -0.23 | (-0.55, 0.10) | 2.49 | (0.64, 9.77) | -0.13 | (-0.33, 0.07) |
| Highest (most agitated): 22+ | -0.14 | (-0.32, 0.03) | -0.38 | (-0.70, -0.06) | 1.90 | (0.51, 7.17) | -0.10 | (-0.30, 0.10) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| NPI-Q-3-Mood |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-8 | Ref |  | 0.38 | Ref |  | 0.08 | Ref |  | 0.68 | Ref |  | 0.59 |
| Middle: 9-14 | 0.12 | (-0.05, 0.30) | 0.00 | (-0.32, 0.32) | 0.58 | (0.14, 2.39) | 0.08 | (-0.12, 0.28) |
| Highest (most symptoms): 15+ | 0.06 | (-0.12, 0.23) | -0.33 | (-0.65, -0.01) | 1.08 | (0.31, 3.79) | 0.09 | (-0.11, 0.29) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| NPI caregiver distress |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-13 | Ref |  | 0.32 | Ref |  | 0.26 | Ref |  | 0.06 | Ref |  | 0.80 |
| Middle: 14-19 | 0.04 | (-0.13, 0.22) | 0.03 | (-0.30, 0.36) | 0.32 | (0.07, 1.51) | 0.01 | (-0.19, 0.21) |
| Highest (most distressed): 20+ | -0.10 | (-0.27, 0.08) | -0.23 | (-0.55, 0.09) | 2.14 | (0.63, 7.22) | -0.06 | (-0.25, 0.14) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| NPI total score tertiles |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-28 | Ref |  | 0.28 | Ref |  | 0.08 | Ref |  | 0.46 | Ref |  | 0.46 |
| Middle: 29-42 | 0.08 | (-0.10, 0.25) | -0.09 | (-0.42, 0.23) | 0.81 | (0.20, 3.23) | 0.08 | (-0.12, 0.28) |
| Highest (most symptoms): 43+ | -0.07 | (-0.25, 0.11) | -0.36 | (-0.69, -0.03) | 1.84 | (0.51, 6.61) | -0.05 | (-0.25, 0.16) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Delusions or hallucinations |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | Ref |  | 0.58 | Ref |  | 0.03 | Ref |  | 0.85 | Ref |  | 0.96 |
| No | 0.04 | (-0.11, 0.19) | 0.29 | (0.03, 0.56) | 1.12 | (0.35, 3.60) | 0.00 | (-0.17, 0.16) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| MMSE |  |  |  |  |  |  |  |  |  |  |  |  |
| Mild impairment: 21+ | Ref |  | 0.54 | Ref |  | 0.70 | Ref |  | 0.96 | Ref |  | 0.06 |
| Moderate: 11-20 | -0.09 | (-0.26, 0.08) | -0.08 | (-0.39, 0.23) | 1.05 | (0.31, 3.54) | -0.14 | (-0.33, 0.05) |
| Severe: 0-10 | -0.02 | (-0.22, 0.17) | -0.15 | (-0.51, 0.21) | 1.25 | (0.26, 5.92) | -0.26 | (-0.48, -0.04) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| ADCS-ADL tertiles |  |  |  |  |  |  |  |  |  |  |  |  |
| Lowest: 0-30 | Ref |  | 0.79 | Ref |  | 0.85 | Ref |  | 0.72 | Ref |  | 0.29 |
| Middle: 31-53 | 0.02 | (-0.15, 0.20) | 0.03 | (-0.29, 0.35) | 0.64 | (0.19, 2.23) | -0.03 | (-0.23, 0.16) |
| Highest (fewest difficulties): 54+ | 0.07 | (-0.13, 0.26) | 0.10 | (-0.25, 0.45) | 1.05 | (0.25, 4.38) | -0.16 | (-0.38, 0.05) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| History of hypertension |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | Ref |  | 0.07 | Ref |  | 0.09 | Ref |  | 0.52 | Ref |  | 0.17 |
| No | 0.13 | (-0.01, 0.28) | 0.23 | (-0.04, 0.50) | 0.70 | (0.24, 2.08) | 0.11 | (-0.05, 0.28) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| History of arthrtis |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | Ref |  | 0.11 | Ref |  | <0.01 | Ref |  | 0.48 | Ref |  | 0.6 |
| No | 0.13 | (-0.03, 0.28) | 0.48 | (0.20, 0.77) | 0.67 | (0.22, 2.05) | 0.05 | (-0.13, 0.22) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| History of diabetes |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | Ref |  | 0.49 | Ref |  | 0.86 | Ref |  | 0.89 | Ref |  | 0.54 |
| No | -0.06 | (-0.24, 0.12) | 0.03 | (-0.29, 0.35) | 1.10 | (0.29, 4.20) | 0.06 | (-0.14, 0.26) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| \*Mixed effects regression results with random intercept for participant. Adjusted model results are shown including control for gender, race, years of education and the baseline scale score. The 'Difference' column is the difference in the outcome variable slope in the category shown compared to the reference category. Negative differences indicate a larger decline in agitation symptoms compared to the reference cell. The p-value is calculated from the F statistic comparing the model including the interaction term (time by risk factor) to a model without the interaction term. All available data were included in the model. | | | | | | | | | | | | |
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| \*\*Logistic regression results for CGIC 'response' (i.e., moderate or marked improvement) at week 9. Adjusted model results are shown including control for gender, race and years of education. The 'OR' column is the odds ratio for CGIC response in the category shown compared to the reference category. ORs greater than 1.0 indicate a higher odds of response compared to the reference cell. The p-value is calculated from the Wald χ2 statistic comparing the model including the risk factor to a model without the risk factor. All available week 9 outcome data were included in the model. | | | | | | | | | | | | |
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