

Individualized Symptom Tracking with SymptomGuide® allows for Clinically Meaningful Interpretation of MMSE Score Changes in a Dementia Drug Trial



Justin Stanley BScE¹, Taylor Dunn MSc¹, Susan Howlett PhD^{1,2}, Kenneth Rockwood MD FRCPC^{1,2}
(1) DGI Clinical Inc., (2) Dalhousie University



Background

Dementia drug trials can detect statistically significant changes in standardized outcome measures. However, these differences may not be clinically meaningful to patients or their caregivers.

Objective

To use individualized symptom tracking with SymptomGuide®-dementia (**SG-D**) to evaluate the clinical meaningfulness of changes in Mini-Mental State Examination (**MMSE**) scores.

Methods

Secondary analysis of VASPECT, a six-month open-label trial of donepezil in people with mild-moderate vascular dementia or mixed Alzheimer/vascular dementia.

- SG-D is a symptom-tracking system with a menu of 32 symptoms and options to add unique symptoms.
- Caregivers identified symptoms important to them and rated change on a 7-point scale at three and six months.
- The Goal Attainment Scaling (**GAS**) formula was applied to quantify goal attainment.

Results

- Most patients (128/148, 86%) had sufficient data to evaluate SG-D (**Table 1**).
- GAS scores correlated with change in MMSE at three and six months (**Figure 1**)
- Executive Function* and *Cognition* symptoms were most often tracked (**Figure 2**).
- Subjects with 2-point MMSE improvement also improved across all goal domains (**Figure 3**).
- The *Social Interaction/Withdrawal* symptom most often responded to change in MMSE (**Figure 4**).

Table 1. Baseline characteristics of patients with SG-D

Characteristic	Patients (N=128)
Mixed dementia (% , N)	46% (59)
Age (mean, SD)	75.4 (9.2)
Sex (% Female, N)	52% (67)
Baseline MMSE (mean, SD)	23.5 (4.5)
Baseline GAS (mean, SD)	50 (0)
Number of symptoms tracked (mean, SD)	7.7 (5.1)

Figure 2. Proportion of symptoms tracked by domain

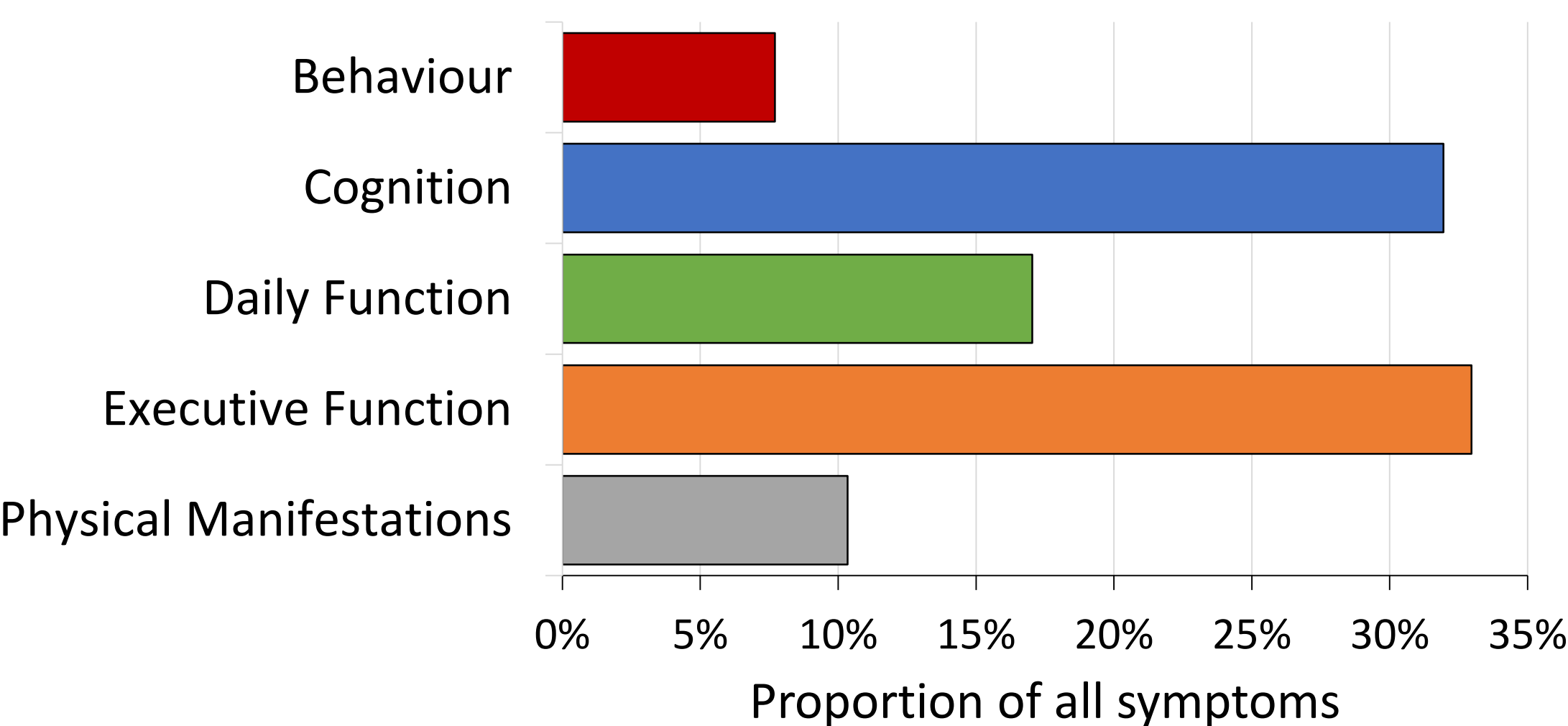
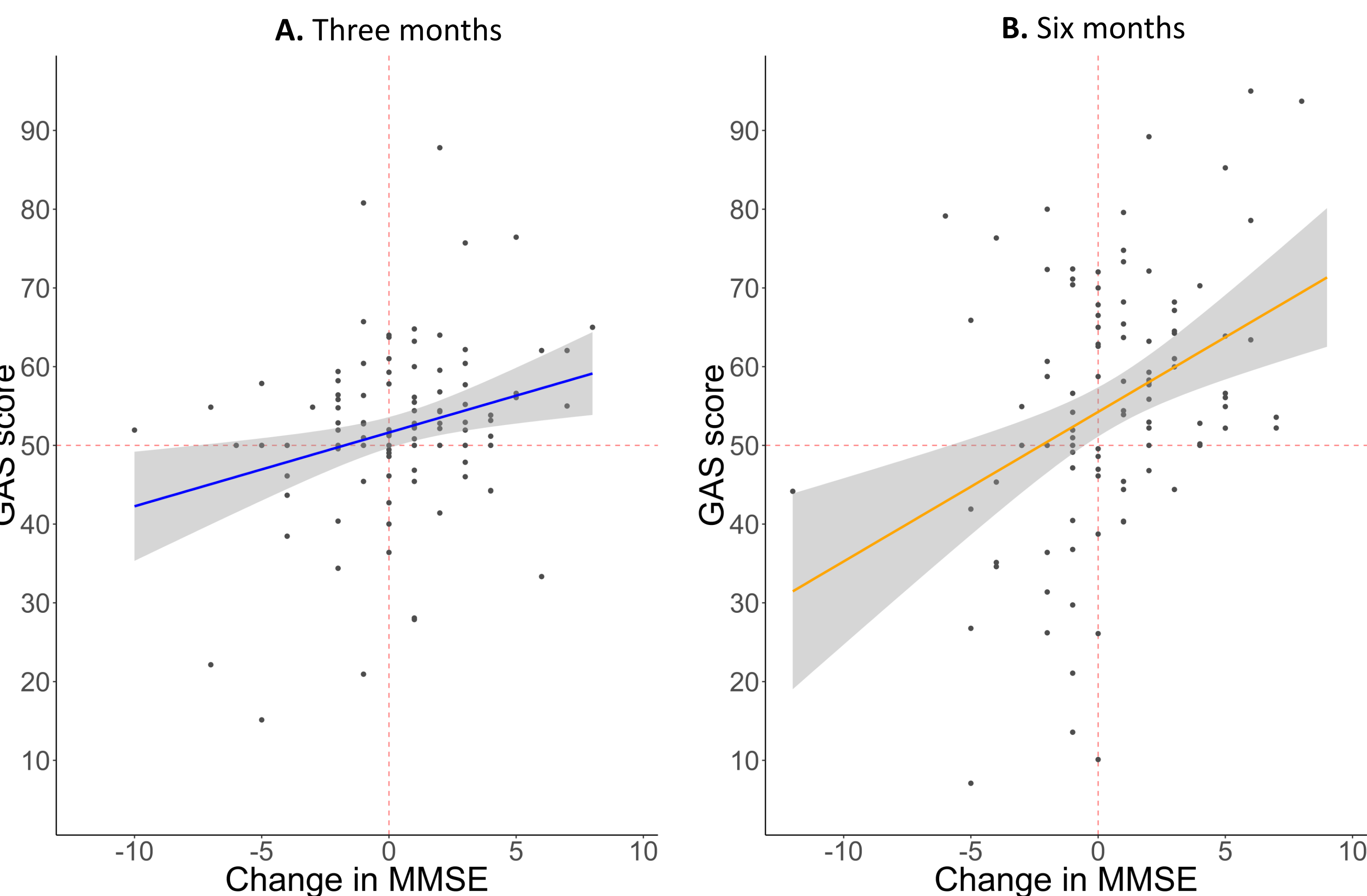
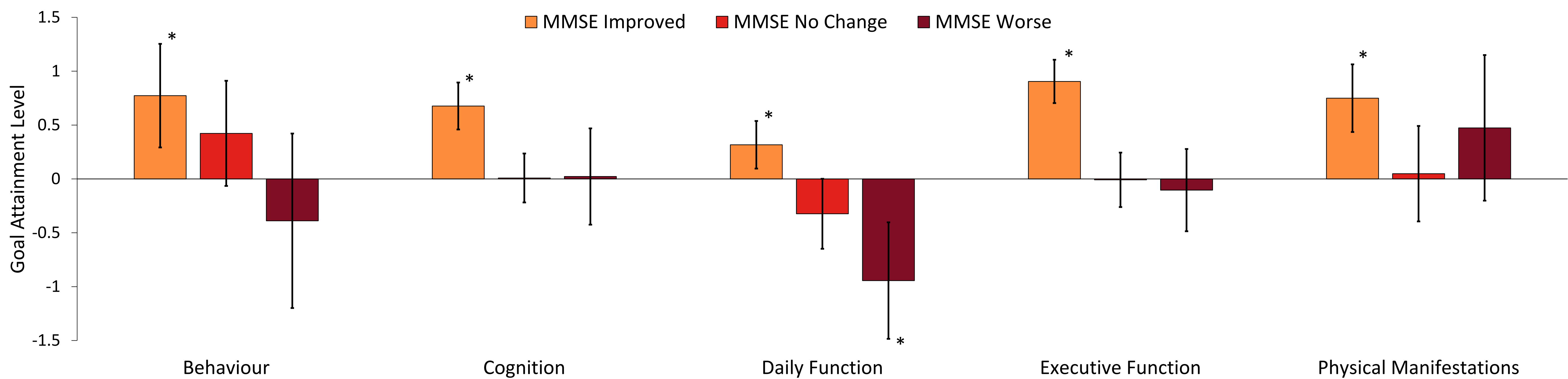


Figure 1. GAS scores correlated with change in MMSE at three and six months



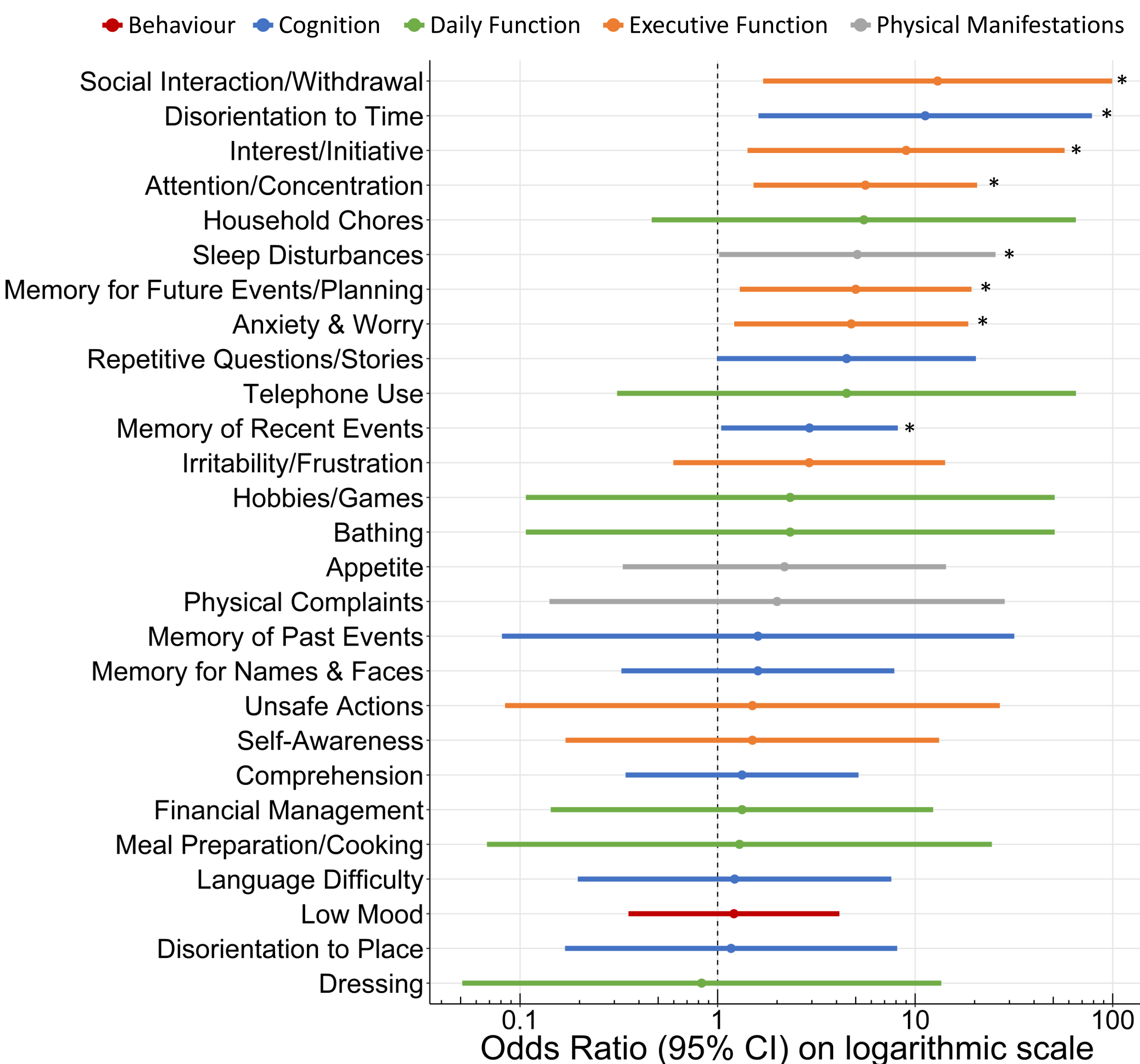
A. Correlation at three months $r=0.27$, $p=0.005$; **B.** Correlation at six months $r=0.37$, $p<0.001$

Figure 3. Mean (\pm 95% CI) goal attainment level by 2-point change in MMSE at six months



* Significantly different from 0 ($p<0.05$)

Figure 4. Executive function symptoms most often improved alongside a 2-point improvement in MMSE



* Odds ratio significantly greater than 1 ($p<0.05$)

Discussion and Conclusions

- A 2-point change in MMSE correlated with changes in individualized SymptomGuide®-dementia symptoms.
- SymptomGuide® can identify critical symptoms that give rise to significant changes in MMSE scores in a dementia drug trial.
- Outcome measures like SymptomGuide®-dementia, that are inherently clinically meaningful, can help translate results from clinical trials to everyday practice.