



Addressing the Unmet Needs of Alzheimer's Disease with Real-World Digital Clinical Measures

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INTRODUCTION

Alzheimer's disease is a leading cause of death with no treatments to cure or slow disease progression.

99.6% failure rate in Alzheimer's disease drug development

(Cummings et al., 2014, *Alzheimer's Res Therapy*)

UNMET NEED

Preserving functional independence during disease progression is a major goal for patients with Alzheimer's disease.

Traditional functional assessments in Alzheimer's disease clinical trials do not accurately capture real-world functioning or other aspects of health that are meaningful to patients.



- Behavioral & neuropsychiatric symptoms
- Social functioning
- Function & dependence
- Physical health & well-being
- Cognition

There is an **unmet need to develop novel outcome measures** that **capture meaningful aspects of health** for patients with Alzheimer's disease.

Real-world digital measures enable holistic assessments of patients with Alzheimer's disease.

- ✓ Measure disease progression and detect treatment benefits with higher sensitivity
- ✓ Enable rigorous investigation into timing of treatment effects
- ✓ Capture aspects of function at high resolution and low patient burden
- ✓ Complement subjective ratings of function
- ✓ Derive multiple endpoints from a single sensor modality
- ✓ Provide large amounts of data to reduce within-patient variability
- ✓ Reduce sample size requirements

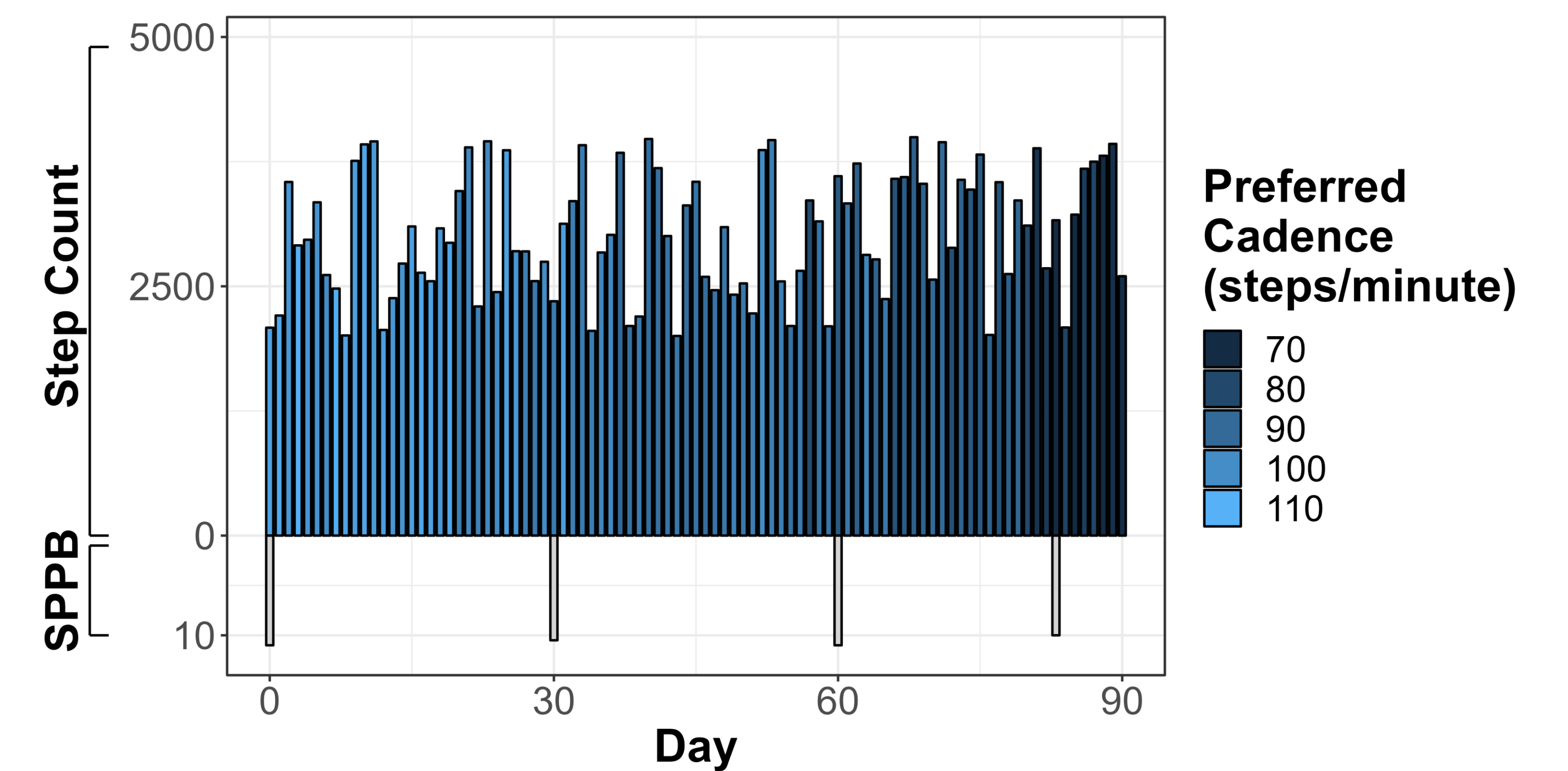


Figure 1: Simulated data illustrating the value of continuous real-world data.

One individual's physical function is assessed episodically with the Short Physical Performance Battery (SPPB; grey bars below the x-axis). Daily step count is assessed continuously with a wearable actigraphy sensor (blue bars). The colors of the bars indicate preferred walking pace (i.e., cadence), with brighter blue indicating a faster walking pace. Over the 90-day period shown, step count varied but daily walking pace slowed progressively, potentially indicative of worsening physical function. In contrast, SPPB scores did not change over time.

DEVELOPING FIT-FOR-PURPOSE DIGITAL CLINICAL OUTCOME MEASURES

Define meaningful aspects of health and measurable digital clinical outcomes

Establish feasibility and acceptability of measuring outcomes with digital health technology

Establish analytical and clinical validity of digital outcomes in patients with Alzheimer's disease



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