



UMassAmherst
Institute for Applied Life Sciences

Developing Real-World Digital Biomarkers From Wearable Sensors in Patients With Alzheimer's Disease

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MassAITC AD/ADRD Focus Pilot Core

Massachusetts AI & Technology Center
for Connected Care in Aging & Alzheimer's Disease

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.

Function is assessed in Alzheimer's disease clinical trials using patient reported outcomes or performance outcome measures.

Inherent limitations of established functional outcome assessments

- Burdensome to patients
- Captured episodically
- Do not comprehensively capture aspects of health that matter to patients



Behavioral & neuropsychiatric symptoms

Social functioning

Function & dependence

Physical health & well-being

Cognition

Real-world measures of physical function could substantially advance research and care in patients with Alzheimer's disease.

There is an **unmet need to develop novel outcome measures** that **capture how patients with Alzheimer's disease function** in their real-world environment.



SCAN HERE



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Learn more about our work developing and validating digital clinical measures at VivoSense.com

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

Walking behaviors are central to functional independence.

Algorithms to derive measures of walking from wearable inertial sensors are not validated for older adults with Alzheimer's disease.



Long Term Goal: regulatory approval of real-world outcome measures of physical function for patients with Alzheimer's Disease (i.e., FDA Clinical Outcome Assessment (COA) Qualification).

FDA FRAMEWORK FOR DEVELOPING VALIDATED 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

PILOT STUDY METHODS

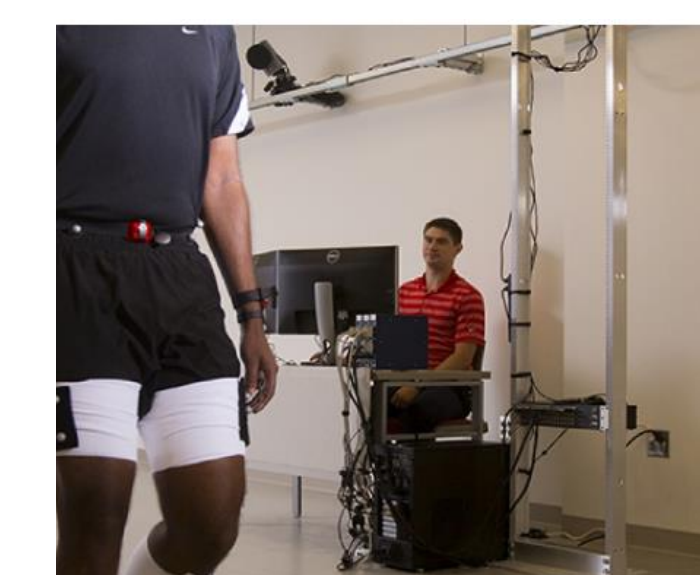
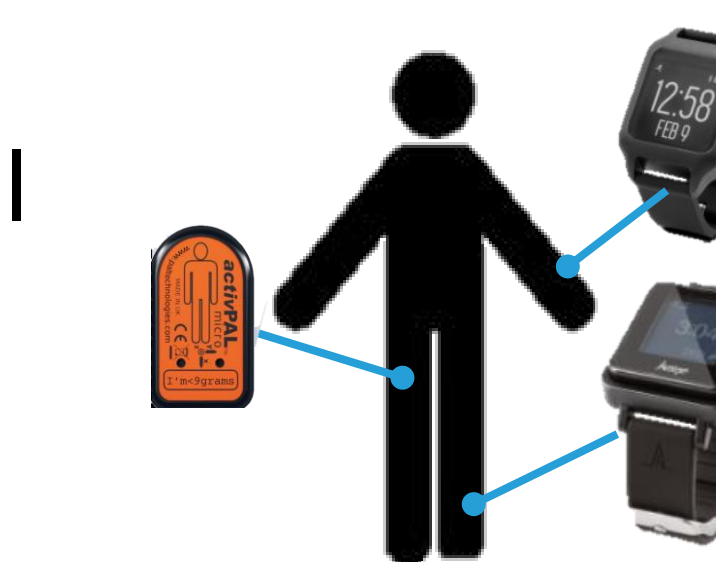
Purpose of Pilot Study: develop machine learning algorithms to derive features of gait and walking behavior from inertial sensors in patients with Alzheimer's disease.

Participants: older adults (≥ 65 years) with (n=15) and without (n=15) mild Alzheimer's disease

MOTION CAPTURE LABORATORY

Multiple assessments of walking behaviors captured while wearing inertial sensors

- Short physical performance battery
- Chair rises
- 6-minute walking test
- Figure 8 walking test
- Walking trail making test



Truth data captured using 9-camera motion capture system

ALGORITHM DEVELOPMENT

Machine learning algorithms will be developed to derive measures of real-world walking behavior in Alzheimer's disease

REAL-WORLD MONITORING

Assess and compare how older adults with and without Alzheimer's disease function at home

