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**USE OF SMARTPHONES TO CAPTURE MEASURES OF
FUNCTIONAL STATUS IN FRAIL AND NON-FRAIL
COMMUNITY DWELLING OLDER ADULTS**

By

Cassia Rye Hanton

A THESIS

Presented to the Faculty of
the University of Nebraska Graduate College
in Partial Fulfillment of the Requirements
for the Degree of Master of Science

Medical Sciences Interdepartmental Area
Graduate Program
(Internal Medicine)

Under the Supervision of Professor Stephen J. Bonasera

University of Nebraska Medical Center
Omaha, Nebraska

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Lani M. Zimmerman, Ph.D.
Bunny J. Pozehl, Ph.D.

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ABSTRACT: USE OF SMARTPHONES TO CAPTURE MEASURES OF FUNCTIONAL STATUS IN COMMUNITY DWELLING OLDER ADULTS

Cassia R. Hanton, M.S.

University of Nebraska Medical Center, 2015

Advisor: Stephen J. Bonasera, M.D., Ph.D.

Numerous important health outcomes directly relate to one's ability to maintain normal gait speed. The purpose of this study is to employ ubiquitous smartphone technology, using algorithms developed and validated by our lab in a controlled setting, to continuously and noninvasively measure aspects of subject health status, including step counts, gait speed, and activity level, in a naturalistic community setting. A total of 33 ambulatory, independently dwelling older adults were recruited from Nebraska Medicine, including 22 healthy control and 11 frail individuals. Clinical performance measurements of frailty (4MW, TUG, F8W) and validated survey responses (LLFDI, SAFFE, PROMIS) were compared to our smartphone based metrics collected in the community over 24-hours. We identified significant differences between control and frail subjects in percent activity ($p < 0.0018$, t-test), active vs. inactive status ($p < 0.0195$, t-test), average step counts ($p < 0.001$, t-test) and gait speed ($p < 0.001$, one-way ANOVA). In non-frail individuals, there was little correlation between activity and gait metrics measured by smartphone and subject responses to survey instruments, or to performance on our physical battery. We suspect that in non-frail individuals, these instruments have a ceiling effect similar to that observed in other surveys and performance batteries evaluating community-dwelling individuals. However, in frail individuals, we find significant correlations between step count and SAFFE activity restriction ($p = 0.011$) and

PROMIS physical health ($p=0.004$). Smartphone-derived gait metrics may estimate both activity restrictions and overall physical health (including gait speed, step count, and activity status) in older adults as they progress through stages of functional loss and ultimately become frail.

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LIST OF ABBREVIATIONS

4MW	Four Meter Walk
AL	Activity Limitation
ALEF	Advanced Lower Extremity Function
ANOVA	Analysis Of Variance
APF	Adult Physical Function
BLEF	Basic Lower Extremity Function
COPD	Chronic Obstructive Pulmonary Disease
F8W	Figure of 8 Walk
FF	Fear of Falling
HICSA	Home Instead Center for Successful Aging
IRB	Institutional Review Board
LLFDI	Late-Life Function and Disability Instrument
MH	Mental Health
PA	Physical Activity
PH	Physical Health
PROMIS	Patient Reported Outcomes Measurement Information System
SAFFE	Survey of Activities and Fear of Falling in the Elderly
TUG	Timed Up and Go
UEF	Upper Extremity Function
UNMC	University of Nebraska Medical Center
WHO	World Health Organization

CHAPTER 1: INTRODUCTION

FRAILITY

One of the most common and major health concerns associated with aging is frailty. While the normal physiologic process of aging does not produce frailty in and of itself, the state of frailty can result from accumulated age-related deficits in multiple physiologic systems.¹ Frailty is best thought of as an inability of the body to maintain constant homeostasis in the presence of stressor events.² The prevalence of frailty increases with advanced age and is a commonly recognized problem. Indeed, for person's 85 years and older the prevalence of frailty is estimated to be in the range of 25-50%.³

Although the concept of frailty has been in use in the clinical field for more than two decades, developing a consensus definition of what constitutes frailty continues to be a challenge.⁴ Most commonly frailty is described as a syndrome consisting of a combination of co-morbidities and their related consequences as opposed to a single specific disease.⁵ Frailty is a dynamic state which can increase or decrease in severity over time, with some previously frail individuals developing better health and no longer being classified as frail.⁶ The more common progression however is for the severity of frailty to increase, which is seen in the majority of cases. The state of frailty

¹ Qian-Li Xue, "The Frailty Syndrome: Definition and Natural History," *Clinics in Geriatric Medicine* 27, no. 1 (February 2011): 1–15, doi:10.1016/j.cger.2010.08.009.

² John E. Morley et al., "Frailty Consensus: A Call to Action," *Journal of the American Medical Directors Association* 14, no. 6 (June 2013): 392–97, doi:10.1016/j.jamda.2013.03.022; Andrew Clegg et al., "Frailty in Elderly People," *Lancet* 381, no. 9868 (March 2, 2013): 752–62, doi:10.1016/S0140-6736(12)62167-9.

³ Clegg et al., "Frailty in Elderly People."

⁴ Fanny Buckinx et al., "Burden of Frailty in the Elderly Population: Perspectives for a Public Health Challenge," *Archives of Public Health* 73, no. 1 (December 2015), doi:10.1186/s13690-015-0068-x.

⁵ L. P. Fried et al., "Frailty in Older Adults: Evidence for a Phenotype," *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences* 56, no. 3 (March 2001): M146–56.

⁶ Buckinx et al., "Burden of Frailty in the Elderly Population."

encompasses all aspects of health and involves losses in one or more domains of human function, including physical, psychological and social.⁷ There has been debate between investigators who include disability and functional decline as components of frailty and those who see disability and functional decline as consequent outcomes of frailty.⁸

Whatever the definition of frailty, the impacts of frailty are far reaching, including increased risk for numerous adverse health outcomes such as falls, delirium, hospitalizations, and ultimately, death.⁹ All-cause mortality rates are greater for frail than non-frail individuals, and frail individuals also have an increased 5-year risk for death.¹⁰ The economic and public health costs associated with these adverse events, not to mention the burden of stress on patients and caregivers, are substantial. Furthermore, the burden of frailty in the United States healthcare system is only expected to increase in the coming years as our population ages. The World Health Organization (WHI) estimates the global population of elderly person's age 80 years and older to increase 315% by 2050.¹¹ Indeed, the US population of older adults aged 65 years and older is already expected to exceed 72 million by 2030.¹² Frailty is consequently a major concern

⁷ Robbert J. Gobbens et al., "Toward a Conceptual Definition of Frail Community Dwelling Older People," *Nursing Outlook* 58, no. 2 (April 2010): 76–86, doi:10.1016/j.outlook.2009.09.005.

⁸ Shelley A. Sternberg et al., "The Identification of Frailty: A Systematic Literature Review," *Journal of the American Geriatrics Society* 59, no. 11 (November 2011): 2129–38, doi:10.1111/j.1532-5415.2011.03597.x.

⁹ Fried et al., "Frailty in Older Adults."

¹⁰ Kenneth Rockwood et al., "Prevalence, Attributes, and Outcomes of Fitness and Frailty in Community-Dwelling Older Adults: Report from the Canadian Study of Health and Aging," *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences* 59, no. 12 (December 2004): 1310–17.

¹¹ "World Health Organization Report 2011: The Burden of Dementia," accessed June 9, 2015, <http://www.dementiatoday.com/world-health-organization-report-2011-the-burden-of-dementia/>.

¹² Jonathan Joe and George Demiris, "Older Adults and Mobile Phones for Health: A Review," *Journal of Biomedical Informatics* 46, no. 5 (October 2013): 947–54, doi:10.1016/j.jbi.2013.06.008.

for the entire healthcare system due to the extra medical care and costly resources these individuals will require as well as the high risk of dependency among frail older individuals with limited functional independence.

The good news is that recent research suggests that frailty may be reversible. Since frailty is a progressive condition, beginning with a preclinical phase, it offers hope of early detection and therefore prevention.¹³ Studies have demonstrated that specific exercise programs as well as nutritional supplementation with vitamin D have a beneficial effect in reducing signs of frailty in older individuals.¹⁴ Reduction of the medication load of polypharmacy has also been shown to improve the symptoms of frailty.¹⁵ One of the challenges in the field is that we continue to lack a single set of clear cut diagnostic criteria for frailty to identify which older adults are most at risk of adverse outcomes and would benefit from these interventions.¹⁶ In the Bonasera lab we study age related changes in functional behavior and are interested in determining measures of functional status and physical activity that could be used to characterize frail older individuals. This characterization of the functional status of frail individuals could allow clinicians to target limited and costly resources, such as the exercise or nutritional interventions outlined above, at those individuals most at risk for adverse events.

¹³ Fried et al., "Frailty in Older Adults."

¹⁴ Marjan J. Faber et al., "Effects of Exercise Programs on Falls and Mobility in Frail and Pre-Frail Older Adults: A Multicenter Randomized Controlled Trial," *Archives of Physical Medicine and Rehabilitation* 87, no. 7 (July 2006): 885–96, doi:10.1016/j.apmr.2006.04.005; Anne M. Kenny et al., "Dehydroepiandrosterone Combined with Exercise Improves Muscle Strength and Physical Function in Frail Older Women," *Journal of the American Geriatrics Society* 58, no. 9 (September 2010): 1707–14, doi:10.1111/j.1532-5415.2010.03019.x.

¹⁵ Morley et al., "Frailty Consensus."

¹⁶ Buckinx et al., "Burden of Frailty in the Elderly Population."

SUBJECTIVE MEASURES OF PHYSICAL ACTIVITY

Numerous tools have been developed to assess aspects of frailty that are either subjective (self-report only), objective (including only directly measured components such as step counts) or use a combination of objective and subjective measures.¹⁷ Many of these tools involve measures of physical activity because frailty has long been shown to be associated with low physical activity level. One of the most commonly employed definitions of frailty, the “Frailty Phenotype,” defines frailty as encompassing five separate components; shrinking, weakness, poor endurance and energy, slowness, and low physical activity level¹⁸. In order to determine physical activity level in older adults, many studies utilize self-report measures, such as written surveys or activity diaries¹⁹. However self-report measures have limitations including recall bias, socially desirable responses, and the influence of other factors such as mood and cognition²⁰. One of the problems with self-report measures is that people tend to overestimate their physical activity level. A study by Watkinson et al. showed that nearly half of respondents who were known to be inactive by objective measures actually reported themselves as active, indicating an overestimation of physical activity level²¹. Another study comparing self-reported measures to an objective measure of physical activity, the accelerometer, indicated that while 62% of respondents classified themselves as meeting WHO

¹⁷ Kim Bouillon et al., “Measures of Frailty in Population-Based Studies: An Overview,” *BMC Geriatrics* 13, no. 1 (2013): 64, doi:10.1186/1471-2318-13-64.

¹⁸ Fried et al., “Frailty in Older Adults.”

¹⁹ F. Marijke Jansen et al., “Physical Activity in Non-Frail and Frail Older Adults,” ed. Thomas Ernst Dorner, *PLOS ONE* 10, no. 4 (April 24, 2015): e0123168, doi:10.1371/journal.pone.0123168.

²⁰ Fei Sun, Ian J Norman, and Alison E While, “Physical Activity in Older People: A Systematic Review,” *BMC Public Health* 13, no. 1 (2013): 449, doi:10.1186/1471-2458-13-449.

²¹ Clare Watkinson et al., “Overestimation of Physical Activity Level Is Associated with Lower BMI: A Cross-Sectional Analysis,” *International Journal of Behavioral Nutrition and Physical Activity* 7, no. 1 (2010): 68, doi:10.1186/1479-5868-7-68.

recommendations for physical activity, only 9.6% of those individuals actually met those recommendations according to objective accelerometer data²². Therefore since self-reported physical activity measures are subject to bias, more studies are needed looking at objective classifications of physical activity in older adults.

OBJECTIVE MEASURES OF PHYSICAL ACTIVITY

In order to mitigate the deficiencies of subjective assessment, myriad measures of physical activity have been developed to objectively quantify aspects of physical activity. These approaches range from complex laboratory procedures (i.e. doubly labeled water study) to more simple methods (i.e. pedometer). The most commonly utilized measures include indirect calorimetry, a doubly labeled water study, clinical measurements (i.e. 4 meter walk), pedometers, and accelerometers²³. Accelerometers represent an easy and straightforward approach since they are built into new smartphones and don't require a subject to wear a separate device or undergo invasive testing. Studies of physical activity using built in phone accelerometers have reported accuracy as high as 52-100%.²⁴ Furthermore, smartphones have become ubiquitous in society, with upwards of 6.8 billion people worldwide using mobile phones²⁵. Even within the Geriatric population, 69% of older adults age 65 or older own a cell phone, and that number is only growing²⁶. Furthermore, older patients are becoming increasingly amenable to the use of mobile

²² Jared M. Tucker, Gregory J. Welk, and Nicholas K. Beyler, "Physical Activity in U.S.: Adults Compliance with the Physical Activity Guidelines for Americans," *American Journal of Preventive Medicine* 40, no. 4 (April 2011): 454–61, doi:10.1016/j.amepre.2010.12.016.

²³ "Physical Activity Resource Center for Public Health," accessed June 9, 2015, <http://www.parcph.org/objDefList.aspx>.

²⁴ Judit Bort-Roig et al., "Measuring and Influencing Physical Activity with Smartphone Technology: A Systematic Review," *Sports Medicine* 44, no. 5 (May 2014): 671–86, doi:10.1007/s40279-014-0142-5.

²⁵ Ibid.

²⁶ Joe and Demiris, "Older Adults and Mobile Phones for Health."

phone technology in their healthcare. A questionnaire based assessment of elders indicated that 83% appreciated the convenience of a telemedicine approach such as using mobile phones and 95% would recommend it to a friend or relative.²⁷

Mobile phones offer further benefits as a monitoring device in the Geriatric population because, being a commonplace device, they avoid the stigma associated with some devices that are commonly viewed as “Geriatric” such as hearing aids that may be seen to convey a lack of independence, which is a key concern for older adults.²⁸ Older adults have also been shown to have difficulty adhering to wearing devices that are physically demanding, large or voluminous so the small and compact nature of the modern mobile phones solves those concerns.²⁹ Furthermore, older adults surveyed have appreciated the mobile phone which allows them to maintain control of their device since privacy is a key concern for older adults who are concerned about being constantly monitored or tracked by separate devices but do not fear the mobile phone that is already under their control.³⁰

PRELIMINARY STUDIES

Our multidisciplinary research team, led by Dr. Bonasera, M.D., Ph.D., has a long and successful track record of employing smartphone devices for remote monitoring in the Geriatric population. Dr. Bonasera has received national recognition for his utilization of

²⁷ Jose A. Loera, “Generational Differences in Acceptance of Technology,” *Telemedicine Journal and E-Health: The Official Journal of the American Telemedicine Association* 14, no. 10 (December 2008): 1087–90, doi:10.1089/tmj.2008.0028.

²⁸ V. Faucounau et al., “Electronic Tracking System and Wandering in Alzheimer’s Disease: A Case Study,” *Annals of Physical and Rehabilitation Medicine* 52, no. 7–8 (October 2009): 579–87, doi:10.1016/j.rehab.2009.07.034.

²⁹ Frank Miskelly, “Electronic Tracking of Patients with Dementia and Wandering Using Mobile Phone Technology,” *Age and Ageing* 34, no. 5 (September 2005): 497–99, doi:10.1093/ageing/afi145.

³⁰ Faucounau et al., “Electronic Tracking System and Wandering in Alzheimer’s Disease.”

smartphones in clinical research, including being recognized as the University of Nebraska Medical Center (UNMC) Distinguished Scientist. In addition, he was awarded Most Promising New Invention award from the UNMC technology transfer office UNeMed and has successfully partnered with Samsung to gain research support and use of their smartphones for his studies, among other notable accomplishments.

The Bonasera lab first demonstrated in a proof of principle study that repurposed cell phones can be used to measure physical activity in the community setting. The study required the participants, all adults without functional limitation, to wear the cell phone monitoring system on their person for a long 30 day period. The majority of subjects were able to adhere to this protocol for the entire study period.³¹

Subsequently, the Bonasera lab showed in a controlled laboratory setting that physical activity counts as measured by the smartphone accelerometer are strongly correlated with subject gait speeds as recorded by a treadmill.³² Furthermore, this treadmill study showed that cell phone physical activity count correlated with treadmill gait speed regardless of the location where the phone was worn (*i.e.* neck lanyard vs hip pocket).³³ However, the hip pocket (either right or left) provided the best predictive model.

Additionally, the team has refined the data classification algorithms for physical activity to distinguish between active and inactive states and further sub classify active states

³¹ Ana Katrin Schenk et al., "Cellular Telephones Measure Activity and Lifespace in Community-Dwelling Adults: Proof of Principle: MOBILE MONITORING OF LIFESPACE AND ACTIVITY," *Journal of the American Geriatrics Society* 59, no. 2 (February 2011): 345–52, doi:10.1111/j.1532-5415.2010.03267.x.

³² Richard H. Carlson et al., "Treadmill Gait Speeds Correlate with Physical Activity Counts Measured by Cell Phone Accelerometers," *Gait & Posture* 36, no. 2 (June 2012): 241–48, doi:10.1016/j.gaitpost.2012.02.025.

³³ Ibid.

into walking, climbing stairs, or otherwise active for non-specified activity.³⁴ Finally, the Bonasera team recently conducted a descriptive study in which they surveyed intensive care ICU patients to determine whether they would be willing to use the mobile phone monitoring system during their recovery post discharge and received a 50% affirmative response.³⁵

THE CASE FOR LONG TERM OBJECTIVE MEASURES OF MOBILITY USING SMARTPHONES

Longer-term measurements of gait performance carry great potential value to both patients and clinicians in all areas of medicine. Walking speed has been called the “sixth vital sign³⁶” due to ample data indicating that changes in gait speed are associated with greater mortality,³⁷ diminished cognition,³⁸ greater functional disability, poorer quality of life, and increased health care spending.³⁹ Evidence also points to a role of improved

³⁴ Kwon Y-J, Aung T, Synovec SM, Oberle AD, Rye-Hanton C, Whittington J, Goulding EH, Witbrodt BC, Bonasera SJ, Schenk AK., “Classifying Smartphone-Based Accelerometer Data to Obtain Validated Measures of Subject Activity Status, Step Count, and Gait Speed.,” *In Submission*, 2015.

³⁵ Michele C. Balas et al., “Measuring Functional Recovery in Older Patients Discharged from Intensive Care Units: Is Advanced Technology an Option?,” *Journal of Applied Gerontology: The Official Journal of the Southern Gerontological Society* 34, no. 3 (April 2015): NP22–40, doi:10.1177/0733464813480267.

³⁶ Stacy Fritz and Michelle Lusardi, “White Paper: ‘Walking Speed: The Sixth Vital Sign,’” *Journal of Geriatric Physical Therapy (2001)* 32, no. 2 (2009): 46–49.

³⁷ Marco Pahor et al., “Effect of Structured Physical Activity on Prevention of Major Mobility Disability in Older Adults: The LIFE Study Randomized Clinical Trial,” *JAMA* 311, no. 23 (June 18, 2014): 2387, doi:10.1001/jama.2014.5616.

³⁸ H. H. Dodge et al., “In-Home Walking Speeds and Variability Trajectories Associated with Mild Cognitive Impairment,” *Neurology* 78, no. 24 (June 12, 2012): 1946–52, doi:10.1212/WNL.0b013e318259e1de.

³⁹ G. Abellan van Kan et al., “Gait Speed at Usual Pace as a Predictor of Adverse Outcomes in Community-Dwelling Older People an International Academy on Nutrition and Aging (IANA) Task Force,” *The Journal of Nutrition, Health & Aging* 13, no. 10 (December 2009): 881–89; Susan E. Hardy et al., “Ability to Walk 1/4 Mile Predicts Subsequent Disability, Mortality, and Health Care Costs,” *Journal of General Internal Medicine* 26, no. 2 (February 2011): 130–35, doi:10.1007/s11606-010-1543-2.

gait speed as a sensitive biomarker for improved overall functional status.⁴⁰ Despite all this evidence, however, gait speed remains an underutilized measure in clinical practice. Resistance to including gait speed in clinical assessments is multifactorial, with time and space constraints, and provider unfamiliarity being major factors.⁴¹ Obtaining longitudinal clinical measures of gait speed is also difficult since collecting these measures may be more subject to confirmation and performance biases than metrics that are easier to obtain such as pulse oximetry or body weight.⁴²

Gait speed studies in the past have traditionally relied on measurements taken in clinic. The standard gait assessment method involves timing an individual while walking a short, predetermined distance (e.g. 4-6 m) at a normal pace. This approach has significant limitations since physical activity, including gait, is influenced by performance biases, as well as ultradian, circadian and seasonal variations which cannot be evaluated during a single clinic visit.⁴³ In addition, gait speed in older adults declines slowly over long periods of time, necessitating repeat observations.⁴⁴

An exciting potential solution to these challenges lies in the rise of ubiquitous electronics offers and remote monitoring of patient health parameters. In the Bonasera lab we have

⁴⁰ W. L. Wong et al., "Reinvestment and Falls in Community-Dwelling Older Adults," *Neurorehabilitation and Neural Repair* 22, no. 4 (December 11, 2007): 410–14, doi:10.1177/1545968307313510.

⁴¹ J. H. J. Allum et al., "Improving Impaired Balance Function: Real-Time versus Carry-over Effects of Prosthetic Feedback" (IEEE, 2011), 1314–18, doi:10.1109/IEMBS.2011.6090309.

⁴² D. E. Krebs, J. E. Edelman, and S. Fishman, "Reliability of Observational Kinematic Gait Analysis," *Physical Therapy* 65, no. 7 (July 1985): 1027–33.

⁴³ G. H. Guyatt et al., "Effect of Encouragement on Walking Test Performance," *Thorax* 39, no. 11 (November 1984): 818–22.

⁴⁴ Hal H. Atkinson et al., "Cognitive Function, Gait Speed Decline, and Comorbidities: The Health, Aging and Body Composition Study," *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences* 62, no. 8 (August 2007): 844–50; N. L. Watson et al., "Executive Function, Memory, and Gait Speed Decline in Well-Functioning Older Adults," *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences* 65A, no. 10 (October 1, 2010): 1093–1100, doi:10.1093/gerona/g1q111.

demonstrated the feasibility of using cell phone technology to measure an individual's activity and Lifespace behavior over prolonged periods of time in a noninvasive, near-continuous, robust, inexpensive, and user friendly manner.⁴⁵ We have designed algorithms to measure clinically relevant aspects of activity (aligned with Healthy People 2010), including gait bout duration, gait speed, and step counts using subject derived smartphone data (Kwon et al., 2015, in submission). In addition, we have shown that the activity metrics we measure by this approach strongly correlate with gait speed under controlled laboratory conditions for a broad group of individuals (ranging in age from 21 to 84).⁴⁶

We show for the first time in this study that smartphones can generate both continuous and aggregate measures of clinically relevant gait and mobility parameters, including gait speed, step count and overall activity status, in a community dwelling population going about their day-to-day lives. Subjects were given a cellular phone and pedometer, along with instruction in their use, and recorded their activities over the next 12-18 hours. Validated algorithms were used to classify this data into clinically relevant gait parameters. Both healthy and frail community dwelling older individuals were studied. Our results suggest that our smartphone-generated gait and mobility measures effectively differentiate older adults without functional limitations from those older adults with a frailty phenotype.

⁴⁵ Schenk et al., "Cellular Telephones Measure Activity and Lifespace in Community-Dwelling Adults."

⁴⁶ Carlson et al., "Treadmill Gait Speeds Correlate with Physical Activity Counts Measured by Cell Phone Accelerometers."

CHAPTER 2: METHODS

SUBJECT ENROLLMENT

We recruited ambulatory older subjects for this case control study from the University of Nebraska Medical Center (UNMC) Geriatrics Clinic and the Engage Wellness Center, both part of UNMC's Home Instead Center for Successful Aging (HICSA). Two cohorts

were included: one of healthy older individuals with no functional impairment (n=22), and one of frail⁴⁷ older individuals (n=11). For our non-frail group, inclusion criteria included: (1) age 55 or older; (2) community dwelling; (3) no serious uncontrolled medical or psychiatric co-morbidities; and (4) a minimum score of 23/30 or greater on the Mini-Mental State Examination⁴⁸ or 19/30 or greater on the Montreal

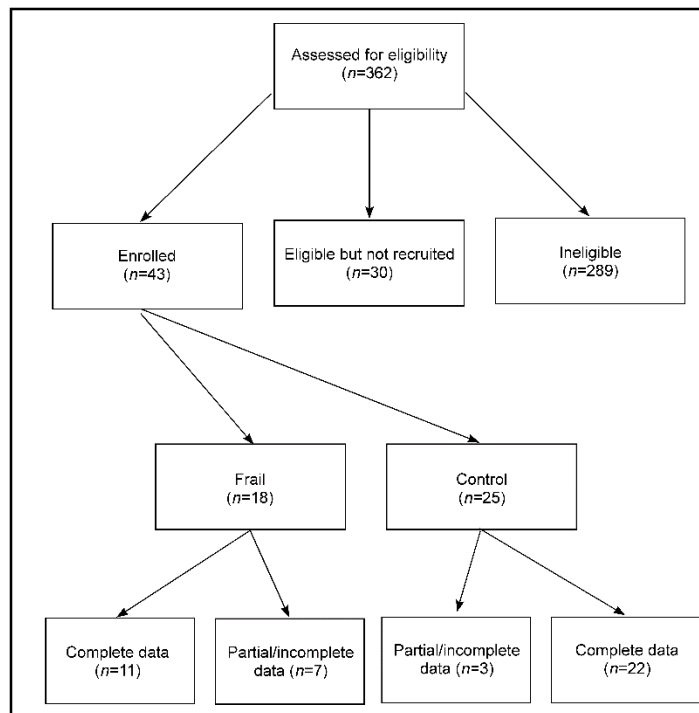


Figure 1: Enrollment Flow Diagram

Overview of the enrollment process for frail and non-frail subjects from initial identification of eligible subjects through consent and enrollment of subjects meeting inclusion and exclusion criteria. After eliminating those subjects who did not provide a complete data set a total of 11 frail and 22 non-frail subjects completed the study.

⁴⁷ Fried et al., "Frailty in Older Adults."

⁴⁸ M. F. Folstein, S. E. Folstein, and P. R. McHugh, "'Mini-Mental State'. A Practical Method for Grading the Cognitive State of Patients for the Clinician," *Journal of Psychiatric Research* 12, no. 3 (November 1975): 189–98.

Cognitive Assessment.⁴⁹ For our frail group, inclusion criteria also required having 3 of the 5 following clinical conditions present at enrollment: (1) >10% unintentional weight loss or BMI <18.5 kg/m²; (2) slow (<0.8 m/s) walking speed⁵⁰; (3) weak grip strength (measured by a hand dynamometer, JAMAR, Bolingbrook, IL), (4) reports of exhaustion, and (5) low activity.

Of note, the cognitive criteria required that we screen a large number of potential subjects for our age-related frailty group. This study was approved by the UNMC Institutional Review Board

(IRB). All participants provided written informed consent. Figure 1 shows our enrollment flow diagram; Table 1 provides baseline subject characteristics for both cohorts.

subject characteristic	functionally intact	frail	p
<i>Overall:</i>	61.1%	38.9%	
<i>Gender:</i>			
Female	77.3%	64.3%	0.606
Male	22.7%	35.7%	
<i>Age:</i>			
50-60 years	4.5%	0%	<0.001
61-70 years	22.6%	7.1%	
71-80 years	63.4%	28.4%	
81-90 years	9.1%	35.5%	
91-100 years	0%	28.5%	
<i>Ethnicity:</i>			
Non-Hispanic White	90.9%	92.9%	0.366
Other	9.1%	7.1%	
<i>Current Residence:</i>			
Apartment	9.1%	35.7%	0.307
Home (rented or owned)	86.4%	57.1%	
Other	4.5%	7.1%	
<i>Living with:</i>			
Alone	63.6%	7.1%	0.845
Spouse or Significant Other	27.3%	14.3%	
Other (i.e., children, caretaker)	9.1%	71.5%	
<i>Education:</i>			
Grades 9-11	36.4%	7.1%	0.309
Grade 12 or GED	22.7%	42.9%	
College 1-3 years	9.1%	14.3%	
College 4 years	4.5%	21.4%	
Graduate school	27.3%	7.1%	
<i>Body Mass Index (BMI):</i>			
<20	4.5%	0%	0.474
20-25	36%	42.6%	
26-30	36%	35.5%	
31-35	18%	21.3%	
35+	4.5%	0%	

Table 1: Baseline Subject Demographics

Comparison of baseline subject characteristics between non-frail and frail cohorts at the onset of the study. The p-values indicate that there are no significant differences between the two cohorts in any of the demographic measures (alpha=0.05) except for age. The frail cohort was slightly older, which is not surprising given that the prevalence of frailty increases with age. This difference in age between the cohorts did not impact our final results since we adjusted for this in our final statistical model.

⁴⁹ Ziad S. Nasreddine et al., "The Montreal Cognitive Assessment, MoCA: A Brief Screening Tool for Mild Cognitive Impairment," *Journal of the American Geriatrics Society* 53, no. 4 (April 2005): 695–99, doi:10.1111/j.1532-5415.2005.53221.x.

⁵⁰ Maria-Victoria Castell et al., "Frailty Prevalence and Slow Walking Speed in Persons Age 65 and Older: Implications for Primary Care," *BMC Family Practice* 14, no. 1 (2013): 86, doi:10.1186/1471-2296-14-86.

SELF-REPORTED FUNCTION AND GAIT MEASURES

Subject self-perceived gait and mobility function was assessed using previously validated survey instruments. These instruments included the (1) functional component of the Late Life Function and Disability Instrument (LLFDI, a comprehensive assessment of function and disability for use in community-dwelling older adults that evaluates self-reported difficulty performing 32 physical activities, with higher scores indicating higher functional status⁵¹); (2) the Survey of Activities and Fear of Falling in the Elderly (SAFFE, a questionnaire evaluating fears associated with performing 11 activities of everyday life necessary for independent living⁵²); (3) PROMIS Global Health version 1.0-1.1 (aka PROMIS APF)⁵³, and (4) PROMIS Physical Health short form 10a, two outcome measures designed to assess patient experience of health outcomes such as pain, fatigue, physical function, depression, anxiety and social function.⁵⁴ PROMIS instruments are based on strong psychometrics and consequently have fewer problems with floor and ceiling effect than other traditional self-report survey instruments such as the SF-36.

⁵¹ Stephen P. Sayers et al., "Validation of the Late-Life Function and Disability Instrument," *Journal of the American Geriatrics Society* 52, no. 9 (September 2004): 1554–59, doi:10.1111/j.1532-5415.2004.52422.x.

⁵² Fuzhong Li et al., "Fear of Falling in Elderly Persons: Association with Falls, Functional Ability, and Quality of Life," *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences* 58, no. 5 (September 2003): P283–90.

⁵³ "Patient Reported Outcomes Measurement Information System PROMIS Instruments Available for Use in Assessment Center" (National Institutes of Health NIH, March 24, 2015), PMID: 15341561.

⁵⁴ Margaret Bevans, Alyson Ross, and David Cella, "Patient-Reported Outcomes Measurement Information System (PROMIS): Efficient, Standardized Tools to Measure Self-Reported Health and Quality of Life," *Nursing Outlook* 62, no. 5 (September 2014): 339–45, doi:10.1016/j.outlook.2014.05.009; Dennis A. Revicki et al., "Predicting EuroQol (EQ-5D) Scores from the Patient-Reported Outcomes Measurement Information System (PROMIS) Global Items and Domain Item Banks in a United States Sample," *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation* 18, no. 6 (August 2009): 783–91, doi:10.1007/s11136-009-9489-8.

CLINICAL GAIT MEASURES

All subjects performed a 4 meter walking test⁵⁵ (4MW) consisting of a 1-meter untimed startup followed by a 4 meter timed evaluation with the instruction to “walk at your usual speed.” Assistive devices such as a walker or cane were permitted at the subject’s discretion. Next, subjects completed a 10 foot “Timed Up and Go” test⁵⁶ (TUG). To begin the test subjects were seated with their back against the backrest of an armless chair. Subjects were then instructed to stand up and “walk at your usual speed” to a mark 10 feet directly in front of the chair, turn around, return to the chair, and sit down again. Timing stopped once the subject’s back again touched the chair backrest. Finally, subjects were asked to complete a Figure of 8 Walk⁵⁷ (F8W). For purposes of step count and gait evaluation we video-recorded subject performance with the camera focused on the subject’s lower legs and feet during the test. No identifying features of the subjects were photographed. Two cones were placed 5 feet apart in the center of the room and participants were placed in the center of the cones instructed to walk a figure-of-eight around the cones at their self-selected pace. Subjects were permitted to circle either cone first since the order was not important. The direction they preceded to walk the figure-of-eight didn’t matter as long as they looped around each cone and ended back in the center of the two cones again to successfully complete the F8W. Total completion times, the number of steps to complete the F8W, and gait smoothness were recorded.

⁵⁵ Carmen L. Muñoz-Mendoza et al., “Reliability of 4-M and 6-M Walking Speed Tests in Elderly People with Cognitive Impairment,” *Archives of Gerontology and Geriatrics* 52, no. 2 (March 2011): e67–70, doi:10.1016/j.archger.2010.06.020.

⁵⁶ Emma Barry et al., “Is the Timed Up and Go Test a Useful Predictor of Risk of Falls in Community Dwelling Older Adults: A Systematic Review and Meta-Analysis,” *BMC Geriatrics* 14 (2014): 14, doi:10.1186/1471-2318-14-14.

⁵⁷ R. J. Hess et al., “Walking Skill Can Be Assessed in Older Adults: Validity of the Figure-of-8 Walk Test,” *Physical Therapy* 90, no. 1 (January 1, 2010): 89–99, doi:10.2522/ptj.20080121.

Two trials of all physical assessment tests were performed. All physical assessment tests were demonstrated by the examiner before asking the subjects to complete the test. All clinical assays were well tolerated by the subjects without problem. Gait speed calculations depended upon stride length, which we derived from treadmill locomotion videos (1.38 m non-frail; 0.83 m frail).

GAIT DATA ACQUISITION

For both cohorts we used Nokia N79 SmartPhones (White Plains, NY) with a built in tri-axial accelerometer (Lumia 630-IC SMD sensor) to measure mobility and locomotion in these community dwelling individuals for extended periods of time while going about their normal daily routines (Figure 2).⁵⁸ The advantage

of the tri-axial accelerometer rather than uniaxial accelerometers is that it can measure movement in the X, Y and Z planes. Acceleration values were sampled and written to memory using custom Python software (Python for S60 v1.9.7, <https://garage.maemo.org/projects/pys60>) running on a Symbian S60 V3FP2 OS (San Francisco, CA). Subjects were instructed to place the mobile phone in either their right or left pant pocket, over the hip, and the location was then recorded. Our previous studies show that location does not impact data collection⁵⁹ Validated New Lifestyle NL-2000 pedometers (Lees Summit, MO) were also utilized to collect step data for

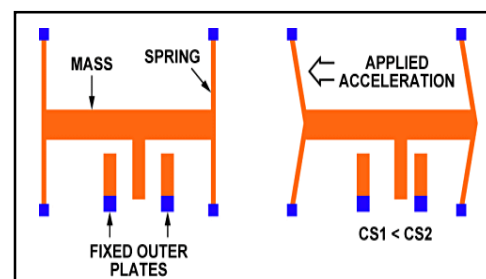


Figure 2: Smartphone Accelerometer

Simple schematic of a smartphone microelectromechanical systems (MEMS) accelerometer like the Nokia N79 tri-axial accelerometer (Lumia 630-IC SMD sensor) used in the study.

⁵⁸ "Sonic Nirvana: MEMS Accelerometers as Acoustic Pickups in Musical Instruments | Sensors," accessed June 17, 2015, <http://www.sensormag.com/sensors/acceleration-vibration/sonic-nirvana-mems-accelerometers-acoustic-pickups-musical-i-5852>.

⁵⁹ Carlson et al., "Treadmill Gait Speeds Correlate with Physical Activity Counts Measured by Cell Phone Accelerometers."

comparison. Pedometers were worn horizontal and flat over the hip and attached to a straight belt loop or non-slanted pocket.

PROTOCOL

Participants were fitted with both a pedometer and smartphone. A study investigator educated the subjects in proper use and correct placement of these. Subjects were

instructed to wear these devices for the next 24 hours, except when sleeping, bathing, or swimming since the devices are not waterproof.

Subjects were then asked to walk briefly on a treadmill (SCIFIT, Tulsa, OK, scifit.com)

at a comfortable pace for 5 minutes (normally 2 mi/hr but flexible to subject's comfort) and again videotaped below the waist only for gait analysis. Subjects unable to walk on the treadmill, either due to limited mobility, need for assistive devices, or other factors, were not asked to complete this portion of the study.

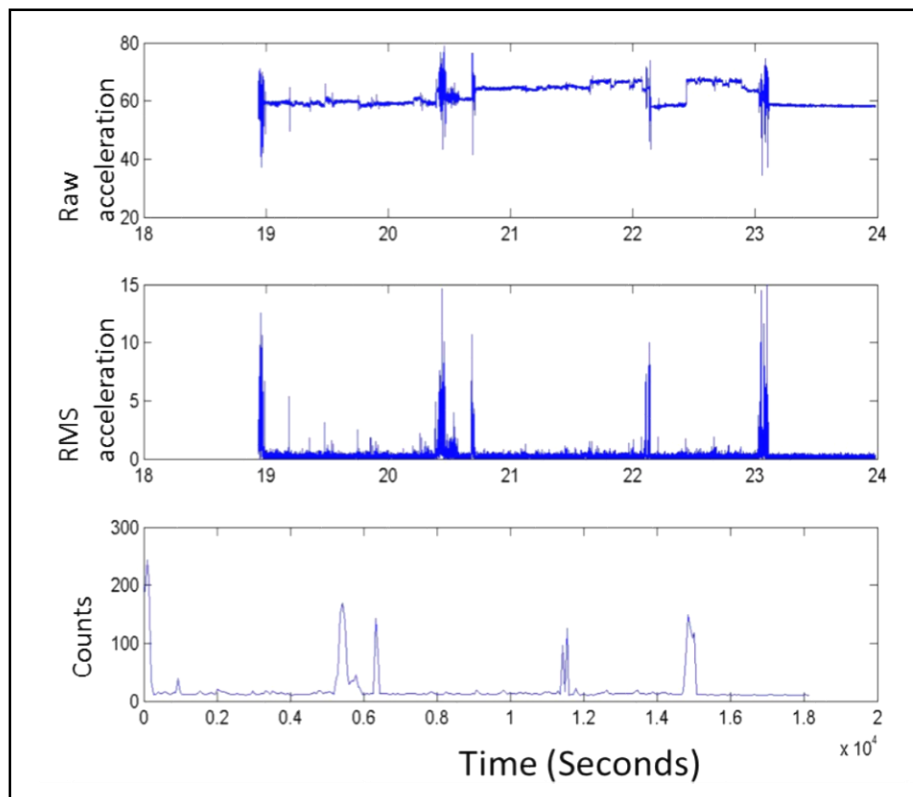


Figure 3: Conversion of Raw Acceleration to Counts

Raw acceleration from the smartphone accelerometer (top panel) is transformed by taking the root mean square of the acceleration (middle panel) and then finally converted into counts (lower panel). These counts are then transformed into functional performance measures such as step counts, gait speed, and physical activity using algorithms developed in our lab.

DATA QUALITY CONTROL AND CLASSIFICATION

Instrument instructions were used to score survey data. Raw acceleration data was low-pass filtered, and baseline acceleration normalized to 1 g (Figure 3) over the entire duration of data collection.⁶⁰ Our classification algorithm first identified epochs of “forgotten phone” vs epochs of subject carrying the phone. For epochs of subject carrying the phone, we then classify behavior into active or inactive states, using a windowed (68 s long) Fourier analysis approach.⁶¹ Active states are further differentiated into states with minimal locomotion, states with ongoing locomotion, and states where subject is climbing stairs. Ongoing locomotion was then quantified for step count and gait speed. Gait speed calculations depended on treadmill video derived values of stride length (control subjects: 1.38 m; frail subjects: 0.83 m).

STATISTICAL ANALYSIS

All smartphone based measures by two-way analysis of variance (ANOVA). Step count, gait speed, and activity count were our primary outcomes with cohort (non-frail vs frail) and time as factors. Our first models included all interaction terms, and interactions not found to be significant were dropped from later models. We managed multiple comparisons testing by Bonferroni correction. All post hoc testing was performed using Tukey’s test. Functional questionnaire data and clinical physical performance measures were analyzed by one-way ANOVA. Spearman correlations were determined to assess agreement between smartphone based measures and the survey-/performance-based

⁶⁰ Kwon Y-J, Aung T, Synovec SM, Oberle AD, Rye-Hanton C, Whittington J, Goulding EH, Witbrodt BC, Bonasera SJ, Schenk AK., “Classifying Smartphone-Based Accelerometer Data to Obtain Validated Measures of Subject Activity Status, Step Count, and Gait Speed.”

⁶¹ Noriko Ichinoseki-Sekine et al., “Improving the Accuracy of Pedometer Used by the Elderly with the FFT Algorithm;,” *Medicine & Science in Sports & Exercise* 38, no. 9 (September 2006): 1674–81, doi:10.1249/01.mss.0000227641.68360.c2.

metrics. Finally, cohort demographic factors were compared using independent samples t-test assuming equal variances (2-tailed test). All analyses were performed using SPSS (IBM SPSS Statistics 22.0, Armonk, New York, USA).

CHAPTER 3: RESULTS

Over the full 24 hour study day, all study subjects adhered to recording data for at least 8 waking hours, the minimum time considered a full study day for purposes of analysis. All 22 non-frail subjects recorded at least 14 hours of data (mean=17.3 hours; range 14-20 hours) for a total of 380 hours suitable for analysis. All 11 frail subjects recorded at least 9 hours of data (mean=19.9 hours; range 9-24 hours) for a total of 210

hours of which 209 were suitable for analysis (one hour was prematurely truncated). We found no significant difference in the number of hours recorded for the non-frail vs. frail cohort ($p=0.165$) when normalized over the 24 hour day.

Therefore, comparable amounts of data were collected from both non-frail and frail older individuals. Reference

demographics of the two cohorts were equivalent, with the exception of age as the lone significant difference (Table 1: Baseline Subject Demographics

Survey Instrument	F	p
LLFDI Overall Function	27.7	<0.001
LLFDI Basic Lower Extremity Function	23.4	<0.001
LLFDI Advance Lower Extremity Function	35.8	<0.001
LLFDI Upper Extremity Function	1.3	0.257
SAFFE Activity Level	17.3	<0.001
SAFFE Fear of Falling	4.1	0.052
SAFFE Activity Restriction	25.2	<0.001
PROMIS Short Form v1.0	33.7	<0.001
PROMIS Global Physical Health	19.4	<0.001
PROMIS Global Mental Health	4.5	0.042
Performance Measure		
10 ft Timed "Get Up and Go"	11.6	<0.001
4 Meter Walk	63.8	<0.001
Figure of 8 Walk	17.8	<0.001

Table 2: Survey Instruments & Performance Measures

Statistical analysis of the survey measures (LLFDI, SAFFE, PROMIS) and clinical performance measures (4MW, F8W, TUG) indicated that they all distinguished significant differences between the frail and non-frail cohorts. The only exception was the LLFDI Upper Extremity Function subsection, which is not surprising given that upper extremity function is not directly related to gait and mobility.

PERFORMANCE MEASURES AND SURVEY DATA DISTINGUISH NON-FRAIL FROM FRAIL SUBJECTS

Our questionnaires and performance batteries were selected based on previous validation, and current clinical use. Of the 33 subjects, 31 had sufficient survey response

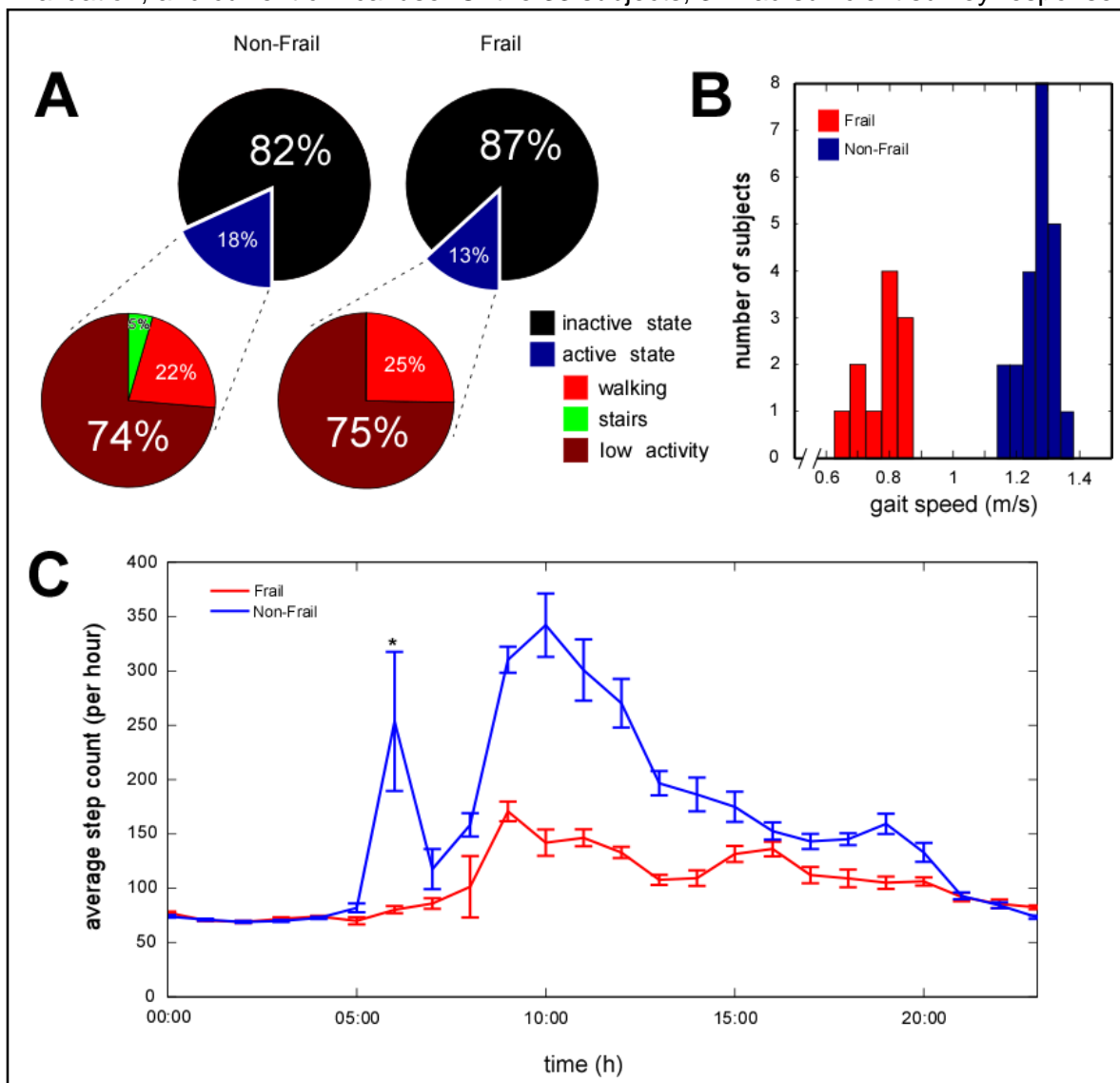


Figure 4: Average Activity, Gait Speed and Step Counts

A. Pie graph comparing average percent activity over the 24 hour day. Non-Frail individual's have a significantly greater percent activity throughout the 24 hour day, approximately 5% greater than non-frail individuals. B. Histogram comparing the number of subjects (y-axis) in different average gait speed ranges (m/s). Non-Frail individual's have a significantly greater average walking speed than frail individual's. C. Analysis of average number of step counts per hour (y-axis) over the 24 hour day in military time (x-axis). Non-Frail individual's take a significantly greater average number of steps per hour than frail individuals.

data for analysis. Our analysis demonstrated that all four survey instruments utilized (LLFDI, SAFFE, PROMIS Global version 1.0-1.1 and PROMIS short form 10a) effectively differentiated non-frail from frail individuals, as anticipated ($F_{1,30}=27.7$, $p<0.001$ for LLFDI overall function transformed score; $F_{1,30}=17.3$, $p<0.001$ for SAFFE activity level, $F_{1,30}=33.7$, $p<0.001$ for PROMIS physical function short form; $F_{1,30}=19.4$, $p<0.001$ for PROMIS global physical health, all p values Bonferroni corrected; Table 2). Similarly, all three physical performance measures (4MW, TUG, and F8w) showed robust differences between our frail and non-frail cohorts ($F_{1,30}=11.6$, $p<0.001$ for TUG; $F_{1,30}=63.8$, $p<0.001$ for 4MW; $F_{1,30}=17.8$, $p<0.001$ for F8W).

SMARTPHONE BASED FUNCTIONAL MEASURES DISTINGUISH NON-FRAIL FROM FRAIL SUBJECTS

Following confirmation of the validity of both the survey questionnaire-based measures and the standard clinical physical performance in distinguishing non-frail from frail individuals, we assessed whether our smartphone based measures of physical activity also distinguished frail from healthy older individuals. We defined active states as

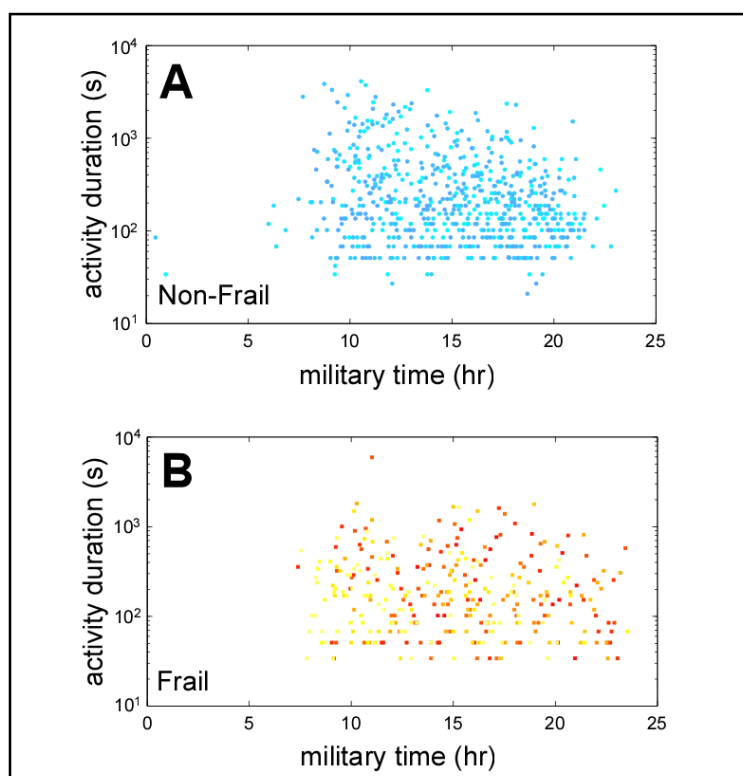


Figure 5: Activity State Duration

Comparison of average duration of a single active state in seconds (y-axis) between frail and non-frail cohorts at a given time (x-axis). Overall, the durations of active periods were longer for non-frail than for frail individuals.

periods where the subject was walking, climbing stairs, or otherwise active but not walking (walking (high physical activity classification per Kwon et al., 2015). We defined inactive states (low physical activity per Kwon et al., 2015) as periods when the subject was resting (i.e. sitting down or lying on the couch). We noted significant differences in subject 24-hour and active state time budgets (Figure 4A). Overall, the non-frail group were active ~18% of the day (18.13 ± 5.54 min); while the frail group displayed significantly less activity (13.19 ± 5.20 min; $p < 0.019$ for non-frail vs. frail groups, two-sided t test). There were no phenotypic differences in active state onset rate between non-frail and frail individuals (non-frail 2.63 ± 0.162 per hour; frail 2.48 ± 0.219 per hour; $p < 0.598$, two sided Student t test). Non-frail individuals had longer active state durations (373.85 ± 20.66 s) compared to frail individuals (300.19 ± 25.79 s; $p < 0.036$; two sided Student t-test; Figure 5). Similarly, average gait speed (measured over 24 hour window; Figure 4B) differed significantly between frail and non-frail groups (non-frail 1.22 ± 0.14 m/s, frail 0.76 ± 0.08 m/s; $F_{1,30}=21.1$, $p < 0.001$).

The average step counts also differed between frail and non-frail groups throughout an entire 24 hour circadian day (Figure 4C). Both functional status, time, and the interaction between functional status and time were observed to be significant by one-way ANOVA analysis with gait speed as the dependent variable and functional status and time as independent variables ($F_{1,30}=40.5$, $p < 0.001$ for functional status; $F_{1,30}=44.1$, $p < 0.001$ for time; $F_{1,30}=20.01$, $p < 0.001$ for functional status x time interaction). Taken collectively, all our smartphone collected measures, including step count, gait speed, activity classification, and percent activity, were statistically significant in our study, indicating important differences between non-frail and frail subjects.

SURVEY MEASURES AND SMARTPHONE MEASURES ASSESS DIFFERENT ASPECTS OF GAIT

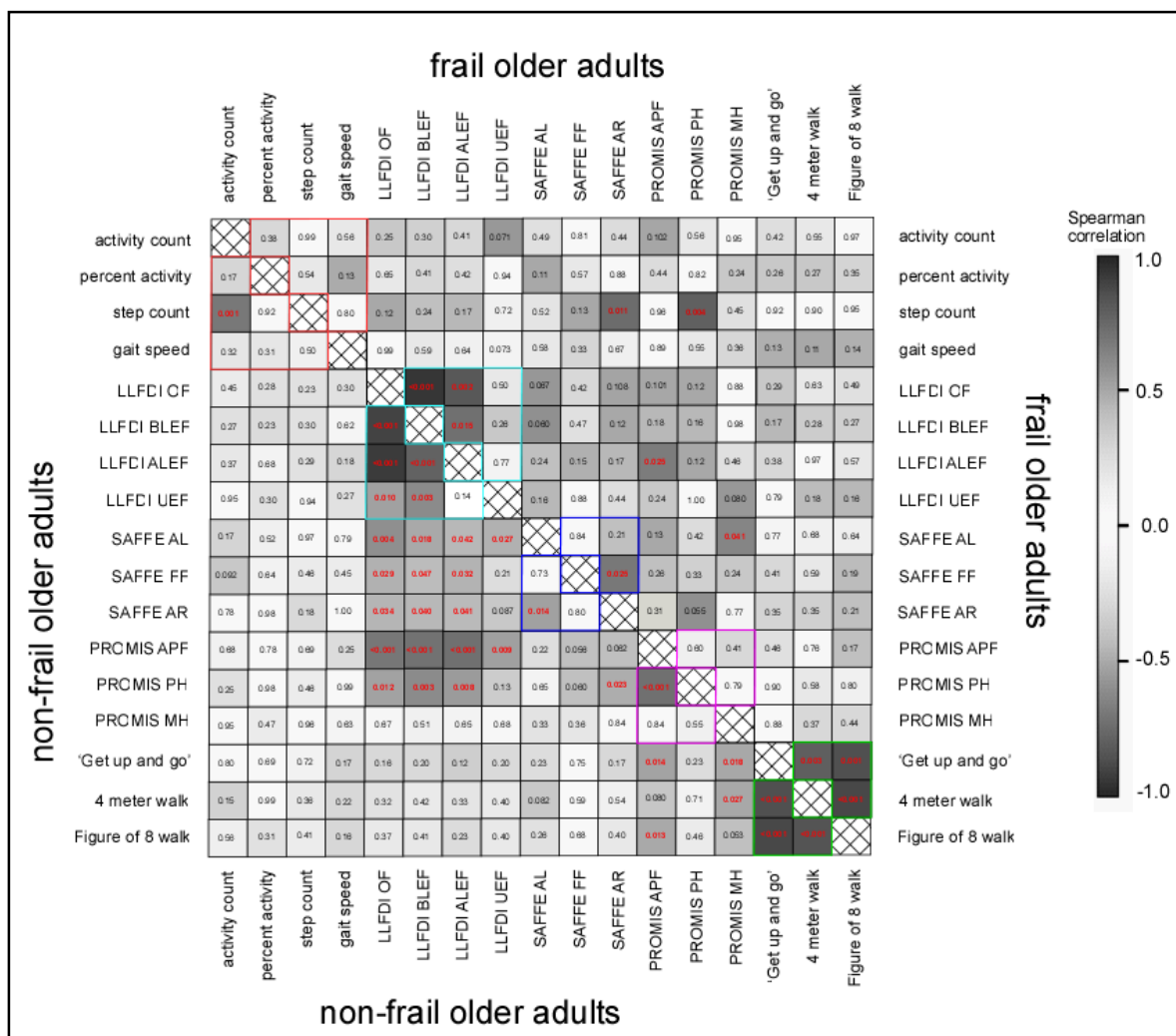


Figure 6: Correlation of Smartphone Based Measures, Survey Metrics and Performance Measures

Spearman correlations are given in the boxes. A darker shade of color indicates a higher degree of correlation. A diagonal line in the middle of the matrix separates the two cohorts. The upper right half of the matrix above the diagonal line contains the frail cohort. The lower left half of the matrix below the diagonal line contains the non-frail cohort.

Once we had established that our smartphone based measures identified significant differences between frail and non-frail individuals, we wanted to determine if our smartphone based measurements were identifying similar elements of frailty as the clinical performance measures. We therefore calculated Spearman correlations between our -based functional measurements and the clinical performance measures (Figure 6;

values below diagonal correspond to non-frail subjects, values above diagonal correspond to frail subjects).

In non-frail subjects, we noted significant within-test correlations for our smartphone-based monitoring metrics (step and activity count), all LLFDI metrics (except for those measuring upper extremity function, UEF), SAFFE metrics (activity restriction and limitation), PROMIS metrics (APF and PROMIS PH), and all performance battery results. LLFDI metrics (except UEF) also strongly correlated with results from both SAFFE and PROMIS (except MH). By contrast, both within-instrument and across-instrument correlations were overall much weaker in adults with functional impairment. Only performance battery and subsets of LLFDI scores remained significantly correlated with one another. Much of the correlation between LLFDI and SAFFE/PROMIS metrics was no longer observed. In frail individuals, step and activity counts no longer correlated with one another. However, step count now showed significant correlations with both SAFFE activity restriction and PROMIS Global physical health in frail individuals.

CHAPTER 4: DISCUSSION

This work represents the first demonstrated employment of smartphones to measure clinically relevant functional metrics, including overall activity, gait speed, and step count in community dwelling older adults. As these measures were captured in naturalistic conditions and real-life settings within the community, they provide valuable insights regarding individual daily function outside of the clinical setting. This work provides further validation of the LLFDI, SAFFE, PROMIS global, PROMIS 10a, timed 4-meter walking test, timed “get up and go”, and Figure of eight walk assays in older adults. Furthermore, our results demonstrate that cognitively intact individuals with frailty had worse performance on all of these assays compared to non-frail individuals. In non-frail individuals, our smartphone-based measures and questionnaire/physical performance battery results did not correlate strongly with one another, suggesting that these different tools measure distinct aspects of physical function. However, in cognitively intact individuals with functional loss, smartphone-based functional metrics strongly correlate with components of both SAFFE and PROMIS.

SMARTPHONES MEASURE INDIVIDUAL FUNCTIONAL STATUS

Our utilization of a smartphone monitoring system advances the goal of developing an accurate, simple, user friendly, familiar system that measures clinically relevant measures of activity (onsets, durations, step counts, and gait speeds) in diverse populations of ambulatory adults. This goal is achievable with the appropriate hardware and software. For example, more than fifty years ago, researchers demonstrated the viability of using pedometers to estimate individual walking distance over long periods of observation.⁶² Since then, data accuracy and temporal precision have been increased

⁶² A. Stunkard, “A Method of Studying Physical Activity in Man.,” *The American Journal of Clinical Nutrition*. 8, no. 5 (1960): 595–601.

through technical modifications (improved accelerometer technology, device durability, device data logging).⁶³ Devices dedicated to measuring individual activity status have not been adopted by the population at large, however, despite validation in many smaller trials. A likely reason they have not “caught on” is because these devices haven’t successfully addressed human usability factors.⁶⁴ Smartphones, by contrast, have become a nearly omnipresent technology, particularly among younger and middle-aged adults.⁶⁵ The quality of life of these individuals could benefit considerably from advances in smartphone-based platforms for health care delivery and follow-up.

VALIDATION OF LLFDI, SAFFE, PROMIS 10A, PROMIS GLOBAL, 4MW, TUG, AND F8W IN NON-FRAIL AND FRAIL OLDER ADULTS

This study afforded us the additional opportunity to further validate a number of questionnaire and performance based instruments designed to measure functional status. The LLFDI evaluates two separate outcomes: function (ability to do discrete actions or activities), and disability (performance of socially defined life tasks).⁶⁶ Prior studies have validated the LLFDI for identifying functional deficits in independent older

⁶³ C. E. Matthews and P. S. Freedson, “Field Trial of a Three-Dimensional Activity Monitor: Comparison with Self Report,” *Medicine and Science in Sports and Exercise* 27, no. 7 (July 1995): 1071–78; Gary Kochersberger et al., “The Reliability, Validity, and Stability of a Measure of Physical Activity in the Elderly,” *Archives of Physical Medicine and Rehabilitation* 77, no. 8 (August 1996): 793–95, doi:10.1016/S0003-9993(96)90258-0; Kristi L. Storti et al., “Gait Speed and Step-Count Monitor Accuracy in Community-Dwelling Older Adults,” *Medicine & Science in Sports & Exercise* 40, no. 1 (January 2008): 59–64, doi:10.1249/mss.0b013e318158b504.

⁶⁴ Neil Charness and K. Warner Schaie, eds., *Impact of Technology on Successful Aging*, Societal Impact on Aging (New York: Springer Pub, 2003).

⁶⁵ “Smartphone Ownership 2013 | Pew Research Center,” accessed June 24, 2015, <http://www.pewinternet.org/2013/06/05/smartphone-ownership-2013/>.

⁶⁶ Sayers et al., “Validation of the Late-Life Function and Disability Instrument.”

adults⁶⁷, institutionalized older adults⁶⁸, older adults with knee osteoarthritis⁶⁹, older adults with chronic renal disease⁷⁰ and incontinence⁷¹, and persons undergoing cardiac physical therapy.⁷² The LLFDI has comparable psychometric properties to performance-based measures of upper and lower extremity function.⁷³ Interestingly, there is greater bias between self-reported (via LLFDI) and clinician assessment of upper extremity function compared to lower extremity function.⁷⁴ Our results suggest that LLFDI can discriminate functional status between a cohort of non-frail older adults and persons with functional impairment who meet frailty criteria. We also demonstrate that in non-frail, but not frail, individuals, LLFDI is highly correlated across functional submeasures (LLFDI BLEF, LLFDI ALEF, etc.), and is significantly correlated to both SAFFE and PROMIS

⁶⁷ Rona Feuring et al., “Differences between Self-Reported and Observed Physical Functioning in Independent Older Adults,” *Disability and Rehabilitation* 36, no. 17 (August 2014): 1395–1401, doi:10.3109/09638288.2013.828786.

⁶⁸ Pedro Abizanda et al., “Effects of an Oral Nutritional Supplementation Plus Physical Exercise Intervention on the Physical Function, Nutritional Status, and Quality of Life in Frail Institutionalized Older Adults: The ACTIVNES Study,” *Journal of the American Medical Directors Association* 16, no. 5 (May 1, 2015): 439.e9–439.e16, doi:10.1016/j.jamda.2015.02.005.

⁶⁹ Leena Sharma et al., “Knee Instability and Basic and Advanced Function Decline in Persons with Knee Osteoarthritis,” *Arthritis Care & Research*, March 2, 2015, doi:10.1002/acr.22572.

⁷⁰ Ulla K. Seidel et al., “Physical, Cognitive and Emotional Factors Contributing to Quality of Life, Functional Health and Participation in Community Dwelling in Chronic Kidney Disease,” *PloS One* 9, no. 3 (2014): e91176, doi:10.1371/journal.pone.0091176.

⁷¹ Kyung Rim Shin, Younhee Kang, and Jiwon Oak, “The Relationship of Quality of Sleep, Depression, Late-Life Function and Disability (LLFDI) in Community-Dwelling Older Women with Urinary Incontinence,” *Journal of Korean Academy of Nursing* 38, no. 4 (2008): 573, doi:10.4040/jkan.2008.38.4.573.

⁷² Tanya Kinney Lapier and Ryan Mizner, “Outcome Measures in Cardiopulmonary Physical Therapy: Focus on the Late Life Function and Disability Instrument (LLFDI),” *Cardiopulmonary Physical Therapy Journal* 20, no. 2 (June 2009): 32–35.

⁷³ Marla K. Beauchamp et al., “Predictive Validity and Responsiveness of Patient-Reported and Performance-Based Measures of Function in the Boston RISE Study,” *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences* 70, no. 5 (May 2015): 616–22, doi:10.1093/gerona/glu227.

⁷⁴ Feuring et al., “Differences between Self-Reported and Observed Physical Functioning in Independent Older Adults.”

(except PROMIS-MH). For all subjects, LLFDI was not significantly correlated with either physical performance battery measures or smartphone derived gait speed.

SAFFE evaluates how fear of falling influences subject activity participation or restriction. The SAFFE has been validated in a number of populations including community dwelling older adults⁷⁵, older adults with mobility limitations⁷⁶, and extensively utilized in studies of persons with Parkinson's disease⁷⁷ as well as individuals receiving post-fall physical therapy who have a fear of falling.⁷⁸ Our results further suggest that SAFFE can successfully discriminate functional status between a cohort of non-frail older adults and persons with functional limitations meeting frailty criteria (of note, however, we did not evaluate balance or falls in any of our subjects). As mentioned above, SAFFE showed significant correlations to both LLFDI and PROMIS (except PROMIS-MH) scores in non-frail (but not frail) individuals. For all subjects, correlations of submeasures within SAFFE (e.g. SAFFE FF, SAFFE AL) were weaker. SAFFE scores also did not significantly correlate with either smartphone derived gait speed or

⁷⁵ Li et al., "Fear of Falling in Elderly Persons"; Kim Delbaere et al., "The Risk of Being Fearful or Fearless of Falls in Older People: An Empirical Validation," *Disability and Rehabilitation* 28, no. 12 (June 30, 2006): 751–56, doi:10.1080/09638280500304794.

⁷⁶ Leslie M. Julius et al., "Perceived Effort of Walking: Relationship with Gait, Physical Function and Activity, Fear of Falling, and Confidence in Walking in Older Adults with Mobility Limitations," *Physical Therapy* 92, no. 10 (October 2012): 1268–77, doi:10.2522/ptj.20110326.

⁷⁷ S. Rahman et al., "On the Nature of Fear of Falling in Parkinson's Disease," *Behavioural Neurology* 24, no. 3 (2011): 219–28, doi:10.3233/BEN-2011-0330; M. H. Nilsson, S. Rehncrona, and G.-B. Jarnlo, "Fear of Falling and Falls in People with Parkinson's Disease Treated with Deep Brain Stimulation in the Subthalamic Nuclei," *Acta Neurologica Scandinavica* 123, no. 6 (June 2011): 424–29, doi:10.1111/j.1600-0404.2010.01418.x; Maria H. Nilsson, Anna-Maria Drake, and Peter Hagell, "Assessment of Fall-Related Self-Efficacy and Activity Avoidance in People with Parkinson's Disease," *BMC Geriatrics* 10 (2010): 78, doi:10.1186/1471-2318-10-78.

⁷⁸ Li et al., "Fear of Falling in Elderly Persons."

physical performance battery measures. Previous studies have also demonstrated weak correlation between SAFFE scores and accelerometer-based activity measures.⁷⁹

PROMIS global health instruments provide a more all-inclusive view of health status by assessing an individual's physical, mental and social health domains.⁸⁰ Form 10a is a shorter 10 question instrument that provides a quicker physical health assessment of an individual without necessitating use of a lengthy full physical function instrument.⁸¹ The PROMIS Global and short form 1a assessments were developed for a general adult population as compared to LLFDI and SAFFE, which were developed specifically for use in an older population.⁸² Both of these PROMIS instruments have previously been validated in a large, cross-sectional sample of

⁷⁹ Victoria Hornyak et al., "What Is the Relation between Fear of Falling and Physical Activity in Older Adults?," *Archives of Physical Medicine and Rehabilitation* 94, no. 12 (December 2013): 2529–34, doi:10.1016/j.apmr.2013.06.013.

⁸⁰ J. F. Fries et al., "More Relevant, Precise, and Efficient Items for Assessment of Physical Function and Disability: Moving beyond the Classic Instruments," *Annals of the Rheumatic Diseases* 65 Suppl 3 (November 2006): iii16–21, doi:10.1136/ard.2006.059279.

⁸¹ David Cella et al., "The Patient-Reported Outcomes Measurement Information System (PROMIS) Developed and Tested Its First Wave of Adult Self-Reported Health Outcome Item Banks: 2005–2008," *Journal of Clinical Epidemiology* 63, no. 11 (November 2010): 1179–94, doi:10.1016/j.jclinepi.2010.04.011.

⁸² David Cella et al., "The Patient-Reported Outcomes Measurement Information System (PROMIS): Progress of an NIH Roadmap Cooperative Group during Its First Two Years," *Medical Care* 45, no. 5 Suppl 1 (May 2007): S3–11, doi:10.1097/01.mlr.0000258615.42478.55; Cella et al., "The Patient-Reported Outcomes Measurement Information System (PROMIS) Developed and Tested Its First Wave of Adult Self-Reported Health Outcome Item Banks."

independently dwelling US adults,⁸³ as well as persons with chronic pelvic pain,⁸⁴ cancer,⁸⁵ and adult patients preparing for laparoscopic surgical procedures.⁸⁶ Our results again suggest that PROMIS 10a and PROMIS global can discriminate functional status between a cohort of non-frail older adults and individuals with functional impairment meeting frailty criteria. As mentioned above, in non-frail (but not frail) individuals, we noted significant correlations between PROMIS and both LLDFI and SAFFE measures. PROMIS submeasures APF and PH were also significantly correlated for non-frail individuals, as were multiple physical performance battery measures. However, in frail individuals, PROMIS measures correlated poorly with all other measures we quantified except for smartphone-derived step count, LLFDI ALEF, and SAFFE AL.

⁸³ Cella et al., "The Patient-Reported Outcomes Measurement Information System (PROMIS) Developed and Tested Its First Wave of Adult Self-Reported Health Outcome Item Banks"; John P. Barile et al., "Monitoring Population Health for Healthy People 2020: Evaluation of the NIH PROMIS® Global Health, CDC Healthy Days, and Satisfaction with Life Instruments," *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation* 22, no. 6 (August 2013): 1201–11, doi:10.1007/s11136-012-0246-z; Ron D. Hays et al., "U.S. General Population Estimate for 'Excellent' to 'Poor' Self-Rated Health Item," *Journal of General Internal Medicine*, April 2, 2015, doi:10.1007/s11606-015-3290-x.

⁸⁴ Bradford W. Fenton et al., "Application of Patient-Reported Outcomes Measurement Information System to Chronic Pelvic Pain," *Journal of Minimally Invasive Gynecology* 18, no. 2 (April 2011): 189–93, doi:10.1016/j.jmig.2010.12.001.

⁸⁵ Roxanne E. Jensen et al., "Validation of the PROMIS Physical Function Measures in a Diverse US Population-Based Cohort of Cancer Patients," *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, May 3, 2015, doi:10.1007/s11136-015-0992-9; Karen Kaiser et al., "Development and Validation of the Functional Assessment of Cancer Therapy-Antiangiogenesis Subscale," *Cancer Medicine* 4, no. 5 (May 2015): 690–98, doi:10.1002/cam4.385.

⁸⁶ Juliane Bingener et al., "PROMIS for Laparoscopy," *Journal of Gastrointestinal Surgery: Official Journal of the Society for Surgery of the Alimentary Tract* 19, no. 5 (May 2015): 917–26, doi:10.1007/s11605-015-2789-0.

A variety of physical performance measures have been adapted for clinic use, including the 4 meter walk,⁸⁷ the timed get up and go test,⁸⁸ and the figure of 8 test.⁸⁹ Both the timed get up and go and Figure of 8 tests focus on older populations, and have been used to assess community dwelling older adults and individuals with Parkinson's disease. The four meter walk test is designed for persons ranging from 7-85 years old, and is a validated to measure functional measure in persons with peripheral arterial disease⁹⁰ and cerebrovascular disease,⁹¹ among others. Our results demonstrated that all of these gait-associated performance batteries reliably distinguished between non-frail older adults and older adults with functional limitations who meet frailty criteria. We also noted high correlations across these physical performance tests in both non-frail and frail individuals. However, none of these measures correlated well with our smartphone-derived activity and gait metrics.

SMARTPHONE GAIT METRICS SHOW A CEILING EFFECT IN NON-FRAIL INDIVIDUALS

In non-frail individuals, there was little correlation between smartphone measured activity and gait and subject responses to the LLFDI, SAFFE or PROMIS instruments, or to performance on the physical battery. We suspect that in non-frail individuals, these

⁸⁷ Denise M. Peters, Stacy L. Fritz, and Debra E. Krotish, "Assessing the Reliability and Validity of a Shorter Walk Test Compared with the 10-Meter Walk Test for Measurements of Gait Speed in Healthy, Older Adults," *Journal of Geriatric Physical Therapy* (2001) 36, no. 1 (March 2013): 24–30, doi:10.1519/JPT.0b013e318248e20d.

⁸⁸ S. Mathias, U. S. Nayak, and B. Isaacs, "Balance in Elderly Patients: The 'Get-up and Go' Test," *Archives of Physical Medicine and Rehabilitation* 67, no. 6 (June 1986): 387–89.

⁸⁹ Hess et al., "Walking Skill Can Be Assessed in Older Adults."

⁹⁰ Mary McGrae McDermott et al., "Physical Performance in Peripheral Arterial Disease: A Slower Rate of Decline in Patients Who Walk More," *Annals of Internal Medicine* 144, no. 1 (January 3, 2006): 10–20.

⁹¹ F. A. Sorond et al., "Cerebrovascular Hemodynamics, Gait, and Falls in an Elderly Population: MOBILIZE Boston Study," *Neurology* 74, no. 20 (May 18, 2010): 1627–33, doi:10.1212/WNL.0b013e3181df0982.

instruments have a ceiling effect similar to that observed in other surveys and performance batteries evaluating community-dwelling individuals.⁹² In frail individuals, however, we found significant correlations between step count and SAFFE activity restriction ($p=0.011$) and PROMIS physical health ($p=0.004$). Therefore, smartphone-derived gait measures may estimate both activity restrictions and overall physical health (as well as gait speed, step count, and activity status) in older adults as they progress through stages of functional loss and ultimately become frail.

POTENTIAL STUDY LIMITATIONS

We recognize several limitations in this study, mostly regarding subject characteristics. Our selection of participants was significantly impaired by our desire to test cognitively intact individuals with functional impairments. While we ultimately envision that this technology will be used by cognitively impaired persons, for validation purposes we wanted to ensure that differences between our groups could be attributed mostly to functional differences rather than cognitive deficits. Although we did not enroll a large group of cognitively intact individuals with functional deficits, we had ample statistical power for discrimination given our effect size. Our non-frail group included more health literate and highly educated individuals⁹³ compared to community averages

⁹² Poonam K. Pardasaney et al., "Sensitivity to Change and Responsiveness of Four Balance Measures for Community-Dwelling Older Adults," *Physical Therapy* 92, no. 3 (March 2012): 388–97, doi:10.2522/ptj.20100398; Chitralakshmi K. Balasubramanian, "The Community Balance and Mobility Scale Alleviates the Ceiling Effects Observed in the Currently Used Gait and Balance Assessments for the Community-Dwelling Older Adults," *Journal of Geriatric Physical Therapy (2001)* 38, no. 2 (June 2015): 78–89, doi:10.1519/JPT.0000000000000024.

⁹³ René Möttus et al., "Towards Understanding the Links between Health Literacy and Physical Health," *Health Psychology: Official Journal of the Division of Health Psychology, American Psychological Association* 33, no. 2 (February 2014): 164–73, doi:10.1037/a0031439; Bas Geboers et al., "The Association of Health Literacy with Physical Activity and Nutritional Behavior in Older Adults, and Its Social Cognitive Mediators," *Journal of Health Communication* 19 Suppl 2 (2014): 61–76, doi:10.1080/10810730.2014.934933.

because these participants were self-selected from persons enrolled in a UNMC fitness program at the Engage Wellness Center. In addition, we didn't quantify additional confounders, including medical comorbidities and pharmacotherapy. However, adjustment of study outcomes for these factors would have had only minimal impact on study outcome. Not surprisingly, we continued to note variable subject adherence to wearing the smartphone on their person throughout the study. While some subjects successfully carried the phone on their person and collected data for the entire 24 hour time frame, other individuals only carried the phone for ten hours or less. However, in practice, even if individuals only collected data for brief, random periods each day, they would still produce a significant and robust dataset suitable for functional inference when evaluated over longer time periods.

Given the increasing presence of smartphone technology worldwide, and decreasing costs associated with smartphone ownership, this study suggests health care programs should consider leveraging smartphones as part of their health care model. The benefits of this technology are manifold, including the ability to collect specific individual functional status data (respecting individual privacy and autonomy), develop patient functional trends, and hone algorithms to not only calculate activity and gait functional measures as above, but also to further characterize acute and preclinical functional changes for a specific individual in a reliable and efficient manner. This approach to individualized health care has only begun to be explored, and promising evidence suggests that this accurate knowledge of individual day-to-day patterns of behavior and functional status can be used to improve diagnoses of acute disease

states.⁹⁴ In addition, smartphones also measure lifespace,⁹⁵ an independent measure strongly associated with clinically important healthcare outcomes, with high accuracy.⁹⁶ Ultimately, assimilating these approaches into a comprehensive patient care platform may lead to significant improvements in patient quality-of-life, decreased health-care spending, and improved outcomes for persons with chronic disease.

⁹⁴ Jeffrey A. Kaye et al., "Intelligent Systems For Assessing Aging Changes: Home-Based, Unobtrusive, and Continuous Assessment of Aging," *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences* 66 Suppl 1 (July 2011): i180–90, doi:10.1093/geronb/gbq095.

⁹⁵ Lisa L. Barnes et al., "Correlates of Life Space in a Volunteer Cohort of Older Adults," *Experimental Aging Research* 33, no. 1 (March 2007): 77–93, doi:10.1080/03610730601006420; Qian-Li Xue et al., "Life-Space Constriction, Development of Frailty, and the Competing Risk of Mortality: The Women's Health And Aging Study I," *American Journal of Epidemiology* 167, no. 2 (January 15, 2008): 240–48, doi:10.1093/aje/kwm270.

⁹⁶ Neng Wan et al., "Assessing Smart Phones for Generating Life-Space Indicators," *Environment and Planning B: Planning and Design* 40, no. 2 (2013): 350–61, doi:10.1068/b38200.

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APPENDIX A: STUDY CONSENT FORM IRB #552-09-FB



COLLEGE OF MEDICINE

Department of Internal Medicine

Adult Subject Consent Form

Title of Research Study:

MOBILE MONITORING OF FUNCTIONAL BEHAVIORS IN AMBULATORY PATIENTS**(PHASE I & II)****Invitation**

You are invited to take part in a research study. The information in this form is to help you decide whether or not to participate. If you have any questions, please ask!

Why are we asking you to be in this research study?

We are asking you to participate in this study because you:

- Are healthy, or in newly stable health,
- Are in one of the target age groups we are studying,
- Might be interested in seeing how you perform functional behaviors, such as being active, eating, drinking, washing, dressing, and socializing, both throughout a complete day and/or over weeks of time.

Why are we conducting this research?

First, we need to develop the tools that collect functional data. Second, we need to develop tools that prepare the collected data for analysis. Third, we need to validate these studies to ensure that our new measurement approaches really work. Finally, we need to develop analysis tools comparing functional data obtained from one group (say, older people three weeks before their elective knee surgery) to data obtained from another group (say, these same people 6 weeks after that surgery).

What will be done during this research study?

A total of 280 subjects will be enrolled in this study. Most of this study is being conducted at two sites, UNMC and the Omaha/Western Iowa VA Medical Center. A separate, one week long validation study of our GPS data collection will be performed at the State Health Department, Lincoln, NE. If you decide to participate in the mobile monitoring phase of this study, you will need to visit the hospital or study doctor's office twice over 14-31 days. Each visit would last about 45 minutes. If you decide to participate in the treadmill validation phase of this study, we may ask you to participate in a single research session where you walk on an exercise treadmill for about one hour. Finally, if you decide to participate in the GPS validation phase of this study, we will visit you at your place of work twice: once at study start, and once at study finish (7 days later).

For all subjects:

During the first study visit, you will meet with an investigator. After a series of questions regarding your medical history and medications, you may undergo a brief evaluation by a geriatrician to assess you for functional impairment. This exam may test your ability to

walk and get up from your chair. Depending on your medical history, we may also ask you questions from simple screening tools that help us to determine your memory and cognitive abilities. The screening tools which may be used include the Mini-Mental Status Exam, the Montreal Cognitive Assessment, the Geriatric Depression Screen, questionnaires about your activities of daily living, and the SF-36 Questionnaire.

For subjects participating in the mobile monitoring phase of the study:

We may ask you to participate in the longer duration, “mobile monitoring” phase of this study. If this is the case, at the first visit, you will be given a cell phone. We will show you how to charge the device, how to ensure it is working, and how to use the voice, data, internet, and text capabilities of the phone. We will show you how to respond to 20-40 random voice or text messages per week which ask you where you are and what you are doing at that time in order to validate the data the phone is collecting.

We may also give you an activity watch. If so, we will have programmed the watch before giving it to you, so all you have to do is wear it just like a wristwatch. Unlike the cell phone, this watch can be exposed to water when you shower, bathe, or swim. Please don't take the watch to a water depth greater than 12 feet. We ask that you wear the watch nonstop while participating in this study.

If you are participating in the mobile monitoring phase of this study, we will also ask to briefly visit you at home. We will place two types of small devices that detect your motions (called Bluetooth emitters and wifi-based sensors) in many, if not all the rooms of your home. Some – particularly larger rooms – may have more than one emitter placed. These emitters are very small (the length and width of a business card, about an inch deep), and

plug into wall electrical outlets. They use a tiny amount of power to continuously transmit a single digital identification number. They do not take pictures or transmit video data. They do not record voice.

In order to evaluate the size of the space you move around in, or your social network, the cell phone will collect data when it comes in communication with non-beacon Bluetooth devices, such as personal computers and other wireless devices. This information will be downloaded to the researchers' computer daily and be deleted from your phone.

We may also place sensors on specific places such as the refrigerator or plumbing drains. These sensors only transmit information if the surrounding environment is light, or wet, or some other defined condition.

Other than when the phone is charging or when you are bathing, we ask that you keep the phone with you as much as possible, no matter where you are going and what you are doing. The phone will detect your body movements using the built-in 3-dimensional accelerometer (just like the activity watch we may ask you to wear). As you move from room to room in your house, the bluetooth emitters transmit their different ID numbers to the phone. As you do different tasks in your home, the sensors will report specific events. As you move outside the home your phone's global positioning system (GPS) will record your location and the time. All this data is stored in a coded form in the phone's memory, and transmitted to our study computers between 3:00 and 6:00 in the morning.

At the end of the study, we will ask that you return your cell phones and all data collecting hardware. This can be done at the final visit or you can mail them to us in a FedEx envelope. We would provide the envelope and cover the cost of shipping.

For subjects participating in the treadmill locomotion validation phase of the study:

If we ask you to walk on the treadmill, then we will bring you to the UNMC cardiac rehabilitation suite after their business hours are complete (after 4:00 PM weekdays). Here, we will attach a cell phone to your right ankle and left ankle, place a cell phone in your right pocket and left pocket, and attach a cell phone to your right wrist and left wrist using an elastic sweatband. We will also give you a light pendant carrying a cell phone to wear very loosely around your neck. You will thus be able to walk “hands free.” We will set up a video camera to tape your footfalls on the treadmill. Then, we will ask you to perform 5 minute bouts of walking on the treadmill at different speeds, interspersed with 1 minute rest intervals. We are most interested in determining the performance of the cell phone motion sensors at low speeds, so we will not be asking you to walk any faster than a steady pace. If you enjoy running or jogging as an exercise, we may ask you to also jog at a comfortable pace for you. If you don’t run or jog, we will only ask you to walk. After we are finished testing your walking over different treadmill speeds, your involvement in the study is finished. We won’t ask you to carry the phone for a month. Finally, you will be welcome to use the shower and locker room in the rehab facility if you desire.

For all subjects participating in the GPS validation phase of this study:

If we ask you to participate in the GPS validation phase of this study, you will be given one cell phone. We will show you how to charge the device, how to ensure it is working, and how to use the voice, data, internet, and text capabilities of the phone. We will show

you how to respond to 20-40 random voice or text messages per week which ask you where you are and what you are doing at that time in order to validate the data the phone is collecting. You may also be asked to write down information of selected activities in a journal provided by us. Other than when the phone is charging or when you are bathing, we ask that you keep the phone with you as much as possible, no matter where you are going and what you are doing. As you move outside the home your phone's global positioning system (GPS) will record your location and the time. All this data is stored in a coded form in the phone's memory, and transmitted to our study computers between 3:00 and 6:00 in the morning. At the end of the study, we will ask that you return your cell phones and all data collecting hardware. This can be done at the final visit or you can mail them to us in a FedEx envelope. We would provide the envelope and cover the cost of shipping. Finally, we will ask you to participate in a brief internet-based survey ("SurveyMonkey") that will ask you a series of questions about your movements throughout the community while you were carrying the watch. We may contact you by telephone to complete this survey if you are unable or do not want to navigate the internet based survey.

What are the possible risks of being in this research study?

If you participate in the mobile monitoring phase of the study, the most significant risk involves potential loss of some features of personal privacy. One of our desired goals is to collect data telling us at any time whether you are resting or active, eating, drinking, dressing, washing, or performing other important behaviors that are required to remain independent. This represents a clear loss of some aspects of your privacy, aspects we

hope you are temporarily willing to give up in order to help us with this important research. We also have tried to perform this research with the maximum of privacy safeguards:

We never take any photographic or video data.

- a. We encrypt the data prior to its transmission, and use a secure internet channel to transmit the data.
- b. Any data temporarily stored on the phone will be secured in a manner to prevent unauthorized viewing of the data files.
- c. We allow you to press a button on the phone that immediately disables data logging,
- d. We allow you to contact the data team to erase any collected data between two time points, no questions asked,
- e. We do not monitor phone voice, text, or internet activity.

We also ask that you use good sense while you have your phone. Don't talk or text and drive at the same time – many studies have shown that using a cell phone (even with a wireless handset) while driving can impair your concentration and divert your attention away from the road. We also recommend not texting and walking at the same time.

If we ask you to perform the treadmill walking part of this study, then the above risks don't apply to you. The most significant risk is that you might lose your balance when you try to step onto the moving treadmill at higher speeds (greater than 3.5 mi/hr). To minimize this possibility, we begin trials of these higher speeds with the treadmill moving more slowly, and once you feel comfortable walking, we then manually increase the treadmill speed.

There are additional, very low probability risks of participating in the treadmill walking part of this study. These risks are no greater than the risks you take when you enjoy a brisk walk. We asked you to fill out a questionnaire, and then reviewed your answers to determine if you had any significant heart, lung, joint, or neurological problems – people with uncontrolled problems in any of these systems were thanked but not asked to participate. It is possible that you may have an asymptomatic, undiagnosed problem with your heart or lungs that no one, even your doctor, is currently aware of. If you should start to have symptoms like chest pain, significant shortness of breath, dizziness, light-headedness, palpitations

(skipped heart beats), nausea, or tingling in your arms and hands, we will immediately stop your exercise session and obtain medical care for you at UNMC.

Again, we do not want you strenuously exercising on the treadmill. You have full control about how fast you want to walk, and if you begin to feel winded or tired, you can quit at any time. In this way, the risk of more serious health problems or injuries is no greater than what you would experience walking in a shopping mall or supermarket.

If you participate in the GPS validation phase of the study, your risks are very similar to those of individuals participating in the mobile monitoring phase. Since this phase does not include any at-home monitoring, there would be no loss of privacy for this kind of information. However, since this phase does include an internet or telephone based survey, there is a small risk of additional loss of private information from these sources. Since we use an internet-based survey tool that sends data in an encrypted form (and alternatively, if we call we will do so from a private room, and ensure you are in a private room to answer questions), we anticipate that this risk will be small.

What are the possible benefits to you?

If you have curiosity about how much time you spend doing important functional behaviors, this is a way to find out. You can work closely with a group of scientists and engineers to help us build this technology. If you participate in the mobile monitoring phase of this study, you will have unlimited use of a cell phone for the duration of the study. The cell phone must be returned to the researchers at the end of the study.

If we ask you to perform the treadmill walking part of the study, the benefit to you is that you will have a chance to exercise in a controlled setting with a physician or nurse present who can give you tips or pointers (if you want) regarding your exercise capacity.

What are the possible benefits to other people?

We think that obtaining continuous, high quality, high resolution, data streams showing the patterns of how people perform important functional behaviors may change how we take care of older people. We think that this technology may be useful to older people who have early and subtle problems with their ability to move, eat, drink, dress, and perform other important day-to-day behaviors. Currently, we can't get this kind of data anywhere.

What are the alternatives to being in this research study?

You may choose not to participate.

What if you lose the phone during the study?

If the battery has not run out, we will first try to contact the phone using our technology to see where it is located. If we cannot find it, do not worry. We will not bill you for the lost phone.

If we ask you to perform the treadmill walking part of the study, losing a phone will not be a problem.

What if you lose a sensory type device (bluetooth or wifi emitter)?

Do not worry. Even though these sensors are small, it is really hard to lose an emitter that remains plugged in or connected to its battery. We have the technology to find it.

If we ask you to perform the treadmill walking part of the study, losing a phone will not be a problem.

What will participating in this research study cost you?

There is no cost to you.

Will you be paid for being in this research study?

For persons participating in the mobile monitoring phase of this study, you will be paid \$20 per completed visit to partially cover your transportation, parking, meals, or other expenses related to participation in this study. There will be no compensation for participation in the treadmill validation or GPS validation phases of this study.

Who is paying for this research?

This research is being paid for by grant funds pending from The Alzheimer's Association, startup funds received by Dr. Bonasera through The University of Nebraska Medical Center, a funded NIH R03 grant, and future grant applications currently being written in the Bonasera lab.

What if you get injured or have a medical problem during this research study?

If you are injured or have a problem as a result of being in this research study, you should immediately contact one of the people listed at the end of this consent form.

How will your information be protected?

You have rights regarding the privacy of information collected before and during this research. This information, called "protected health information" (PHI) will include different kinds of data that are personal to you. For example, we will collect simple demographic measures like your home address, layout of rooms and halls within your home, and your birth date. As previously discussed, the majority of our research efforts focus on obtaining reliable patterns of your functional behaviors: our estimates of when you started and stopped doing things like eating, drinking, dressing, washing, *etc.*, as well as where you

were when you performed these behaviors (living room, kitchen, master bath, *etc.*). We will also examine how you traveled through your home and community throughout each day. Finally, we will collect routine aspects of your medical history, including your current medical problems and your current medications.

By signing this consent form, you are allowing the research team to have access to this PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC, the Nebraska Medical Center, Northwestern University (Chicago, IL), and Randolph College (Lynchburg, VA).

Your PHI will be used only for the purpose(s) described in the section **"Why are we conducting this research?"**

Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. Your consent also allows the research team to share your PHI with other people or groups listed below. All of these persons or groups listed below are obligated to protect your PHI.

-
- Researchers at the University of Nebraska Medical Center who are involved in this study,
- Researchers at the Veterans Affairs Medical Center, Omaha, NE who are involved in this study,
- Researchers at the Northwestern University and Randolph College, who are involved in this study,
- The Alzheimer's Association, which sponsors this research and provides funds to UNMC/THE NEBRASKA MEDICAL CENTER to conduct this research; and
- A Data and Safety Monitoring Committee (DSMC).

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

By signing this authorization, you are temporarily giving up your right to see this research related information while the research is ongoing. You will be able to see this information if you wish after the research is completed.

You may cancel authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, we will ask you to withdraw from this research.

The results of tests and therapy performed as part of this research may be included in your medical record. Information from this study will be published in scientific journals or presented at scientific meetings. Your identity will be kept strictly and absolutely confidential.

What are your rights as a research subject?

You have rights as a research subject. These rights are explained in this consent form and in the Rights of Research Subjects handout that you have received. If you have any questions concerning your rights, or if you have complaints about this research, talk to the investigator or contact the *Institutional Review Board* (IRB) by:

- Telephone: (402) 559-6463
 - Email: IRBORA@unmc.edu
 - Mail: UNMC Institutional Review Board

987830 Nebraska Medical Center

Omaha, NE 68198-7830

What will happen if you decide not to participate in this research study?

You can decide not to participate in this research study. This decision will not change your medical care or relationships with the investigator, the University of Nebraska Medical Center or The Nebraska Medical Center. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating in this research study?

You can stop being in this research study (“withdraw”) at any time before, during, or after the testing begins. Deciding to withdraw will otherwise not affect your care or relationship with the investigator, the University of Nebraska Medical Center, or The Nebraska Medical Center. You will not lose any benefits to which you are entitled.

You may be taken off the study if you are unable to follow instructions of the investigator or the research team.

Documentation of informed consent

You are freely making a decision whether to participate in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to enroll in the research study.

If you have any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Subject

Date

Time

Printed Name of Subject

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent Date

AUTHORIZED STUDY PERSONNEL

PRINCIPAL INVESTIGATOR

Stephen J. Bonasera, M.D., Ph.D. (402) 559-8409.

SECONDARY INVESTIGATORS/PARTICIPATING PERSONNEL

Brenda Keller, M.D. (402) 559-9600

Jane F. Potter, M.D. (402) 559-9600

Edward Vandenberg, M.D. (402) 559-9600

Jackie Whittington (402) 559-9600

William L. Lyons, M.D. (402) 559-9600

Debra E. Mostek, M.D. (402) 559-9600

Elizabeth Harlow, M.D.	(402) 559-9600
Daniel Murman, M.D.	(402)-559-4496
Barbara Bayer, A.P.R.N.	(402)-552-6007
Diane Bessette, P.A.	(402)-552-6007
Ge Lin, Ph.D.	(402) 559-5260
Neng Wan, Ph.D.	(402) 552-7252
Kelly Shaw-Sutherland, MPA	(402) 559-9412
Cassie Rye Hanton	(402) 559-9600
Yong Jun Kwon	(402) 559-9600
Anthony Oberle	(402) 559-9600
Sarah Synovec	(402) 559-9600
Courtney Schroeder	(402) 559-9600

Any of the above investigators can be reached during business hours by calling the numbers listed by their name. At other times, please call **(402) 559-9600** and ask that the mobile monitoring team be contacted or paged at **402-888-0856**. The person on call will be immediately contacted to answer your questions. If you wish to speak to a specific investigator, the person on call will help you get in touch with that individual.

APPENDIX B: LATE-LIFE FUNCTION AND DISABILITY INSTRUMENT⁹⁷ (LLFDI)

Disability Questions

For each Question below please indicate:

How often do you? . . .(very often, often, once in a while, almost never, never)

To what extent do you feel limited in? . . .(not at all, a little, somewhat, a lot, completely)

D1. keep (keeping) in touch with others through letters, telephone, or e-mail

D2. visit (visiting) friends and family in their homes

D3. provide (providing) care or assistance to others

D4. take (taking) care of the inside of your home

D5. work (working) at a volunteer job outside your home

D6. take (taking) part in active recreation

D7. take (taking) care of household business, finances

D8. take (taking) care of your own health

D9. travel (traveling) out of town for at least an overnight stay

D10. take (taking) part in a regular fitness program

D11. invite (inviting) people into your home for a meal or entertainment

D12. go (going) out with others to public places such as restaurants or movies

D13. take (taking) care of your own personal care needs

D14. take (taking) part in organized social activities

D15. take (taking) care of local errands

D16. prepare (preparing) meals for yourself

Function Questions

For each Question below please indicate:

How much difficulty do you have? . . .(none, a little, some, quite a lot, cannot do)

F1. unscrewing the lid off a previously unopened jar without using any devices

F2. going up and down a flight of stairs inside, using a handrail

F3. putting on and taking off long pants (including managing fasteners)

F4. running half a mile or more

F5. using common utensils for preparing meals (e.g., can opener, potato peeler, or sharp knife)

⁹⁷ Sayers et al., "Validation of the Late-Life Function and Disability Instrument."

- F6. holding a full glass of water in one hand
 - F7. walking a mile, taking rests as necessary
 - F8. going up and down a flight of stairs outside, without using a handrail
 - F9. running a short distance, such as to catch a bus
 - F10. reaching overhead while standing, as if to pull a light cord
 - F11. sitting down in and standing up from a low, soft couch
 - F12. putting on and taking off a coat or jacket
 - F13. reaching behind your back as if to put a belt through a belt loop
 - F14. stepping up and down from a curb
 - F15. opening a heavy, outside door
 - F16. ripping open a package of snack food (e.g., cellophane wrapping on crackers) using your hands
 - F17. pouring from a large pitcher
 - F18. getting into and out of a car/taxi (sedan)
 - F19. hiking a couple of miles on uneven surfaces, including hills
 - F20. going up and down three flights of stairs inside, using a handrail
 - F21. picking up a kitchen chair and moving it, to clean
 - F22. using a step stool to reach into a high cabinet
 - F23. making a bed, including spreading and tucking in bed sheets
 - F24. carrying something in both arms while climbing a flight of stairs (e.g., laundry basket)
 - F25. bending over from a standing position to pick up a piece of clothing from the floor
 - F26. walking around one floor of your home, taking into consideration thresholds, doors, furniture, and variety of floor coverings
 - F27. getting up from the floor (as if you were lying on the ground)
 - F28. washing dishes, pots, and utensils by hand while standing at the sink
 - F29. walking several blocks
 - F30. taking a 1-mile, brisk walk without stopping to rest
 - F31. stepping on and off a bus
 - F32. walking on a slippery surface outdoors
- Please visit the following Website (www.bu.edu/roybal) for information on the LLFDI instrument, users' manual, and scoring software.

Source: SAYERS ET AL.

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APPENDIX C: PROMIS V.1.0 – PHYSICAL FUNCTION ⁹⁸ QUESTIONNAIRE

PROMIS Item Bank v1.0 –Physical Function - Short Form 10a

Physical Function – Short Form 10a

Please respond to each item by marking one box per row.

		Not at all	Very little	Somewhat	Quite a lot	Cannot do
PFA01	Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFC36	Does your health now limit you in walking more than a mile?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFC37	Does your health now limit you in climbing one flight of stairs?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA05	Does your health now limit you in lifting or carrying groceries?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA03	Does your health now limit you in bending, kneeling, or stooping?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA11	Are you able to do chores such as vacuuming or yard work?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA16	Are you able to dress yourself, including tying shoelaces and doing buttons?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFB26	Are you able to shampoo your hair?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA55	Are you able to wash and dry your body?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFC45	Are you able to get on and off the toilet?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

⁹⁸ “Patient Reported Outcomes Measurement Information System PROMIS Instruments Available for Use in Assessment Center” (National Institutes of Health NIH, March 24, 2015), PMID: 15341561.

APPENDIX D: PROMIS V.1.1 – GLOBAL HEALTH 99QUESTIONNAIRE

PROMIS v.1.1 - Global

Global Health

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global02	In general, would you say your quality of life is:	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global03	In general, how would you rate your physical health?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
		Completely	Mostly	Moderately	A little	Not at all
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

⁹⁹ “Patient Reported Outcomes Measurement Information System PROMIS Instruments Available for Use in Assessment Center.”

PROMIS v.1.1 - Global

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always						
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5						
		<hr/> None Mild Moderate Severe Very severe										
Global08	How would you rate your fatigue on average?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5						
Global07	How would you rate your pain on average?.....	<input type="checkbox"/> 0 No pain	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10 Worst imaginable pain

APPENDIX E: SURVEY OF ACTIVITIES AND FEAR OF FALLING IN THE ELDERLY ¹⁰⁰(SAFFE)

Appendix.

Fear of Falling Avoidance-Behavior Questionnaire^a

Name: _____

Date: _____

Please answer the following questions that are related to your balance. For each statement, please check one box to say how the fear of falling has or has not affected you. If you do not currently do the activities in question, try and imagine how your fear of falling would affect your participation in these activities. If you normally use a walking aid to do these activities or hold on to someone, rate how your fear of falling would affect you as if you were not using these supports. If you have questions about answering any of these statements, please ask the questionnaire administrator.

	Please check <u>one box</u> for each question				
Due to my fear of falling, I avoid . . .	Completely disagree (0)	Disagree (1)	Unsure (2)	Agree (3)	Completely agree (4)
1. Walking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Lifting and carrying objects (eg, cup, child)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Going up and downstairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Walking on different surfaces (eg, grass, uneven ground)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Walking in crowded places	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Walking in dimly lit, unfamiliar places	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Leaving home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Getting in and out of a chair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Showering or bathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Preparing meals (eg, planning, cooking, serving)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Doing housework (eg, cleaning, washing clothes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Work or volunteer work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Recreational and leisure activities (eg, play, sports, arts and culture, crafts, hobbies, socializing, traveling)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please make sure you have checked one box for each question. Thank you!

Total: /56

¹⁰⁰ M. R. Landers et al., "Development of a Scale to Assess Avoidance Behavior Due to a Fear of Falling: The Fear of Falling Avoidance Behavior Questionnaire," *Physical Therapy* 91, no. 8 (August 1, 2011): 1253–65, doi:10.2522/ptj.20100304.

APPENDIX F: 4-METER WALK TEST¹⁰¹

Administration Instructions

Practice Trial:

Show the walking course; say: This activity involves walking from one place to another. This is our walking course (point to the course). I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.

The examiner explains the walk: Let me show you what I want you to do. Put both your feet together behind this line. Walk all the way past the cone on the other end before you stop. Before demonstration, say: 3, 2, 1, Go! After examiner returns, have participant stand with both feet touching the start line and say:

When I want you to start, I will say: 3, 2, 1, go. Do you have any questions?

Say: Now you try. Remember to walk at your usual speed and keep walking until you pass the cone. Ready? 3, 2, 1, Go!

When participant passes the cone, say: That's good. Do you have any questions? (Answer any questions.)

Trial 1: Say: This time, I am going to time you as you walk at your usual speed. Are you ready? 3, 2, 1, Go!

Begin timing (press start/stop button) when the participant steps over (first footfall) the starting line. Walk behind and to the side of the participant as he/she walks. Stop timing when one of the participant's feet is completely across the end/finish line (the line at 4.0 meters –not the line at 5.0 meters). If the participant stumbles or tries to run, void that trial and ask the participant to do another trial.

Record the data on the record form and later transfer to the computer data entry forms.

Trial 2: Say: Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course. I am going to time you as you walk at your usual speed. Are you ready? 3, 2, 1, Go! Begin timing (press start/stop button) when the participant steps over (first footfall) the starting line. Walk behind and to the side of the participant as he/she walks. Stop timing when one of the participant's feet is completely across the end/finish line (the line at 4.0 meters –not the line at

5.0 meters). If the participant stumbles or tries to run, void that trial and ask the participant to do another trial.

Record the data on the record form and later transfer to the computer data entry forms.

If needed, have the participant rest on a chair for at least one minute before the next task

¹⁰¹ "NIH Toolbox 4-Meter Walk Gait Speed Test" (National Institutes of Health NIH, 2012), <http://www.nihtoolbox.org/WhatAndWhy/Motor/Locomotion/Pages/NIH-Toolbox-4--Meter-Walk-Gait-Speed-Test.aspx>.

APPENDIX G: FRAILTY SCREENING TOOL

Subject ID: _____ Date: _____

1. Assess Weight

Weight at age 60: _____ (subject report)

Weight 1 year ago: _____

Current Wt: _____ (measured)

Current height: _____ (measured)

Current calculated BMI: _____ (wt in Kg/ht in meters²)

Per cent wt loss since age 60 = _____

(Calculate Wt at 60-current weight/ weight at 60=% loss)

>10% loss since 60 or < 10 lbs in last year or BMI <18.5 Kg/m ²	YES	NO
--	-----	----

2. Measure Walking Speed

Instruction: "Walk at your usual pace/speed"

Time: _____ sec: _____

Slow if : > 7 secs if height ≤ 63.6 in.

> 6 secs if height > 63.6 in.

Slow walking speed? YES NO

3. Grip Strength: _____

Weakness

Are you left or right handed?

Grip strength of dominant hand

L / R

≤ 17 kg for BMI ≤ 23

1. _____ / _____

≤ 17.3 kg for 23 < BMI ≤ 26

2. _____ / _____

≤ 18 kg for 26 < BMI ≤ 29

3. _____ / _____

≤ 21 kg for BMI > 29

highest measure

Weak grip? YES NO

GO TO NEXT PAGE

Subject ID: _____ Date: _____

4. Exhaustion

a. In the previous month rate your usual energy level compared to the most energy you have ever had _____ (10 point Likert scale 0-10, with 0 being no energy and 10 the most

energy that you have ever had)

b. Have you felt unusually tired in the last week? Yes No

IF Yes: How much of the time?

0. Rarely or none of the time (< 1 day) ____
1. Some or a little of the time (1-2 days) _____
2. A moderate amount of the time (3-4 days) _____
3. All or most of the time_____

Felt unusually weak in the last month ? Yes No

IF Yes: How much of the time?

0. Rarely or none of the time (< 1 day) ____
1. Some or a little of the time (1-2 days) _____
2. A moderate amount of the time (3-4 days) _____
3. All or most of the time_____

Exhaustion is present if any of the above are met:

a. ≤ 3

b. YES and How Much? either 2 or 3

Now Complete the Activity Questionnaire.