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**ORIGINAL ARTICLE**

## **The Boston Rehabilitative Impairment Study of the Elderly: A Description of Methods**

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**Abstract**

**Objectives:** To describe the methods of a longitudinal cohort study among older adults with preclinical disability. The study aims to address the lack of evidence guiding mobility rehabilitation for older adults by identifying those impairments and impairment combinations that are most responsible for mobility decline and disability progression over 2 years of follow-up.

**Design:** Longitudinal cohort study.

**Setting:** Metropolitan-based health care system.

**Participants:** Community-dwelling primary care patients aged  $\geq 65$  years ( $N=430$ ), with self-reported modification of mobility tasks because of underlying health conditions.

**Interventions:** Not applicable.

**Main Outcome Measures:** Late Life Function and Disability Instrument (LLFDI) (primary outcome); Short Physical Performance Battery and 400-m walk test (secondary outcomes).

**Results:** Among 7403 primary care patients identified as being potentially eligible for participation, 430 were enrolled. Participants have a mean age of 76.5 years, are 68% women, and have on average 4.2 chronic conditions. Mean LLFDI scores are 55.5 for Function and 68.9 and 52.3 for the Disability Limitation and Frequency domains, respectively.

**Conclusions:** Completion of our study aims will inform development of primary care-based rehabilitative strategies to prevent disability. Additionally, data generated in this investigation can also serve as a vital resource for ancillary studies addressing important questions in rehabilitative science relevant to geriatric care.

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Adults aged  $\geq 65$  years are the fastest growing segment of the population in the United States and incur a disproportionately high percentage of health care costs. Problems with mobility tasks, such as rising from a chair, walking, and climbing stairs, affect as many as 25% of those 70 years and older and 50% of those older

than 80 years.<sup>1</sup> Mobility performance is recognized as a predictor of disability and institutionalization.<sup>2,3</sup> As a result, mobility performance tests have been advocated for use as screening tools to identify those at risk for disability.<sup>4</sup> Early detection of functional decline creates opportunities to prevent the onset of disability through intervention.

Mobility problems are most commonly treated in the context of rehabilitative care. Ostensibly, any intervention to prevent the onset of disability would include rehabilitative services. Interventions should be directed toward those physical attributes that are (1) most responsible for decline and disability and (2) amenable to rehabilitative care. However, there is limited evidence guiding the

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selection of relevant attributes to target in the treatment of mobility problems.<sup>5-12</sup> To evaluate the effectiveness of different modes of rehabilitative care, it is first critical to provide a clearer evidence base around which interventions can be designed.<sup>11-13</sup>

The purpose of this report is to (1) describe the methods of the Boston Rehabilitative Impairment Study of the Elderly (Boston RISE) and (2) demonstrate the feasibility of developing a cohort study addressing important questions in rehabilitation science. The purpose of this study is to fill the knowledge gap regarding predictors for mobility decline. Certain attributes such as balance, strength, and range of motion are recognized as being linked to mobility.<sup>14,15</sup> Other attributes, such as limb speed, kyphosis, and trunk endurance, have more recently been linked to functional limitation and disability.<sup>14,16-18</sup> Recognizing that older adults commonly manifest multiple chronic medical conditions, care should be parsimonious and target only those treatable attributes most responsible for functional decline and disability.

Conceptually, when a physical attribute is insufficient it is called an impairment. We define the impairments that are targeted in rehabilitative care as *rehabilitative impairments*.<sup>14</sup> Thus, the aim of our study is to determine what combinations of rehabilitative impairments are most responsible for mobility decline and the onset of disability in older adults.

Our study was conceptualized in accordance with the disablement model developed by Nagi (fig 1) and the *International Classification of Functioning, Disability and Health* (ICF) model.<sup>19-21</sup> In both paradigms, impairments are defined as deficits within the performance of an organ or body system. For example, weakness is defined as an impairment of the musculoskeletal system. Functional limitation, which corresponds to activity limitation in the ICF model, refers to deficient performance of basic functional tasks, such as slowed walking speed. Disability, which corresponds to participation restriction in the ICF model, refers to the inability to fulfill a role within the home or community environment (eg, shopping, housework, self-care activities).<sup>21</sup>

Optimally, mobility-related problems would be treated within a continuum of care that includes both primary and rehabilitative care. Relevant impairments would be managed through either rehabilitative or medical interventions. We refer to impairments commonly targeted in the context of medical care as *medical impairments*. Our study is designed to clarify which rehabilitative impairments are most associated with activity limitation and participation restriction as measured by the Late Life Function and Disability Instrument (LLFDI).<sup>22,23</sup> We will also examine how medical impairments modify the relationship between rehabilitative impairments and the outcomes of activity limitation and participation restriction.

#### List of abbreviations:

<b>Boston RISE</b>	<b>Boston Rehabilitative Impairment Study of the Elderly</b>
<b>BWH</b>	<b>Brigham and Women's Hospital</b>
<b>CMS</b>	<b>Center for Medicare and Medicaid Services</b>
<b>ED</b>	<b>emergency department</b>
<b>ICF</b>	<b><i>International Classification of Functioning, Disability and Health</i></b>
<b>LLFDI</b>	<b>Late Life Function and Disability Instrument</b>
<b>MGH</b>	<b>Massachusetts General Hospital</b>
<b>RPDR</b>	<b>Research Patient Data Registry</b>
<b>SPPB</b>	<b>Short Physical Performance Battery</b>
<b>SRH</b>	<b>Spaulding Rehabilitation Hospital</b>

## Methods

### Study design

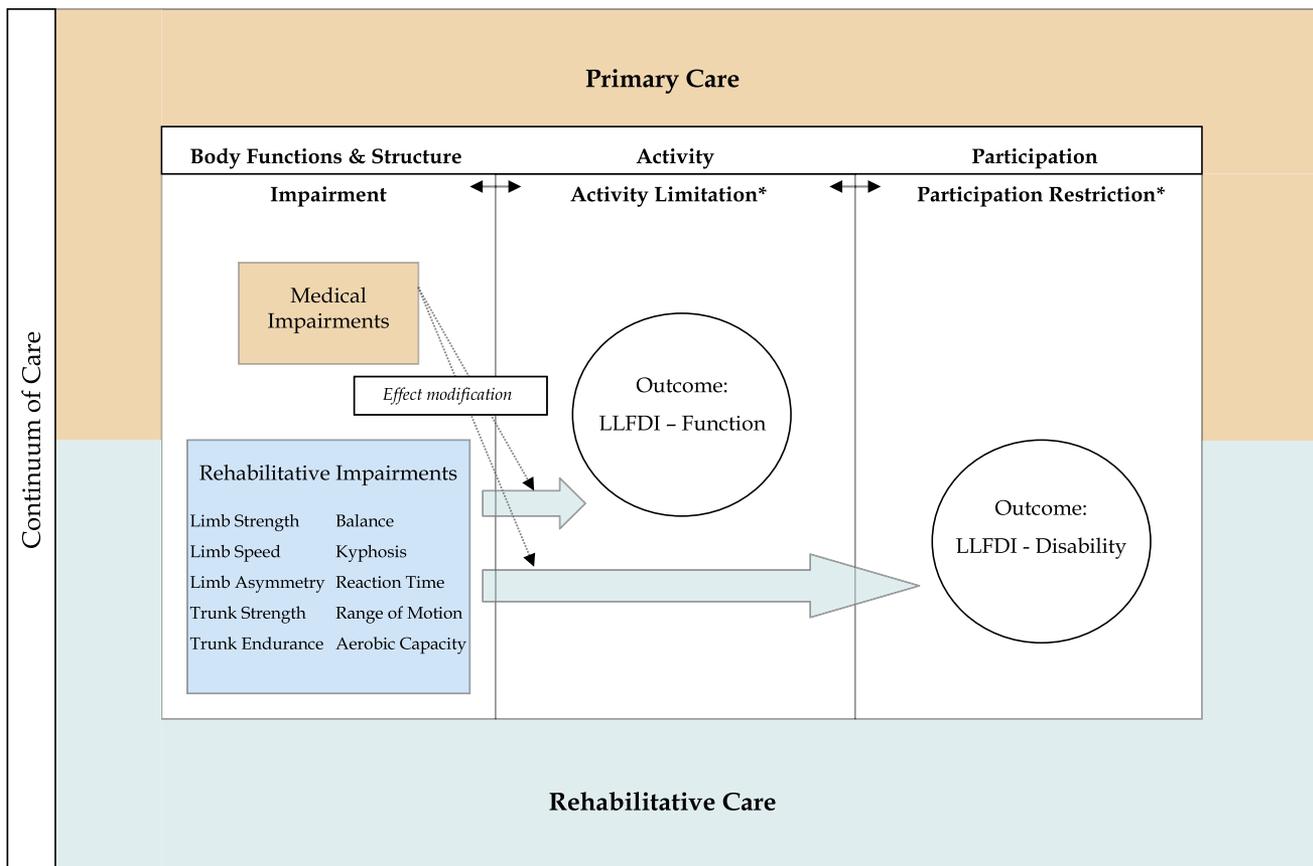
Boston RISE is a prospective cohort study based at Spaulding Rehabilitation Hospital (SRH) in Boston, Massachusetts. SRH is part of Partners HealthCare, a not-for-profit system of affiliated hospitals throughout eastern Massachusetts. The Boston RISE cohort includes 430 primary care patients 65 years and older. Recruitment was initiated in December 2009 and was completed in January 2012. Study operations are centralized at the SRH Cambridge site. All study procedures were approved by the institutional review board at SRH.

### Setting

Older adults were recruited through primary care practices based at Massachusetts General Hospital (MGH) and Brigham and Women's Hospital (BWH), which are Partners HealthCare medical centers located in Boston. Nine primary care practices located across the greater Boston area participated. These practices were approached because of their geographic location, diverse population, and large percentage of eligible patients. Eligibility was determined by a 2-stage screening process, which involved use of a Partners HealthCare patient database and telephone screening interviews. Study staff scheduled baseline assessment visits with individuals who met eligibility criteria. The first baseline visit took place at the MGH Clinical Research Center, where participants went through the final eligibility screening after giving informed consent. Eligible participants completed a second visit at SRH Cambridge within 2 weeks of the first visit (fig 2). Follow-up assessments are conducted at 12 and 24 months at SRH Cambridge and use the same 2-visit structure. Between each set of visits, study staff contact participants by phone every 3 months for a brief interview tracking falls, hospitalizations, emergency department (ED) visits, and rehabilitative care. Recruitment was initiated in December 2009 and was completed in January 2012. Follow-up assessments are ongoing and are projected to be completed in January 2014.

### Participants

Study recruitment targeted adults aged  $\geq 65$  years living within a 10-mile radius who were currently receiving primary care at MGH or BWH. Study staff used the Research Patient Data Registry (RPDR) to generate primary care provider-specific lists of patients meeting the preliminary eligibility criteria.<sup>24</sup> The RPDR is a centralized clinical data registry housing clinical information from Partners HealthCare facilities. Patients meeting the preliminary inclusion criteria within a provider's panel were randomly selected for inclusion on the recruitment master list. The master list was divided into subgroups based on sex, age, and race, and sorted into a random order to ensure random selection from each subgroup. Screening samples of 50 to 100 patients were created and sent to each provider for review. Oversampling did occur within the sample lists with regard to race, age, and sex to ensure recruitment of a cohort representative of the older adult population living within our recruitment catchment area. The providers received the screening sample by e-mail and were asked to respond within 1 week to corroborate eligibility. Study staff sent a reminder e-mail to nonresponding providers after 1 week.



**Fig 1** Boston RISE conceptual paradigm. \*Activity limitation and participation restriction correspond to functional limitation and disability, respectively, from Nagi's disablement model.<sup>20,21</sup>

Participating practices were given posters and brochures to display in waiting areas so interested patients could contact study staff directly.

Potential participants approved for contact were sent either a single letter signed by the provider and the principal investigator (for MGH patients) or 2 letters signed separately by the provider and the principal investigator (for BWH patients). The letters described the study and included a postage-paid postcard to return to decline participation. The letters stated that study staff would try to contact patients by phone if there was no response within 2 weeks. Study staff made up to 7 attempts to reach potential participants by phone.

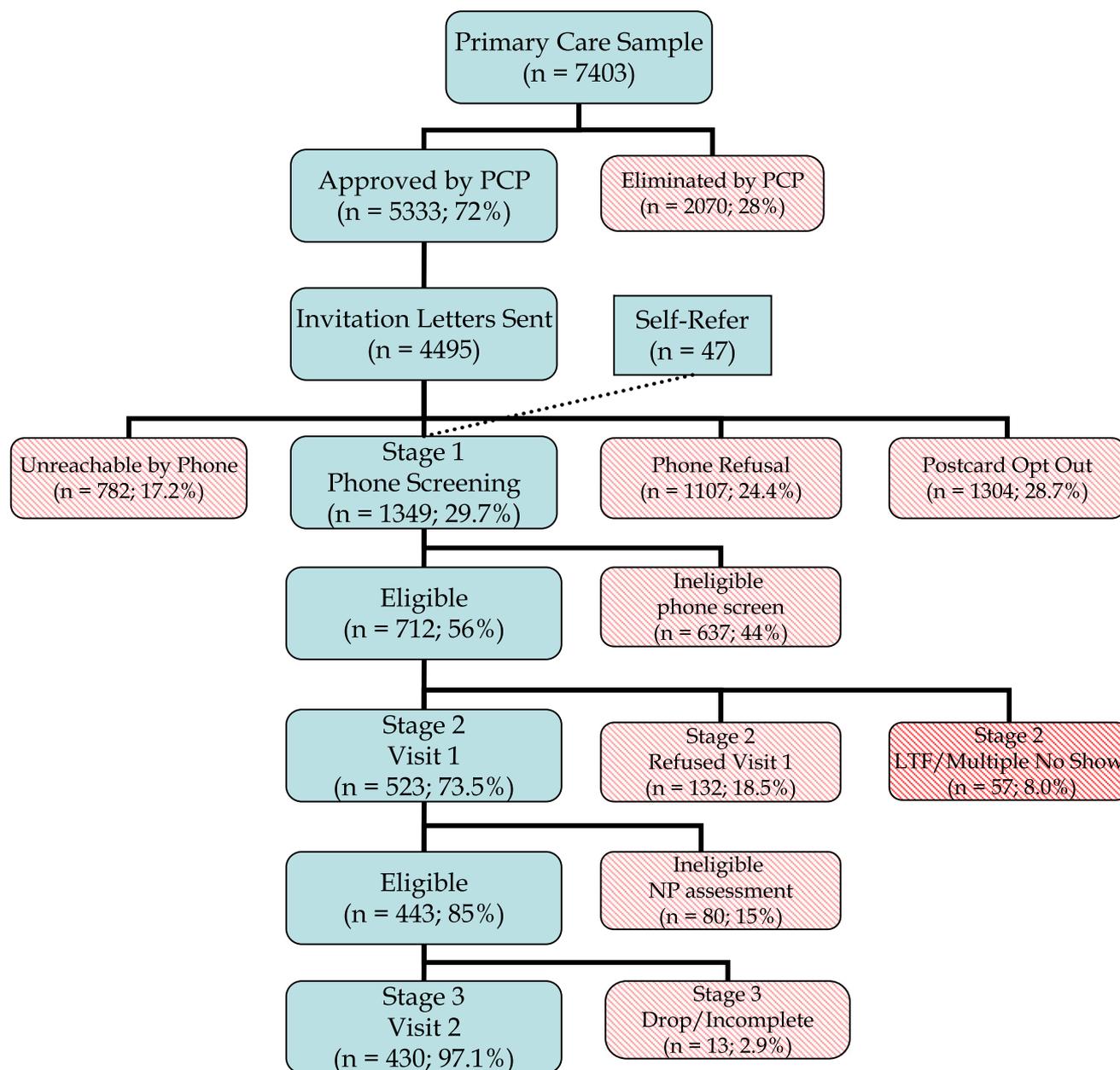
During the initial phone contact, study staff performed an eligibility screening. Eligibility criteria are listed in figure 3. Study staff also asked questions to determine the presence of major medical problems that would interfere with safe completion of the study protocol: significant visual impairment, uncontrolled hypertension, lower extremity amputation, supplemental oxygen use, and myocardial infarction or major surgery in the previous 6 months. Study participation was limited to English speakers because it was not feasible to translate the study instruments and conduct the interviews in the many other languages spoken in the Boston area.

Individuals who expressed interest in participating and met eligibility criteria were scheduled for the 2 baseline visits. Final eligibility was determined at the first visit. We excluded persons with a Mini-Mental State Exam score of less than 18, which indicates moderate or severe cognitive impairment.<sup>25</sup> We also

excluded persons scoring less than 4 on the Short Physical Performance Battery (SPPB), which indicates existing disability.<sup>2</sup> To ensure a broad distribution of baseline physical functioning, we used the SPPB score to group prospective enrollees based on mobility performance. We excluded individuals scoring 11 or 12 (maximum score) on the SPPB once we reached the preselected threshold: 12% and 10% of the total target number enrolled, respectively. We sought to recruit 430 older adults based on power calculations (power  $\geq 0.8$  at medium effect size) predicting changes in function and disability over 2 years of follow-up while accounting for a 7.5% per year attrition rate because of death or lost to follow-up. As of January 2012, Boston RISE recruitment was concluded.

### Data collection

The study visits were designed to collect extensive information on medical and rehabilitative impairments according to the aims of the study. An effort was made to evaluate all relevant attributes while also keeping subject burden manageable. During the first baseline visit, a nurse practitioner and a research assistant obtained informed consent and conducted the final eligibility screening. If the participant screened into the study, the nurse practitioner conducted the baseline visit, which generally required 2.5 hours including informed consent. This assessment included a physical examination, medical history, medication inventory, demographics, neuropsychological testing, and questionnaires on pain. The second baseline visit, which was conducted by



**Fig 2** Boston RISE recruitment flow diagram. Abbreviations: LTF, lost to follow-up; NP, nurse practitioner; PCP, primary care provider.

a research assistant, took place within 2 weeks of the first visit and generally required 2 hours. This assessment included physical performance testing and questionnaires on functional ability, falls, rehabilitative care, and physical activity. Participants received \$20 for each baseline visit. Transportation to both visits using commercial wheelchair-accessible vans was provided for all participants as needed.

### Outcome measures

The LLFDI assesses self-reported activity limitation and participation restriction and served as our primary outcome measure. The Function component includes 48 questions on level of difficulty in performing discrete physical activities. Physical functioning in the LLFDI consists of 1 functional difficulty dimension and 3

separate subdomains: advanced lower extremity function, basic lower extremity function, and upper extremity function.<sup>22</sup> The Disability component assesses the frequency of performing 16 life tasks and limitation in performing each task. The 16 life tasks include a wide variety of activities, including personal maintenance, exchange of information, home life, paid or volunteer work, and involvement in social, community, civic, and personal finance activities.<sup>23</sup> Each LLFDI domain is calibrated on a scale from 0 to 100. It has been validated in several different older cohorts.<sup>22,23,26,27</sup>

Our secondary outcome measure, the SPPB, is used to characterize lower extremity function. The SPPB includes measures of standing balance, 4-meter usual pace walking speed, and ability and time to rise from a chair 5 times. The validity of the SPPB has been demonstrated by showing a gradient of risk for disability and

### Inclusion Criteria

Age  $\geq 65$

Able to understand and communicate in English

Difficulty or task modification with walking  $\frac{1}{2}$  mile (6 blocks) or climbing 1 flight (10 steps) of stairs

### Exclusion Criteria

Presence of a terminal disease

Major surgery or myocardial infarction in past 6 months

Planned major surgery

Planned move from Boston area within 2 years

Major medical problems interfering with safe and successful testing

Mini-Mental State Exam score  $< 18$

Short Physical Performance Battery score  $< 4$

**Fig 3** Inclusion and exclusion criteria.

mortality along the full range of the scale from 0 to 12.<sup>2,28</sup> The other secondary outcome measure is the Long Distance Corridor Walk, which is used to evaluate walking-related disability. Participants walk a 400-m marked course as quickly as possible. Inability to complete this task within 15 minutes without stopping is considered a valid and reliable measurement of performance-based disability.<sup>29,30</sup>

### Impairment measures

As portrayed in figure 1, we assessed the following impairments using physical performance testing: limb strength, asymmetry of limb strength, asymmetry of limb power, limb speed, reaction time, balance, kyphosis, trunk muscle strength and endurance, aerobic capacity, and range of motion. Whenever possible, we used validated measures that were used in previous longitudinal cohort studies of older adults: InCHIANTI, Health Aging and Body Composition Study, Women's Health and Aging Study, and MOBILIZE Boston.<sup>5-9</sup>

### Medical impairments

According to our model in figure 1, medical impairments are factors that are clinically recognized to influence the course of rehabilitative care and that might modify the relationship between rehabilitative impairments and our outcomes. We assessed the following medical impairments: pain, stiffness, fatigue, depression, cognitive impairment, sensory loss, and visual impairment. A full list of rehabilitative and medical impairment measures is shown in figure 4.

### Other adjustment variables

We collected sociodemographic information on all participants, including age, sex, ethnicity, race, education, marital status, and living situation. We recorded height and metabolic weight and calculated body mass index.

Prescription and over-the-counter medications used in the previous 2 weeks were recorded.<sup>31</sup> Medical and surgical history was documented as part of a health history questionnaire, which included the Rose Angina Questionnaire.<sup>32</sup> We used a comorbidity

questionnaire developed and validated by Sangha et al<sup>33</sup> to evaluate for the presence of common medical conditions impacting older adults and whether each condition necessitates treatment or limits activities. A nurse practitioner conducted a brief physical examination that included the following systems: musculoskeletal, neurologic, cardiovascular, and respiratory.

Falls history, hospitalizations, ED visits, and rehabilitative care in the past year were documented. Balance confidence was assessed using the Activities-Specific Balance Confidence Scale.<sup>34</sup> Physical activity was measured with the Physical Activity Scale for the Elderly, which is a reliable and valid measure among older adults.<sup>35</sup>

Study staff contact participants by phone every 3 months between baseline and each of the annual assessments. Participants answer questions about falls, hospitalizations, ED visits, and rehabilitative care in the previous 3 months.

### Bias

In designing this study, we wished to avoid potential sources of bias. Two common sources of bias in longitudinal studies of older adults are missing data and dropouts. We specifically obtained redundant measures for attributes in which missing values might occur (eg, use of leg press power and stair climb power). Also, we used a number of other strategies to avoid missing data. For example, for tests of duration or number of repetitions, a score of zero can be provided for those who attempt but are unable to complete a test.<sup>36</sup> To avoid bias resulting from dropouts, study staff contact participants by phone every 3 months. Additionally, participants who are unable to attend in person follow-up visits at 12 and 24 months are offered the option of a home visit or a phone interview (in that order).

### Planned statistical analysis

In planning this study, we recognized that there is likely to be colinearity between some of the impairments that we are measuring. Statistically, inclusion of predictors that are collinear can provide challenges when interpreting simple multivariable regression models. Thus, we hypothesized that impairment groupings would be identified through confirmatory factor analysis and that these factors would define different domains of

Rehabilitative Attributes	
Domain	Measures
Reaction Time	Reaction time <sup>37</sup>
Limb Strength	Leg press strength <sup>38,39</sup>
Limb Power	Leg press power, <sup>40</sup> Stair climb power test <sup>41</sup>
Balance	FICSIT, <sup>42</sup> Standing on toes
Limb Speed	Heel-shin test, Prono-supination of the hands <sup>6</sup>
Trunk Muscle Integrity	Trunk flexion endurance, Trunk extension endurance, <sup>17,18</sup>
	Trunk extension strength <sup>17</sup>
Range of Motion	Knee and ankle ROM <sup>43</sup>
Kyphosis	Kyphosis index measurement <sup>44</sup>
Aerobic Capacity	Estimated from 400-meter walk time <sup>45</sup>

Medical Attributes	
Domain	Measures
Bionutrition	Height, Weight, Body mass index, Body measurements
Cognition	Mini-Mental State Exam, <sup>25</sup> Hopkins Verbal Learning Test, <sup>46</sup> Verbal Fluency, <sup>47</sup> Trails A and B, <sup>48</sup> Digit Symbol Substitution Test <sup>49</sup>
Stiffness	Stiffness questions
Pain	McGill Pain Map, <sup>50</sup> Brief Pain Inventory Severity and Interference, <sup>51</sup> Low Back Pain Questionnaire <sup>52</sup>
Sensation	Semmes-Weinstein Monofilament Test <sup>53</sup>
Fatigue	Avlund Mobility-Tiredness Scale <sup>54</sup>
Depression	PHQ-9 <sup>55</sup>
Complicated Grief	Brief Grief Questionnaire <sup>56</sup>
Vision	Snellen Vision Test <sup>57</sup>

**Fig 4** Physical attributes evaluated as part of Boston RISE. Abbreviations: FICSIT, Frailty and Injuries Cooperative Studies of Intervention Techniques; PHQ-9, Patient Health Questionnaire-9; ROM, range of motion.

rehabilitative impairments. This hypothesis was based on a previous report evaluating mobility among older adults.<sup>58</sup>

Based on the factor analysis, we will perform a series of regression models of the impairment domains (independent variables) in relation to baseline activity limitations (dependent variables). We will adjust for relevant clinical and demographic confounders.

To address subsequent aims that explore which impairment domains at baseline predict future activity limitation and participation restriction over 2 years, we will use latent growth modeling based on functioning (or disability) at different time points. Potential confounders will be included in the models.

This analytic approach was also guided by our concerns for potential bias. It was based on a recent review<sup>36</sup> addressing strategies to minimize the impact of missing data in longitudinal studies of older adults.

## Results

Among the 7403 primary care patients identified, 5333 (72%) were approved by primary care providers to receive communication about the study (see [fig 2](#)). In total, 4495 people received recruitment letters, and 47 people contacted study staff

independently after seeing recruitment materials in a primary care office or hearing about the study from a friend or family member. Study staff conducted phone screenings with 1349 people, of whom 712 (56%) were eligible for the final screening at the first baseline visit. Of the 523 people who gave informed consent at the first visit, 443 (85%) were eligible to continue in the study, and of those, 430 (96%) completed both baseline visits. Baseline characteristics are presented in [table 1](#). Missing values for baseline were low, with an average completion rate of greater than 95% for the impairment measures.

## Discussion

While a number of longitudinal cohort studies of older adults have examined functional decline and disability (InCHIANTI, Health Aging and Body Composition Study, Women's Health and Aging Study, and MOBILIZE Boston), to the best of our knowledge ours is the first purposely designed around the context of rehabilitative care.<sup>5-9</sup> The aim of this report is to demonstrate the feasibility of successfully developing this unique cohort study in order to facilitate replication for other studies addressing important questions in aging and rehabilitation science. The study design mirrors assessment procedures currently advocated by the Center for

**Table 1** Baseline characteristics of Boston RISE study participants (N=430)

Characteristics	Values
Age (y)	77±7 (65–96)
65–75	202 (47)
76–96	228 (53)
Sex	
Female	291 (67.7)
Male	139 (32.3)
Hispanic or Latino ethnicity	13 (3.0)
Race	
White	355 (82.6)
Black	49 (11.4)
Other	26 (6.0)
BMI (kg/m <sup>2</sup> )	
<25	102 (24)
25.0–29.9	167 (39)
≥30	160 (37)
No. of chronic medical conditions	4.17±1.96 (0–11)
LLFDI—Overall Function	55.48±7.94 (36.13–90.34)
LLFDI—Disability Limitation	68.94±11.77 (46.68–100)
LLFDI—Disability Frequency	52.28±5.65 (32.87–70.61)
SPPB	8.70±2.26 (4–12)
400-m walk (min)	6.16±2.03 (0.94–15.0)

NOTE. Values are mean ± SD (range) or n (%).  
Abbreviation: BMI, body mass index.

Medicare and Medicaid Services (CMS). In 2010, CMS started supporting annual wellness visits to be performed by primary care physicians. The purpose of these evaluations is to comprehensively assess health risks on an annual basis and to establish and maintain personalized prevention plans based on risk profile. Since Boston RISE participants are derived from a primary care population and are being assessed annually, the findings from our study will be uniquely applicable for translation into a care continuum that includes both primary and rehabilitative care.

Additionally, important questions beyond those encompassed in our primary aims can be addressed with this data set. We are tracking morbid events such as ED visits and hospitalizations. Since Boston RISE participants are from a single health care system, access to the electronic medical records can allow for corroboration of these events and of other details that may augment the development of risk prediction tools. These aims could be addressed in future analyses of Boston RISE.

As demonstrated in table 1, our cohort is predominately female and mostly white. This result is consistent with the sex and racial composition of the older population within the geographic region from which we recruited.<sup>59</sup> Our participants had a mean of 4.2 chronic medical conditions. This level of comorbidity is expected among older primary care patients and is consistent with population-based studies conducted in the same geographic region.<sup>5</sup> Boston RISE participants also manifest a broad range of physical function. Baseline SPPB scores indicate a mean score of 8.7, which is consistent with a moderate risk for developing subsequent disability.<sup>2</sup>

Missing values for baseline measures occur within all cohort studies of older adults. Higher rates of missing data could have been expected because of (1) our focus on older adults vulnerable to decline and (2) our comprehensive rehabilitative assessment.

However, our rates of missing values are consistent with the most highly regarded cohort studies of older adults.<sup>36,39,60,61</sup>

## Study limitations

Our findings can be generalized to older, English-speaking primary care patients with mobility limitations. While recruitment was successful overall and completed within our originally proposed timeline, our findings may not be generalizable to more ethnically diverse patient groups. Also, it is acknowledged that our cohort is derived from a single health care system within a large city in the northeastern United States. It will still be important to validate any derived predictive models in other clinical populations.

A strength of Boston RISE is the underlying premise that it is particularly important to account for impairment status if we are to design the most optimal preventive care paradigms for older adults. Much of the disability literature is based on a disease-specific perspective, which attempts to view disability as the result of a single health condition (eg, arthritis or stroke). This becomes particularly challenging when providers attempt to apply these findings to older patients who typically have multiple chronic medical problems and geriatric syndromes.<sup>62</sup> A number of studies have begun to highlight that impairment status and severity may be more optimal means of evaluating older adults at risk for disability.<sup>63,64</sup> To date, these studies have not adequately considered impairments commonly treated within rehabilitative care.

## Conclusions

Boston RISE represents a unique investigation that will advance geriatric rehabilitative research. This clinically based methodological approach provides the opportunity to address important knowledge gaps in the care of older adults and allows the resulting findings to be readily applied within both rehabilitative and primary care settings. Additionally, it can serve as a template for other studies addressing important questions in aging and rehabilitation science.

## Keywords

Aged; Mobility limitation; Primary health care; Rehabilitation

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