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HEALTHY AGING RESEARCH

Predictors of stroke survivors' enrollment in an exercise study

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Abstract

Background: Screening measures prior to study enrollment are needed to determine safety and minimize participant burden. Our objective was to determine if functional disability, physical function, cognitive impairment, age or gender were predictive of enrollment in an exercise study.

Methods: This observational study used cross-sectional data from 233 stroke survivors with mild-moderate disability, who consented to be screened for potential study enrollment.

Results: Participants were on average 68±12 years old (49% women), reported mild-moderate disability (mRS=2.1±0.8), had some impairments in physical functioning (SPPB=6.9 ±2.6), but were without cognitive impairments (MMSE=27.6 ± 3.6). Significant predictors of study enrollment using binary logistic regression included leg strength [$X^2(1)= 29.17$, $p<0.01$], gait speed [$X^2(1)= 36.60$, $p<0.03$], and cognitive function [$X^2(1)= 9.99$, $p=0.03$]. Multiple logistic regression indicated that leg strength, gait speed, and cognitive function together, were predictive of enrollment [$X^2(3)=14.05$, $p<0.01$].

Conclusions: The Short Physical Performance Battery and Mini-Mental Status Exam are quick and easy to administer; to assess various levels of physical and cognitive function, with minimal risk to participants. Fewer screening tests reduced participant burden and may have encouraged participation in an exercise study, even among stroke survivors with impairments in physical and/or cognitive function.

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Introduction

Every 40 seconds, someone in the United States has a stroke—the fourth leading cause of death [1]. After the age of 55, the risk of a stroke event doubles. Women experience more strokes than men, have higher mortality rates, and suffer more serious disabilities afterwards [1]. Regular exercise participation improves the overall health of stroke survivors and aids recovery of their functional, physical and cognitive abilities [2]. Screening prior to participation in exercise is recommended for all adults with a chronic illness, such as stroke survivors [2, 3].

Screening tests are implemented to ensure safety, identify health conditions that require monitoring (e.g. diabetes), and determine functional, physical or cognitive impairments that necessitate adaptations to planned exercises (e.g. wheelchair-bound) [4-7]. Screening tests vary, ranging from physical activity readiness questionnaires [8, 9] to exercise tolerance tests (cycle ergometer or treadmill) [2, 5]. For stroke survivors, an exercise tolerance test may not be feasible to conduct; yet, this should not preclude them from exercise participation (lighter intensity exercise with more frequent sessions will suffice) [2].

Prior to participation in an exercise study, adults with a chronic illness undergo similar screening tests, to determine eligibility. Frequently, this necessitates that these adults—often with a disability—complete an exhaustive battery of tests [5-7]. As a result, many are excluded from exercise studies. It is important to have screening tests that ensure safety, impose minimal participant burden, and not unduly exclude participants with functional, physical or cognitive impairments [10]. The purpose of this study was to screen stroke survivors with mild-moderate disability for participation in an exercise study using three community-based measures; and determine if functional disability, physical function, cognitive impairment, age or gender were predictive of enrollment.

Methods

Design and sample

For this observational study, we used cross-sectional data from 233 stroke survivors who met study eligibility criteria and signed an informed consent to be screened for potential enrollment in an exercise study. Study eligibility and screening data were collected between January 2009 and January 2012. The full study was a randomized clinical trial to determine if a 12-week program of Tai Chi exercise classes among community-dwelling stroke survivors was effective in improving physical function and quality of life, compared to SilverSneakers® or Usual Care [11]. Approval to conduct the study was obtained from the Institutional Review Board at the University of Arizona. The investigation was carried out according to the principles outlined in the Declaration of Helsinki, including written informed consent from all subjects.

Details of the recruitment plan have been previously reported [12]. Briefly, potential stroke survivors were identified through various referral sources including outpatient rehabilitation facilities, physicians, and the local media. Community-dwelling stroke survivors, aged 50 years and older, who had their stroke occur at least 3 months prior to study enrollment were considered eligible. Information on age, gender and self-reported health problems were collected (e.g. other cardiovascular problems, respiratory problems).

Screening measures

The three community-based screening measures used in this study included the: 1) Modified Rankin Scale (mRS) to assess functional disability, 2) Short Physical Performance Battery (SPPB) to assess physical function, and 3) Mini-Mental Status Exam (MMSE) to assess cognitive impairment.

The Modified Rankin Scale (mRS) is most commonly used by clinicians to measure functional disability following a stroke [13]. Functional disability is the degree to which one is unable to individually perform physical tasks and dependence required for successful completion of daily activities and is used as an indicator of stroke severity [14]. The mRS is an important tool because it not only recognizes the independence of stroke survivors, but also allows comparisons to be made between participants with different types of stroke injuries. This measure also assesses for a possible disability that existed prior to stroke for a more accurate assessment of current disability [14]. The mRS has been shown to have good inter-rater reliability and reproducibility of assessment (ICC= 0.95-0.96) [15]. The mRS has a total of 6 grades ranging from 0-5 (0= no symptoms at all, 5=severe disability: bedridden, incontinent and requiring constant nursing care and attention) [13]. The mRS is a simple tool that requires a short interview, taking about 10 minutes to complete. Participants with scores of 3 or less (3= moderate disability: requiring some help but able to walk without assistance) were eligible for study enrollment.

The Short Physical Performance Battery (SPPB) is a simple and important measure specifically designed for older adults to assess balance, gait speed, and lower body strength [16]. The SPPB has been shown to be more valid than self-reported measures and is an efficient, practical, and safe measure to use in adults with chronic diseases or disabilities [16], including stroke survivors [17, 18]. Balance tests are conducted with the participant standing with their feet in three different positions for 10 seconds, increasing in level of difficulty: side-by-side stand, semi-tandem stand, and tandem stand. Gait speed is measured as the time needed to walk a 4-meter course at a normal pace. Lower body strength is a timed measure of their ability to rise out of a chair into an upright position five times without the use of the arms. In addition,

gait speed can be calculated in meters per second and the chair stand test time can be recorded in seconds, to allow for further precision of these tests. Each category (i.e. balance, gait speed and strength) is scored ranging from 0 to 4 (0= inability to complete test, 4= highest level of performance). An overall score is determined by combining the scores from each category (total score range= 0-12) [16]. Participants with a score less than 3 (too frail/predictive of mortality) or greater than 9 (non-disabled adult) were not eligible to participate in this study. The SPPB requires minimal evaluator training and is a simple tool that takes 5 to 10 minutes to complete, yet it can efficiently indicate overall physical function in older adults.

The Mini-Mental Status Exam (MMSE) is a brief screening test that assesses cognitive impairment. The MMSE has been shown to have good reliability (r=0.54-0.96) and validity compared to other cognitive measures [19]. The MMSE assesses 7 cognitive domains through questions and tasks involving orientation (time and place), registration, attention (calculation), three-word memory recall, language and repetition, ability to follow commands, reading and writing (construction). The MMSE requires a trained interviewer to conduct this test and takes about 10 minutes to complete it. MMSE scores range from 0 to 30 classifying cognitive impairment as: none (24-30), mild (18-24), and severe (0-17) [20]. Participants who scored an 18 or higher on the MMSE were eligible for study enrollment.

Data analysis

Descriptive statistics were used to determine characteristics of the participants screened for potential enrollment in an exercise study. Logistic regression was used to determine the probability that a participant would be in one of two categories (i.e. enrolled or not enrolled) based on the scores of the predictor variables [21]. Binary logistic regression is a non-linear model that uses dichotomous data to predict a categorical variable from a set of predictor variables. The odds ratio (ExpB) was calculated to determine the odds of one variable occurring in one group (i.e. enrolled) to the odds of the variable occurring in another group (i.e. not enrolled). The Wald Chi-Square statistic test was used to determine the unique contribution of each predictor, in relation to the other predictors in the model [21]. Probability (p) values of 0.05 or less were considered statistically significant. First, binary logistic regression was conducted using the mRS score, SPPB-balance, gait speed and leg strength times, MMSE score, age and gender as individual predictors of study enrollment. Then, multiple logistic regression was used to explore if the significant individual predictors from the binary logistic regression were together predictive of enrollment. Data were analyzed using IBM SPSS for Windows, Version 20.0 (IBM Corp).

Results

Participant characteristics

Participants were on average 68±12 years old and 49% were women. Participants reported mild-moderate disability (mRS=2.1±0.8), had some impairments in overall physical functioning (SPPB=6.9 ±2.6), diminished leg strength (5-timed chair stands = 15.3 ± 10.7 seconds), moderate balance (2.8 ±1.2), and slow gait speed (0.7 ± 0.3 meters/second), but were without cognitive impairments (MMSE=27.6 ± 3.6). The most common self-reported health problems were hypertension (69%), hypercholesterolemia (61%), and other cardiovascular problems (21%). A total of 62% of the persons screened; enrolled in the study (Table 1).

Prediction of enrollment

To determine significant predictors of study enrollment, a binary logistic regression model was used. Each variable (mRS, SPPB-balance, gait speed, leg strength, MMSE, age and gender) was inserted into the model to determine prediction of study enrollment. Significant predictors of study enrollment included leg strength [$X^2(1)= 29.17$, $p<0.01$], gait speed [$X^2(1)= 36.60$, $p<0.03$], and cognitive function [$X^2(1)= 9.99$, $p=0.03$]. The mRS ($p=0.83$), SPPB-balance ($p=0.90$), age ($p=0.41$), and gender (0.10) were not significant predictors (Table 2).

Multiple logistic regression was conducted to determine if leg strength, gait speed, and cognitive function combined were predictive of enrollment.

Table 1. Participant characteristics

	Persons screened	Enrolled in study	
	All, n=233	Yes, n=145	No, n=88
	Mean ± SD	Mean ± SD	
Age, years	68.4±12.2	68.6±12.7	68.1±11.2
mRS	2.1±0.8	2.1±0.7	2.1±1.0
SPPB, total	6.9±2.6	6.6±1.9	7.3±3.4
Leg Strength, seconds	15.3±10.7	16.6±10.2	13.1±11.1
Gait Speed, meters/second	0.7±0.3	0.7±0.3	0.8±0.4
Balance, score [range 0-4]	2.8±1.2	2.9±1.1	2.8±1.4
MMSE	27.6±3.6	27.9±2.4	27.0±4.9
	%	%	
Women	49.4	46.2	54.5
Self-Reported Health Problems			
Cardiovascular Problems	20.6	18.6	23.9
Hypertension	69.1	73.1	62.5
Peripheral Artery Disease	7.7	9.0	5.7
Respiratory	9.4	9.7	9.1
Diabetes	20.6	24.8	13.6
Currently smoking	6.0	6.2	5.7
Hypercholesterolemia	60.9	66.2	52.3
Painful Walking	20.6	20.0	21.6

Leg Strength=5-timed chair stand test; MMSE=Mini-Mental Status Exam; mRS=Modified Rankin Scale; SPPB=Short Physical Performance Battery

The results indicated that leg strength, gait speed, and cognitive function together were predictive of enrollment [X^2 (3)=14.05, p<0.01] (Table 3). Leg strength was a significant predictor in the model (Wald=6.31, p=0.01), indicating that as test completion time increases, the odds of enrollment increases [Exp(B)=1.04, Cl=1.01-1.07]. Participants that took a longer time to complete the five-time chair stand test (indicating poor leg strength) were more likely to be enrolled into the study.

Table 2. Binary logistic regression

Predictor	B	S.E.	Wald	df	Sig.	Exp(B)
mRS	-0.05	0.22	0.05	1	0.83	0.95
Balance	-0.02	0.14	0.02	1	0.90	0.98
Gait Speed	-1.29	0.60	4.58	1	0.03	0.28
Leg Strength	0.04	0.02	6.43	1	0.01	1.04
MMSE	0.10	0.05	4.65	1	0.03	1.10
Age	0.01	0.01	0.68	1	0.41	1.01
Gender	-0.49	0.29	2.78	1	0.10	0.61

Gait Speed=meters/second; Leg Strength=5-timed chair stand test in seconds; MMSE=Mini-Mental Status Exam; mRS=Modified Rankin Scale

Gait speed was significant predictor in the model (Wald=5.96, p=0.02), indicating that as gait speed increases, the odds of enrollment decreases [Exp(B)=0.31, Cl=0.12-0.79]. Participants with faster gait speed times on the four-meter walking test (indicating better walking ability) were less likely to be enrolled into the study. Cognitive function was also a significant predictor in the model (Wald=4.17, p=0.04), indicating that as the test score increases, the odds of enrollment increases [Exp(B)=1.09, Cl=1.01-1.18]. Thus, participants with better cognitive function were more likely to be enrolled into the study. Overall, prediction success was 64%.

Table 3. Multiple logistic regression

Predictor	B	S.E.	Wald	df	Sig.	Exp(B)
Leg Strength	0.04	0.02	6.31	1	0.01	1.04
Gait Speed	-1.18	0.48	5.96	1	0.02	0.31
MMSE	0.09	0.04	4.17	1	0.04	1.09

Overall X^2 (3)=14.05, p<0.01, Gait Speed=meters/second; Leg Strength=5-timed chair stand test in seconds; MMSE= Mini-Mental Status Exam

Discussion

In this study, slower leg strength and faster gait speed using the SPPB, and better cognitive function using the MMSE were predictive of study enrollment. The SPPB and MMSE are quick and easy to administer with minimal risk to participants and these measures have been shown to accurately assess various levels of physical and cognitive function [22, 23]. The SPPB and MMSE can be used as assessment measures for other community-based exercise studies where assessment of physical and cognitive function is necessary. Both screening measures are simple to administer, taking a total of 15-20 minutes to complete, require little to no cost, with minimal training and equipment needed. Based on the findings of this study, the SPPB and MMSE measures were adequate in screening stroke survivors to ensure safety and ability to follow instructions prior to participation in an exercise study, without the need to perform additional screening tests.

These findings are consistent with other research showing that the SPPB is suitable for older adults with disabilities, to assess physical function. Guralnik and colleagues [16] found the SPPB was successful in predicting hospital admissions and mortality rates among adults age 71 years and older. In another study among adults 65 years and older, the SPPB was predictive of the ability to walk 400 meters [24]. Among chronically ill men and women, researchers found low SPPB scores significantly predicted abnormal pulmonary function ($p<0.01$) [25]. Overall, older adults have reported that the SPPB is acceptable and tolerable to perform [22].

The MMSE is a widely used measure to assess cognitive impairments in both clinical and research settings. Cognitive impairment after a stroke has been shown to predict dependency and institutionalization in stroke patients [26]. Consistent with the findings in this study, the MMSE was reported to be an adequate screening measure among stroke survivors to identify cognitive impairments [23]. The MMSE showed acceptable validity in identifying cognitive dysfunction early post-stroke, while no differences in MMSE scores between stroke survivors with left and right hemisphere lesions were observed [27].

Fewer screening tests may encourage more people with chronic stroke to participate in exercise studies. In this study, a total of 233 stroke survivors were screened using 3 different measures (mRS, SPPB, MMSE) and 145 people enrolled (62%). In contrast, Pang and colleagues [28] screened a total of 187 people with chronic stroke for an exercise study using a total of 7 screening measures and enrolled 63 participants (34%). In another exercise research study, a total of 582 stroke survivors were screened using 6 screening measures and had an even lower enrollment rate (17%) [29].

Interested study investigators may like to consider adding the SPPB and MMSE as screening measures in future studies. Future research could examine the individual test scores (balance, gait speed, leg strength) on the SPPB to determine if fewer tests can be used. Also, the different cognitive domains on the MMSE (orientation, registration, attention and calculation, recall, and language) could be explored to determine which domain(s) may be predictive of enrollment.

Strengths and limitations

This was a cost-effective study that used an existing and complete dataset (no missing data) with a robust sample (n=233) to examine potential predictors of study enrollment. This is one of the first studies conducted among stroke survivors, using a screening measure (SPPB) that is valid and reliable for older adults with disabilities, to assess overall physical function. Results from this study can aid in the development of subsequent research studies, especially when enrolling older adults with disabilities for an exercise study.

Some study limitations include the limited amount of data available from the participants screened, preventing exploration of other potential predictors of study enrollment. This study used an observational design to examine relationships among the variables, so cause and effect between variables are unknown.

Conclusions

Examining potential enrollment predictors can help determine which measures are most effective in finding eligible stroke survivors for exercise research studies, while minimizing participant burden. Participant safety is of utmost importance when enrolling participants into an exercise study. Identifying measures that stroke survivors can safely perform is essential for assessment, promoting physical activity, and encouraging study participation. In the clinical environment, healthcare providers of stroke survivors can use these measures for patient assessments, without needing extensive training or time to complete them. These results provide important insight relevant for other study investigators inquiring about enrollment of participants into their own studies and may help guide them in choosing appropriate screening measures to enhance optimal recruitment of older adults with disabilities, such as chronic stroke.

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