2019

Standard and Cognitive Four Square Step Test (FSST)

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STANDARD AND COGNITIVE FOUR SQUARE STEP TEST (FSST)

by

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A Scholarly Project
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine and Health Sciences
University of North Dakota
In partial fulfillment of the requirements
for the degree of
Doctor of Physical Therapy

Grand Forks, North Dakota
May
2019
This Scholarly Project, submitted by Renee Hoffman and Hannah Bucholz in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

[Signature]
(Graduate School Advisor)

[Signature]
Chairperson, Physical Therapy
PERMISSION

Title          Standard and Cognitive Four Square Step Test

Department     Physical Therapy

Degree         Doctor of Physical Therapy

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Signature

Date  12/11/18
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Thank you to the Senior Center for allowing us to perform our testing at their facility. A special thank you goes to the participants in our study. We appreciate your time, effort, and feedback for this project.
ABSTRACT

Background/Purpose: The Four Square Step Test (FSST) measures dynamic standing balance and agility and was developed to identify older adults at risk for falls. It has a cognitive component for remembering the stepping sequence but has never been tested with an additional cognitive task. The purpose of this study was to collect normative data for the FSST and Cognitive FSST in community dwelling adults for various age groups.

Materials/Methods: Eighty-seven community-dwelling adults (55 females, 32 males) between the age 21 and 86 (48.22 years) were included in the study. Participants completed a fall risk checklist and a cognitive screen prior to the FSST. The best time of the first two successful trials was recorded for statistical interpretation. The participant then performed the FSST without and with a cognitive task involving subtraction by 3s.

Results: Ages were organized into three categories, 20-39 (n=31), 40-59 (n=23), and ≥ 60 years (n=31). Times of the FSST and Cognitive FSST tended to increase within age groups, indicating slower performance. When adding a cognitive task to the FSST, female times were consistent throughout age groups, but male times increased in the oldest age group (60+). There was a trend between fall risk and cognitive memory scores on the Mini-Cog. Two of the three participants were identified as a fall risk on the FSST (cut off score >15 seconds) and CDC Fall Risk Checklist (score of ≥ 4), and had a positive Mini-Cog score.
Conclusion: Age was a factor in performance with the FSST and Cognitive FSST. Gender also appeared to have a greater influence in older individuals. The Cognitive FSST results tended to show a slower time and an increase in errors in performance on a previously learned multi-directional stepping task. There was a more significant challenge noted in adults over the age 60. Further research is needed to identify a fall risk cut off score and establish normative data with the Cognitive FSST.

Clinical Relevance: The FSST is a quick and inexpensive balance assessment commonly used in the clinic to determine if a patient is at risk for falling. It creates a more challenging assessment integrating a multi-task activity when assessing balance allowing the physical therapists to further assess functional abilities.
CHAPTER I

BACKGROUND AND PURPOSE

Balance and mobility are of great concern to maintain independence for community dwelling individuals. Impairments in these can lead to difficulty stepping over small objects, managing uneven terrain, and changing directions while walking, increasing the likelihood of falls. According to the Center for Disease Control, one in four Americans over age 65 will fall this year.\(^1\) Falls are the current leading cause of fatal and non-fatal injuries of older adults treated in the hospital, costing over $50 billion in 2015. Preventing falls is beneficial to the individuals physical health and can save thousands of dollars in additional care.

There are a number of reasons why falls occur, including intrinsic factors (i.e. vision), environmental factors (i.e. obstacles), or a combination of both. In everyday life individuals have countless number of obstacles to maneuver. Reaction times and balance decrease as one ages. This can lead to falls when confronted with situations where one must quickly react to avoid an obstacle in order to prevent a fall, like avoiding cracks in sidewalks.

Physical therapists evaluate balance through various tests including the Four Square Step Test (FSST). This test challenges the participant to perform activities that can cause a loss of balance or even a fall with quickly stepping over objects in multiple directions. Since the FSST test participants in areas that may cause falls, it can determine
how likely it is that an individual may have a fall. The FSST also tests individuals on their cognitive abilities by having to remember the correct pattern to complete the test. This test is often used by physical therapists because it gives clinicians a good idea of how an individual functions in natural setting with obstacles and having to quickly change direction.

The FSST has excellent reliability and validity for dynamic standing balance and mobility in the clinical setting.² The FSST has been established to be used with a variety of ages and several patient populations including strokes,³ Parkinson’s Disease,⁴ vestibular dysfunction,⁵ and transtibial amputation.⁶ It has established scores that place older adults at either a low fall risk or a high fall risk. In the geriatric population (65+) a time of >15 seconds shows an increased risk for multiple falls.² Cut off scores of fall risks for the FSST has been established in many of the patient populations, but there is limited normative data for <60 age groups of healthy, community dwelling individuals.

Cognition can also be a factor in predicting falls. Cognitive deficits detected on clinical assessment are associated with an increased fall risk in community and institution-dwelling older adults.⁷ In a study by Beauchet⁸ found fallers had significantly poorer scores in the Mini-Mental State Examination and the 15-item Geriatric Depression Scale, as well as slower walking times on the Timed Up and Go Test and the Cognitive Timed Up and Go Test. One advantage of the FSST over the TUG is it addresses individual’s ability to react to trip hazards. Preventing a fall requires the individual to pay attention to their surroundings and be able to react appropriately when faced with an obstacle, which requires fast cognitive processing. When an individual has diminished
cognitive abilities, they may miss recognizing a trip hazard or may react too slowly, putting them at greater risk of falling.

Another common reason individuals fall is because they are doing more than one task at a time. This includes walking and talking or walking while carrying an object. This is considered dual tasking and is often used by physical therapists when testing an individual's balance, i.e. Cognitive Timed Up and Go (TUG Cog).\textsuperscript{9} The TUG Cog is a walking test that assess gait speed and reaction time with the added cognitive component. The cognitive piece added to the TUG is often counting backwards by 3's from 100. This test has been established as good clinical predictor of an individual's risk of falling.\textsuperscript{10} There is currently no research on reliability and validity of adding a similar cognitive task to the FSST to predict fall risk.

The purpose of this study was to collect normative data for gender and age groups for community dwelling healthy adults for the standard FSST and to evaluate the impact of adding a cognitive component to the FSST (i.e. predicting fall risk). The hypothesis of this study was the FSST times associated with the cognitive dual task times would increase and could differentiate people who would fall and not fall better than the FSST times alone.
CHAPTER II

METHODS

Approval for this study was received by the University of North Dakota IRB (IRB 201803-277). (Appendix A) Participants were recruited by word of mouth from the University of North Dakota School of Medicine and Health Sciences building and the local community. Prior to testing, all participants signed a written informed consent and were provided a copy. (Appendix B)

Participants

Eighty-seven community-dwelling adults (55 females, 32 males) between the ages of 21 and 86 (mean age = 48.22 years) were tested. Inclusion criteria stated subjects needed to be healthy community-dwelling individuals whom were able to walk independently with or without a cane for community distances. Potential participants were screened and excluded if found to require an assistive device other than a cane for walking, acute injuries limiting their ability to walk, and cognitive impairments limiting their ability to follow directions.

Instrumentation

Instruments used in this study were the CDC Fall Risk Checklist, demographic survey, Mini-Cog test, and the FSST without and with a cognitive task. These valid and reliable tests were chosen because they were quick to administer and allowed to screen a large number of participants.
CDC Fall Risk Checklist

The CDC Fall Risk Checklist allows individuals to self-recognize, acknowledge, and discuss fall prevention. It was created and revised by Vivrette et al\(^1\) and is from the CDC STEADI website which asks 11 questions about potential risk factors for falling (i.e., the number of falls, current medications, etc.).\(^1\) A score of 4 or more on the checklist correlates with having an increased risk of falling. The CDC Fall Risk Checklist is considered valid and reliable (sensitivity 100%, specificity 83.3%) in a community dwelling older adult population.\(^{12}\) (Appendix C)

Demographic Survey

A demographics and descriptive survey was completed prior to balance testing. The survey gathered information regarding age, gender, past or recent injuries that would affect ability to walk, and exercise type as inactive, minimal, moderate, or highly active with frequency of exercise. (Appendix D)

Mini-Cog Test

The Mini-Cog test was developed by Borson\(^{13}\) and is a commonly used standardized cognitive test. It consists of a quick mental screening of word recall and a simple clock drawing, which tests short term verbal memory, complex cognitive abilities, and memory. The Mini-Cog is considered a sensitive and specific (79%, 88%, respectively) tool to diagnose dementia in older adults. Participants are awarded one point for each word they can recall (out of 3), and can get 2 points for a normal clock drawing. If the clock drawing is abnormal (missing numbers, incorrect hand placement), the participant scores 0 points on that section. The total possible score is out of 5, with a
score of 3 or more showing low likelihood of having dementia, but does not rule out forms of mild cognitive impairment (Appendix E).

Four Square Step Test (FSST)

The FSST tests dynamic balance and mobility by requiring the subject to complete a sequence of stepping forward, sideways, backward, and in a clockwise direction, then reversed, over four 1/2-inch PVC pipes placed in a cross configuration on the ground (Figure 1 and 2). Participants are instructed to step as fast as possible without touching the PVC pipes and with both feet making contact with the floor in each square in order for the trial to be considered successful. The time to complete the test is then recorded. One demonstration and one practice trial are completed to ensure the subject knew the sequence. If a participant has an error during the practice trial, another practice trial is performed to ensure understanding and ability to perform the test. The FSST trials are completed until two successful trials are obtained and the number of trials need to successfully complete the test is recorded. A trial is repeated if the participant fails to complete the sequence successfully, loses balance, or makes contact with the PVC pipes during the sequence. The FSST has a sensitivity of 92% and specificity of 93%, excellent intra-rater reliability (ICC=0.98), excellent inter-rater reliability (ICC=.99).²

Cognitive FSST

There is currently no established Cognitive FSST. This study repeated the FSST with an added cognitive task (Cognitive FSST). Participants were instructed to count backwards by 3s while completing the FSST, similar to what is used in the TUG Cog. Participants were given a practice trial to ensure understanding and ability to complete the test with cognitive task. If a participant is unable to count backwards by 3s,
Figure 1. Stepping pattern of the FSST.\textsuperscript{14}

Figure 2. Participant at starting position of the FSST. Stepping pattern is forward, sideways, backward, sideways, and reversed.
they will be instructed to count backwards by 5s. If they are unable to count backwards by 5s, they will be instructed to list colors or fruits while doing the test. Trials will be performed until two successful trials are completed. If the subject fails to complete the sequence successfully, loses balance, or makes contact with the PVC pipes during the sequence, the trial will be repeated.

**Procedure**

All tests and surveys were completed in a short (5-10 minutes), single session. One researcher instructed and administered the FSST while another researcher recorded the performance scores and video recorded. Participants completed a demographic survey and a CDC Fall Risk Checklist. The Mini-Cog test was used to screen for cognitive impairment prior to the FSST. The participant completed the FSST and the Cognitive FSST respectively. The time to complete the FSST and Cognitive FSST was recorded. One demonstration and one practice trial were completed to ensure the subject knew the sequence. The FSST and Cognitive FSST trials were completed until two successful trials are obtained and the number of trials need to successfully complete the test was recorded. Each participant wore a gait belt in case of a loss of balance and a spotter was present while performing the test. Video recording was used to record each participant in case researchers needed to review the participant’s performance.

**Data Analysis**

Analytical statistics were done with parametric and non-parametric tests. If the null hypothesis was rejected in both cases, the parametric tests were reported. ANOVA tests and paired t-tests were used. For all statistical tests, significance was set at ≤ 0.05. Statistical analysis was performed on SPSS, version 24. The best time of the first two
successful trials was used during the data analysis. Faster times on the FSST and Cognitive FSST show improved performance. The data was divided by age, gender, exercise frequency, activity levels, fall risk scores, and number of falls in the past year.
CHAPTER III
RESULTS

The purpose of this study was to collect and analyze normative data for the FSST and Cognitive FSST for gender and age. The FSST and Cognitive FSST times were evaluated as to the number of trials required to successfully complete the test, the associated activity levels, and risk of falling.

Participant Demographics

Eighty-seven individuals enrolled in the study; two were unable to follow the instructions of the standardized protocol and were removed from the analyses. Of the 87 enrolled subjects, 54 (64%) were female and 31 (36%) were male. Ages were initially reported in years and subsequently organized into three categories, with 31 individuals at 20-39 years, 23 at 40-59 years, and 31 at 60 or more years. Enrollee’s demographic information by gender and age group is reported in Table 1.

Mini-Cog, FSST, and Cognitive FSST Times

Out of the 85 participants in the data analysis, four were positive for cognitive impairment based on the Mini-Cog Test (ages 23, 42, 70, 86 years). Out these four participants, two (ages 70 and 86) had slower times than the average FSST of their respective age and gender groups on both the FSST and Cognitive FSST. The other two participants demonstrated faster times than their respective gender and age groups. The differences in function between these four individuals with cognitive impairment are
Table 1. Demographics of the Initially Enrolled Participants

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>20-39 years</th>
<th>40-59 years</th>
<th>≥ 60 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled Participants</td>
<td>87</td>
<td>31</td>
<td>23</td>
<td>33</td>
</tr>
<tr>
<td>Male</td>
<td>32</td>
<td>12</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Female</td>
<td>55</td>
<td>19</td>
<td>13</td>
<td>23</td>
</tr>
<tr>
<td>Exercise</td>
<td>63</td>
<td>21</td>
<td>16</td>
<td>26</td>
</tr>
<tr>
<td>No Exercise</td>
<td>24</td>
<td>10</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Inactive</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Min. Active</td>
<td>21</td>
<td>8</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Mod. Active</td>
<td>55</td>
<td>13</td>
<td>16</td>
<td>26</td>
</tr>
<tr>
<td>Highly Active</td>
<td>10</td>
<td>9</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>CDC Fall Risk ≥ 4</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td># of Falls</td>
<td>15</td>
<td>3</td>
<td>4</td>
<td>8</td>
</tr>
</tbody>
</table>

reflected in the large standard deviations around the mean times for both the FSST and Cognitive FSST. There was a significant increase in time (increased impairment) in the Cognitive FSST for those with positive impairments. (Table 2)

FSST and Cognitive FSST Times by Gender

On the FSST, there was no significant difference in times between genders. On the Cognitive FSST, males had faster mean times than females (Table 3). During testing, males seemed to have less difficulty than females when counting backwards by 3s; this may account for the differences in time on the Cognitive FSST.
Table 2. FSST and Cognitive FSST Times in Those with and without Cognitive Impairment

<table>
<thead>
<tr>
<th></th>
<th>FSST Time (sec) M ± SD</th>
<th>Cognitive FSST Time (sec) M ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>No impairment noted, Mini-Cog Test (n=81)</td>
<td>7.43 ± 3.10</td>
<td>11.26 ± 4.04</td>
</tr>
<tr>
<td>Impairment noted, Mini-Cog Test (n=4)</td>
<td>11.22 ± 6.84</td>
<td>11.95 ± 6.02</td>
</tr>
<tr>
<td>Cognitive impairment, lower function (n=2)</td>
<td>16.00 ± 0.89</td>
<td>16.11 ± 5.59</td>
</tr>
<tr>
<td>Cognitive impairment, higher function (n=2)</td>
<td>5.40 ± 3.19</td>
<td>7.77 ± 6.87</td>
</tr>
</tbody>
</table>

Table 3. FSST and Cognitive FSST by Gender: Means, Standard Deviations, and t-Tests

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Time (sec)</th>
<th>t Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>54</td>
<td>8.04 ± 3.65</td>
<td>t (83) = 1.584, p = .117</td>
</tr>
<tr>
<td>Male</td>
<td>31</td>
<td>6.85 ± 2.77</td>
<td></td>
</tr>
<tr>
<td>Cognitive FSST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>54</td>
<td>12.09 ± 3.66</td>
<td>t (83) = 2.422, p = .018</td>
</tr>
<tr>
<td>Male</td>
<td>31</td>
<td>9.91 ± 4.51</td>
<td></td>
</tr>
</tbody>
</table>

FSST and Cognitive FSST Times by Age Group

A recorded FSST or Cognitive FSST score was the best time of two sequential trials. Mean times and comparisons between age groups are reported in Table 4. Times on the FSST and Cognitive FSST increased with age and ANOVA tests demonstrated a significance difference in performances between age groups. Scheffe’s pairwise
comparisons determined the oldest individuals required significantly more time to complete the FSST than either the middle or youngest age groups, and significantly more time than the youngest age group on the Cognitive FSST. Pairwise differences demonstrated significance at $p \leq .001$.

Table 4. FSST and Cognitive FSST by Age Group: Means, Standard Deviations, and ANOVA Tests

<table>
<thead>
<tr>
<th>Age Group</th>
<th>FSST Time (sec) M ± SD</th>
<th>ANOVA</th>
<th>Cognitive FSST Time (sec) M ± SD</th>
<th>ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-39</td>
<td>6.14 ± 1.27</td>
<td>F (2,82) = 12.940</td>
<td>9.64 ± 3.41</td>
<td></td>
</tr>
<tr>
<td>40-59</td>
<td>6.68 ± 1.68</td>
<td>$p &lt; .001$</td>
<td>10.75 ± 4.17</td>
<td>F (2,82) = 7.69</td>
</tr>
<tr>
<td>≥ 60</td>
<td>9.77 ± 4.56</td>
<td></td>
<td>13.36 ± 3.92</td>
<td>$p = .001$</td>
</tr>
</tbody>
</table>

Figure 3. FSST times by gender and age.
FSST by Gender and Age

Times for the FSST were analyzed by gender and age groups using a Two-Way ANOVA test. There was no demonstrated interaction between gender and age for the FSST ($F[2, 79] = .222, p = .802, power = .084$); females and males responded similarly across the age groups. In addition, there was no difference between males and females for the main effect of gender ($F[1, 79] = 1.326, p = .253, power = .206$). There was a significant difference for the main effect of age groups, ($F[2,79] = 11.353, p < .001$, power = .991). The ≥ 60 age group required significantly more time to complete the FSST than either the youngest or middle age group, $p < .001$ and $p < .002$, respectively. (Figure 3 and Table 5)

Table 5. FSST Data by Gender and Age: Means, Standard Deviations, and Two-Way ANOVA Test Results

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Females</th>
<th></th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Time in Seconds M±SD</td>
<td>n</td>
</tr>
<tr>
<td>20-39</td>
<td>19</td>
<td>6.68 ± 0.96</td>
<td>12</td>
</tr>
<tr>
<td>40-59</td>
<td>13</td>
<td>6.93 ± 1.45</td>
<td>10</td>
</tr>
<tr>
<td>≥ 60</td>
<td>22</td>
<td>9.88 ± 5.07</td>
<td>9</td>
</tr>
</tbody>
</table>

Two-Way ANOVA Test Results

<table>
<thead>
<tr>
<th>Interaction, Gender and Age</th>
<th>$F[2,79] = .222, p = .802, power = .084$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Effect, Gender</td>
<td>$F[1, 79] = 1.326, p = .253, power = .206$</td>
</tr>
<tr>
<td>Main Effect, Age</td>
<td>$F[2,79] = 11.353, p &lt; .001, power = .991$</td>
</tr>
</tbody>
</table>
Cognitive FSST by Gender and Age

Times for the Cognitive FSST were analyzed by gender and age using a Two-Way ANOVA test. There was a demonstrated interaction between gender and age (F [2, 79] = 7.368, p = .001, $\eta^2 = .157$, power = .931). Females and males did not respond similarly across the age groups. (Figure 4 and Table 6) In addition, the simple main effects for gender and age were significant. (Gender: F [1, 79] = 5.441, p = .022. Age: (F [2, 79] =12.951, p < .001). Mean times for the males were significantly faster than the times for women in the younger and middle age groups. The mean times for the women were not significantly difference between the age groups. The males in the ≥ 60 age group required significantly more time to complete the FSST than males in either younger age group (p < .001 for both comparisons).

![Figure 4. Cognitive FSST scores by gender and age.](image)
Table 6. Cognitive FSST Data by Gender and Age: Means, Standard Deviations, and Two way ANOVA Test Results

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>Females</th>
<th></th>
<th></th>
<th>Males</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Time (sec) M ± SD</td>
<td>n</td>
<td>Time (sec) M ± SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-39</td>
<td>19</td>
<td>11.15 ± 3.22</td>
<td>12</td>
<td>7.26 ± 2.14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-59</td>
<td>13</td>
<td>12.52 ± 3.75</td>
<td>10</td>
<td>8.44 ± 3.65</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 60</td>
<td>22</td>
<td>12.65 ± 3.97</td>
<td>9</td>
<td>15.09 ± 3.39</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Two-Way ANOVA Test Results

<table>
<thead>
<tr>
<th>Interaction, Gender and Age</th>
<th>F [2, 79] = 7.368, p = .001, ( \eta^2 = .157 ), power = .931</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Effect, Gender</td>
<td>F [1, 79] = 5.441, p = .022, ( \eta^2 = .064 ), power = .635</td>
</tr>
<tr>
<td>Main Effect, Age</td>
<td>F [2,79] = 12.951, p &lt; .001, ( \eta^2 = .247 ), power = .996</td>
</tr>
</tbody>
</table>

Unsuccessful Trials on the FSST and Cognitive FSST prior to Completion of a Test

Prior to recording the FSST and Cognitive FSST times, the participant must have completed two consecutive trials with no error in sequencing or touching of the sticks. The number of unsuccessful trials prior to completion of either test was recorded as ‘0,’ ‘1,’ or ‘≥ 2.’ The number of unsuccessful trials did not impact FSST or Cognitive FSST times; i.e., there were no differences in times between trial groups for either the FSST (F (2,82) = .445, p = .643, power = .120) or Cognitive FSST (F (2,82) = 1.113, p = .333, power = .240).
Exercise and Activity Levels Effects on the FSST and Cognitive FSST Times

Times on the FSST and Cognitive FSST were investigated relative to exercise habits and activity levels. There was no significant difference in test times between exercises and non-exercisers on the FSST (t (83) = 1.003, p = 0.319) or on the Cognitive FSST (t (83) = 0.779, p = 0.438). Frequency of activity, categorized as inactive/minimally active, moderately active, or highly active, did not impact FSST and Cognitive FSST times, with F (2, 82) = 0.609, p = 0.547, power = 0.148 and F (2, 82) = 0.071, p = 0.931, power = 0.060, respectively.

FSST and Cognitive FSST Times and Fall Risk

Participants’ fall risk scores were calculated using the CDC Fall Risk Checklist; a score of four or more indicates an increased risk of falling. Individuals at risk of falling demonstrated longer FSST times than those not at risk of falling (12.71±4.61 and 7.29±3.07 seconds, respectively; t (83) = 3.724, p < .001). Fall risk scores were also categorized into three groups, i.e., a risk score of ‘0’, ‘1-3’, or ‘≥ 4’. Again, there were significant differences in FSST times between categories (F (1, 82) = 10.474, p<.001, $\eta^2=.203$, power=.986. In pairwise comparisons, each of the means was significantly different from the other means; as the risk score increased, so did the FSST time. On the Cognitive FSST, there was no significant difference in times between the fall risk groups. (t(83) = 1.69, p=.095, or F(2, 82) = 1.610, p=206, power=.332.)

FSST and Cognitive FSST Times and Fall History

Participants reported the number falls experienced in the past year. Fifteen of the 85 participants (18%) reported at least one fall in the past year. While those who had fallen demonstrated longer times on the FSST than non-fallers, mean times were still under the
15 second marker for risk of falling. Neither the FSST nor Cognitive FSST times were significantly different between those who fell and those who had not fallen (Table 7).

Table 7. FSST and Cognitive FSST Times of Non-Fallers compared to Fallers, Means, Standard Deviations, and t-Tests

<table>
<thead>
<tr>
<th></th>
<th>Non-Fallers</th>
<th>Fallers</th>
<th>t-Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Time (sec) M ± SD</td>
<td>n</td>
</tr>
<tr>
<td>FSST</td>
<td>70</td>
<td>7.11 ± 2.08</td>
<td>15</td>
</tr>
<tr>
<td>Cognitive FSST</td>
<td>70</td>
<td>11.11 ± 3.92</td>
<td>15</td>
</tr>
</tbody>
</table>

FSST and Cognitive FSST Times Relative to Fall History and Age

FSST times were influenced by the fall history and age. (Table 8 and Figures 5 and 6) For the non-fallers, times were significantly longer for the oldest versus the youngest age group; for fallers, times were significantly longer for the oldest and both younger groups. FSST times were similar for non-fallers and fallers in the younger and middle age groups. In the 60+ age group, however, times were significantly longer for those who reported having fallen in the past year. There were proportionately more fallers in the 60+ age group compared to the younger and middle age groups (26% versus 10% and 17%, respectively). No group exceeded the FSST fall risk cut-off score of 15 seconds previously established for geriatric individuals.

Cognitive FSST Times Relative to Fall History and Age

For the Cognitive FSST, age and fall history did not interact to influence test time; in addition, the fall history alone did not affect test times. As seen in earlier analyses, age did influence times on the Cognitive FSST. (Table 9 and Figures 7 and 8)
Table 8. FSST Times of Non-Fallers and Fallers by Age Group

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>Non-Fallers</th>
<th>Fallers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time (sec)</td>
<td>n</td>
</tr>
<tr>
<td></td>
<td>M ± SD</td>
<td></td>
</tr>
<tr>
<td>20-39</td>
<td>6.01 ± 1.26</td>
<td>28</td>
</tr>
<tr>
<td>40-59</td>
<td>6.94 ± 1.62</td>
<td>19</td>
</tr>
<tr>
<td>≥ 60</td>
<td>8.61 ± 2.37</td>
<td>23</td>
</tr>
</tbody>
</table>

Two-Way ANOVA Test Results

Interaction, Fall History and Age: F [2,79] = 5.207, p = .008, $\eta^2 = .116$, power = .816

Main Effect, Fall History: F [1, 79] = 2.982, p = .088, power = .400

Main Effect, Age: F [2, 79] = 15.666, p < .001, $\eta^2 = .284$, power = .999

Figure 5. FSST Scores of fallers vs. non-fallers by age group.
Figure 6. FSST scores of non-fallers vs. fallers for those ≥ 60 years.

The mean time from the oldest age group was significantly longer than the times from either of the younger groups. Again, no group exceeded the FSST fall risk cut-off score of 15 seconds previously established for geriatric individuals.

Figure 7. Cognitive FSST scores of fallers vs. non-fallers by age group.
Table 9. Cognitive FSST Times of Non-Fallers and Fallers by Age Group

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>Non-Fallers</th>
<th>Fallers</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Time (sec)</td>
<td>n</td>
<td>Time (sec)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>M ± SD</td>
<td></td>
<td>M ± SD</td>
</tr>
<tr>
<td>40-59</td>
<td>19</td>
<td>11.34 ± 4.13</td>
<td>4</td>
<td>7.95 ± 3.53</td>
</tr>
<tr>
<td>≥ 60</td>
<td>23</td>
<td>12.91 ± 14.64</td>
<td>8</td>
<td>14.64 ± 4.94</td>
</tr>
</tbody>
</table>

Two-Way ANOVA Test Results

- Interaction, Fall History and Age: $F[2, 79] = 2.166, p = .121, \text{power} = .431$
- Main Effect, Fall History: $F[1, 79] = .000, p = .996, \text{power} = .050$
- Main Effect, Age: $F[2, 79] = 6.247, p = .003, \eta^2 = .137, \text{power} = .884$

Figure 8. Cognitive FSST scores by age group.
CHAPTER IV
DISCUSSION

The purpose of this study was to collect normative data for gender and age groups in healthy community dwelling adults and the impact of adding a cognitive component to the FSST. This is the first study to describe the impact of a cognitive task with the FSST. According to the results, score times on the FSST and Cognitive FSST tended to increase within age groups. When adding a cognitive task to the FSST, female score times were consistent throughout age groups, but male score times increased in the oldest age group (60+). There was a trend between fall risk and cognitive memory scores on the Mini-Cog. Two of the three participants were identified as a fall risk on the FSST (cut off score >15 seconds) and CDC Fall Risk Checklist (score of ≥4), and had a positive Mini-Cog score.

This study found of an average time of 9.76 +/- 4.56 seconds for 60+ age group. In a study done by Isik et al\textsuperscript{16} found an average FSST score in 60+ age group to be 15.24 +/- 5.06 seconds. The average age of the participants was 72.67 +/- 5.09 years compared to the average age 67.8 year. The inclusion and exclusion criterion was similar to this study, but their population focus was 65-85 years old. Their data showed a larger mean score for this age group, with a difference of 5.48 seconds. This could be explained by a larger sample size (n=80) in their study. Isik et al\textsuperscript{16} also had more males (55%) than females (45%), whereas this study had two and a half times more females than males.
(60+) which could affect average scores. Both this study and Isik’s had large standard deviations, showing variability within the group.

This study found that in the 20-39 years group, males scored 5.28 +/- 1.27 seconds and females scored 6.68 +/- 0.96 seconds. A study done by Wilken et al\textsuperscript{17} found average FSST scores to be in males (n=130), it found the average FSST to be 5.7 +/- 1.0 seconds and females (n=50) 6.0 +/- 1.0 seconds for ages 18-43 years old. The study was done on military personnel and had similar inclusion and exclusion criteria. The study did not assess the averages for specific age groups, but has similar results when compared to our study. These results are within 0.42 - 0.68 seconds of this study’s findings. Some reasons for the difference may be that Wilken’s study was done on active training military personnel, who may be in better physical condition than this study’s participants. Wilken also had a significantly larger sample size for males and females. However, these results are still comparable and show the validity of our results.

There was also a significant difference in scores when assessing falls and falls risk. There were twice as many falls reported in the 60+ year’s group compared to the 40-59 years group. Those who reported at least one fall had significantly higher scores only in the 60+ years group. Also, those who had an increased risk of falls according the CDC Fall Risk Checklist had higher scores than those with lower CDC fall risk scores. The significance was only found with the FSST, and no significant difference on fallers with the Cognitive FSST. This adds validity and reliability to this study’s findings and the ability of the FSST to detect falls risk. This also shows that there is further research needed to assess the ability of the Cognitive FSST to detect falls and to establish fall risk cut off scores. However, a study by Muir-Hunter and Wittwer\textsuperscript{18} found the use of dual-
task testing in balance assessment, specifically quiet stance or stepping reactions responses was of no benefit in identifying individuals who were at an increased risk of falls. Muir-Hunter and Wittwer’s findings agree with this study’s findings of no significant difference in identifying fallers using dual-task (Cognitive FSST).

There were only three participants who scored greater than 15 seconds on the FSST, which is the cut-off score for being at risk of falling. However, there were 12 participants who reported falling in the past year, but were not identified as a fall risk by the FSST. This causes question to the environment and situations in which these 12 participants fell. If it was strictly an environmental reason that the participant fell (i.e. icy driveway), then they might not have FSST scores showing a fall risk. If the fall was related to an internal loss of balance or not clearing their foot over an obstacle, they would be more likely to have higher scores on the FSST. Trends in the testing showed that up to half of the people in all age groups experienced at least one incomplete test trial due to inaccurate sequencing or touching the sticks, as opposed to losing their balance. However, data was not collected on the participant’s reason and environment when his/her fall(s) occurred.

Limitations of this study included a small sample size within each age group (n~30) and a disparity between genders, impacting the statistics for score times. This study found that males tended to have lower scores on the FSST and Cognitive FSST. There was a significant increase in scores in males from 40-59 years group to the 60+ years group. However, the 60+ male group only had 9 participants, which could have affected the data and is a limitation of this study. A majority of the younger adults were recruited as a sample of convenience due to the location of testing, while a majority of
the older adults were members of the senior center. A third possible limitation would be
the reliability of the Mini-Cog for testing cognitive impairment. The Mini-Cog is
considered a valid and reliable tool to diagnosis dementia in community-dwelling older
adults. However, it is not recommended to be the only assessment performed when
screening for mild cognitive impairments. There were 2 participants in the study that had
positive scores for cognitive impairment on the Mini-Cog, but performed similar to their
peers on the cognitive FSST. One of these participants was late to his/her scheduled time
and seemed rushed and stressed while going through the research study. This could have
been a reason why he/she did not perform well on the Mini-Cog. This calls to question
the validity of the Mini-Cog for screening for cognitive impairment in the general
population and how personal and environmental factors may have an effect on the
participants score. The Mini-Cog has only been evaluated in older adults. A systematic
review found executive function impairment, even subtle deficits in healthy community-
dwelling older adults, was associated with an increased risk for any fall.

Future studies could include a continuation of the study with an increase in the
sample size and more focus on the Cognitive FSST to establish a fall risk cut off score,
reliability, and validity. It would also be beneficial to look into using different cognitive
screening tasks.
CHAPTER V

CONCLUSION

More than one out of four older people fall each year, but less than half tells their doctor. Falling once doubles your chances of falling again.¹ Physical therapist role is to identify individuals with increased risk of falls and to work with them on fall prevention strategies and environmental adaptations to decrease the likelihood of a fall occurring. This is why it is important to develop valid and reliable tests and measures to assess those at risk of falling. The FSST is a quick and inexpensive balance assessment commonly used in the clinic to determine if a patient is at risk for falling. Cognitive FSST creates a more challenging assessment integrating a multi-task activity when assessing balance allowing the physical therapists to further assess functional abilities.
APPENDIX A

IRB
March 29, 2018

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Kristin Johnson Thomanschefsky, DPT and Meridee Danks, DPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td>Establishing Normative Data for the Four Square Step Test</td>
</tr>
<tr>
<td>IRB Project Number:</td>
<td>IRB-201803-277</td>
</tr>
<tr>
<td>Project Review Level:</td>
<td>Expedited 4, 7</td>
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<tr>
<td>Date of IRB Approval:</td>
<td>03/26/2018</td>
</tr>
<tr>
<td>Expiration Date of This Approval:</td>
<td>03/25/2019</td>
</tr>
<tr>
<td>Consent Form Approval Date:</td>
<td>03/26/2018</td>
</tr>
</tbody>
</table>

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your original consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. **You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

**The Principal Investigators must provide a Letter of Support from Grand Forks YMCA, Choice Health and Fitness Center, and/or Grand Forks Senior Center to the UND IRB Office prior to beginning any research.**

Prior to implementation, submit any changes to or departures from the protocol or consent form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: [http://und.edu/research/resources/human-subjects/](http://und.edu/research/resources/human-subjects/)

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Manager

MLB/sb
Enclosures

Cc: Chair, Physical Therapy
All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted — responses must be typed on the form.

**Principal Investigator:** Kristin Johnson Thomschefskey (co-PI) and Meridee Danks (co-PI)

**Telephone:** 777-2831

**E-mail Address:** Kristin.L.Johnson@med.und.edu  
Meridee.Danks@med.und.edu

**Complete Mailing Address:** 1310 N Columbia Road Stop 9037, Grand Forks, ND 58202-9037

**School/College:** UND SMHS  
**Department:** Physical Therapy

**Student Advisor (if applicable):**

**Telephone:**

**E-mail Address:**

**Address or Box #:**

**School/College:**

**Department:**

***All IRB applications must include a Key Personnel Listing.***

**Project Title:** Establishing Normative Data for the Four Square Step Test

**Proposed Project Dates:**

**Beginning Date:** March 2018  
**Completion Date:** Ongoing (Including data analysis)

**Funding agencies supporting this research:**

**Did the grant proposal with the funding entity go through UND Grants & Contracts Admin.?**

- [ ] YES  
- [X] NO

Attach a copy of the grant proposal. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the grant proposal submitted to the funding agency.

- [ ] YES  
- [X] NO

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

- [X] YES  
- [ ] NO

Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

- [X] YES  
- [ ] NO

Will any data be collected at or obtained from another organization outside the University of North Dakota?
If yes to either of the previous two questions, list all organizations: Grand Forks YMCA, Choice Health and Fitness Center, and/or Grand Forks Senior Center

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB? □ YES □ NO □ N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? □ YES □ NO □ N/A

(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

<table>
<thead>
<tr>
<th>Date submitted:</th>
<th>Status: □ Approved □ Pending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date submitted:</td>
<td>Status: □ Approved □ Pending</td>
</tr>
</tbody>
</table>

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

**Type of Project:** Check "Yes" or "No" for each of the following.

□ YES or □ NO New Project
□ YES or □ NO Continuation/Renewal
□ YES or □ NO Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.
□ YES or □ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA
□ YES or □ NO Does your project include Genetic Research?

**Subject Classification:** This study will involve subjects who are in the following special populations: Check all that apply.

□ Children (< 18 years) □ UND Students
□ Prisoners □ Pregnant Women/Fetuses
□ Cognitively impaired persons or persons unable to consent
□ Other ____________

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

**This study will involve:** Check all that apply.

□ Deception (Attach Waiver or Alteration of Informed Consent Requirements) □ Stem Cells
□ Radiation □ Discarded Tissue
□ New Drugs (IND) IND # _______ Attach Approval □ Fetal Tissue
□ Investigational Device Exemption (IDE) # _______ Attach Approval □ Human Blood or Fluids
□ Non-approved Use of Drug(s) □ Other ______

**I. Project Overview**

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

For community dwelling individuals, balance and mobility are of great concern to maintain independence. Impairments can lead to difficulty stepping over small objects, managing uneven terrain, and changing directions while walking. Physical Therapists evaluate balance through various tests including the Four Square Step Test (FSST). The FSST is a multidirectional stepping test that examines a person's ability to...
quickly step over objects forward, sideways, and backward. There is limited normative data established for the FSST. The aim of this study is to establish normative data for community dwelling adults for the standard and dual task FSST.

II. Protocol Description
Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.
   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. Participants will be recruited by word of mouth and flyers to be set up at the UND School of Medicine and Health Science, YMCA, Choice Health and Fitness Center, and/or Grand Forks Senior Center.
   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the “Subject Classification” section above. Participants need to be healthy community-dwelling individuals who are 18 years or older and able to walk independently with or without a cane for community distances.
   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Exclusion criteria includes anyone who requires an assistive device other than a cane for walking, acute injuries limiting their ability to walk, and cognitive impairments limiting their ability to follow directions.
   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. The goal is to recruit at least 30 subjects with a variety of age ranges to participate in the research study.
   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.
      N/A, this is a pilot study.

2. Description of Methodology.
   a) Describe the procedures used to obtain informed consent. Participants will be asked if they would like to be a part of this study. If they are interested, they will be given an informed consent form to review. Questions will be addressed and if willing to participate signatures will be obtained. Each volunteer will be given a copy of the consent form.
   b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research. University of North Dakota School of Medicine Health Sciences, Physical Therapy lab room, in Grand Forks, ND. A private room will be designated at the YMCA, Choice Health and Fitness Center, and/or Grand Forks Senior Center.
   c) Indicate who will carry out the research procedures. Meridee Danks and Kristin Johnson Thomanschefsky, physical therapists and instructors from UND physical therapy department; UND-PT graduate students will be assisting as needed.
   d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them. Assessment will take place within a single session (approx. 25-30 minutes) for each subject. Assessment will include the following:
      1. Baseline Questionnaire and Fall Risk Survey will be filled out as part of the research study. Questionnaire and survey are to gather demographic, mobility, and fall information. Time to complete is ~ 10 minutes.
2. Mini Cog is completed to quantify cognitive function ~ 5 minutes. The Mini Cog is a commonly used cognitive test that consists of a quick mental screening.

3. Four Square Step Test - This is a standardized test used to assess balance and reaction time. The test requires the subject to complete a sequence of stepping forward, backward, and sideways in a clockwise direction, then reversed, over four 1/2-inch PVC pipes placed in a cross configuration on the ground. The participant is instructed to step as fast as possible without touching the PVC pipes. Both feet must make contact with the floor in each square. The time to complete the activity is recorded. One demonstration and one practice trial is completed to ensure the subject knows the sequence. FSST trials are completed until two successful trials are obtained. The test will be repeated with a cognitive task (dual task FSST). Participants will be instructed to count backwards by 3's (or by other numbers) while completing the FSST. A trial is repeated if the subject fails to complete the sequence successfully, loses balance, or makes contact with the PVC pipes during the sequence. Two successful trials will be obtained. A safety gait belt will be used and a spotter present when performing the assessment. Time to complete is less than 10 minutes.

e) Describe audio/visual procedures and proper disposal of tapes.
   A designated iPad will be used to record subjects trials during the FSST. The iPad will be used just for this research and the recordings will be downloaded to a protected computer and then deleted from the iPad. The recordings will be kept a minimum of 3 years and then will be deleted.

f) Describe the qualifications of the individuals conducting all procedures used in the study.
   Meridee Danks, DPT, NCS has been a practicing physical therapist for 34 years and has a speciality certification in Neurologic Physical Therapy. Kristin Johnson Thomanschefsky, DPT, NCS, GCS has been practicing physical therapy for 33 years and has a speciality certification in both Neurologic and Geriatric Physical Therapy. Physical therapy graduate students will be assisting with the project. UND-PT students will be supervised and trained as needed. All students have IRB training completed.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).
   N/A

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.


   a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
      There is a minimal risk of loss of balance with the Four Square Step Test. This test will be performed with a safety gait belt and spotter to prevent any falls. Some participants may feel overly challenged by the cognitive portion of the test. If it proves too challenging, this portion of the test will be adapted (counting backwards by 5's, etc.) or excluded. The subject will be instructed they can quit the activity at any time if they do not feel safe performing the activity or if it is too challenging.

   b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
      There will be a link to the subject's consent form to compare to questionnaire and survey data.

   c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
      NA

   d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
      NA
4. Subject Protection.

   a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

   A safety gait belt and spotter will be used during each trial of the assessment. If it proves too challenging, this portion of the test will be adapted (counting backwards by 5's, etc.) or excluded. The subject will be instructed they can quit the activity at any time if they do not feel safe performing the activity or if it is too challenging.

   b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

   All data will be coded and identifying information removed once all data is gathered. Any reporting will be in aggregate form. The assessments will be performed in a private room.

   c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

   Each subject will be provided with a copy of the consent form prior to participation.

   d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

   Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)

   2) who will have access to the data

   3) how the data will be destroyed

   4) the storage location of consent forms and personal data (separate from research data)

   5) how the consent forms will be destroyed

   1. The research data will be stored in a locked office in the physical therapy department. It will be stored separately from the consent form and other personal data.

   2. Only the researchers will have access to the data. If statistician is required, only unidentified data with be shared.

   3. The data will be kept a minimum of 3 years and will be shredded once data analysis is completed.

   4. Consent forms/personal data and research data will be stored in separate files in the locked office of the researcher.

   5. The consent forms will be kept a minimum of 3 years and then will be shredded.

   e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

   Referrals will be made to family physician if any adverse reactions occur during testing or if subjects have concerns regarding their balance or mobility.

   f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

   Participants will be referred for medical treatment if required for any injury that may occur during assessment. The responsibility of cost related to any treatment will be the responsibility of the subject.

III. Benefits of the Study

   Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

   Subjects will be able to have their balance assessed at no cost. This study will benefit physical therapists by further testing the FSST for clinical use.

IV. Consent Form

   Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply
stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form:

1) The person who will conduct the consent interview
2) The person who will provide consent or permission
3) Any waiting period between informing the prospective participant and obtaining consent
4) Steps taken to minimize the possibility of coercion or undue influence
5) The language (English, French, German, etc.) to be used by those obtaining consent
6) The language (English, French, German, etc.) understood by the prospective participant or the legally authorized representative
7) The information to be communicated to the prospective participant or the legally authorized representative

1. Meridee Danks and/or Kristin Johnson Thomanschefsky will conduct the consent interview
2. Meridee Danks and/or Kristin Johnson Thomanschefsky will provide the consent forms.
3. No waiting period. Testing will be done the same day. Clients will be given time to consider if they want to participate.
4. Prospective subjects will be told that research is voluntary and if they do decide to participate they are able to stop at any time without any penalty.
5. English
6. English
7. The consent form will indicate the assessments to be performed and the amount of time to perform them and who will be performing the assessments.

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. **Please note:** All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8th grade reading level and must be written in the second person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

**Necessary attachments:**

- Signed Student Consent to Release of Educational Record Form (students and medical residents only);
- Investigator Letter of Assurance of Compliance; (all researchers)
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Key Personnel Listing
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
- Advertisements (flyer, social media postings, email/letters, etc.).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

**Signatures:**

[Signature]

(Principal Investigator)  

[Signature]

(Student Advisor)  

Date:

**All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.**

**Requirements for submitting proposals:**

Additional information can be found on the IRB website at: [http://www.unc.edu/research/resources/human-subjects/index.cfm](http://www.unc.edu/research/resources/human-subjects/index.cfm)
APPENDIX B

INFORMED CONSENT
THE UNIVERSITY OF NORTH DAKOTA

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Establishing Normative Data for the Four Square Step Test
PROJECT DIRECTOR: Kristin Johnson Thomanschefsky
PHONE #: 701-777-2831
DEPARTMENT: Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be a volunteer in a research study about the Four Square Step Test (FSST). The FSST is a stepping test that looks at the person's ability to quickly step over small objects forward, sideways, and backward. Participants are required to be a community dwelling adult (18 years and older), be able to walk without an assistive device and be able to follow directions. You will be excluded if you have any recent injuries impairing your walking.

The purpose of this research study is to establish normative data on the Four Square Step Test for healthy adults. There is currently limited data established for the FSST. For the community dwelling individuals, balance and mobility are of great concern to maintain independence. Impairments can lead to difficulty stepping over small objects, walking over uneven surfaces and changing direction.

HOW MANY PEOPLE WILL PARTICIPATE?

At least 30 people will take part in this study. Participants will be recruited from the local Grand Forks area.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last approximately 25-30 minutes for a single session.

Approval Date: MAR 26 2018
Expiration Date: MAR 25 2019
University of North Dakota IRB
WHAT WILL HAPPEN DURING THIS STUDY?

1. You will fill out a baseline questionnaire and Fall Risk Survey as part of the research study. Questionnaire and survey are to gather demographic, mobility, and fall information. Time to complete is ~ 10 minutes. When completing the questionnaire and survey, you may skip questions that you would prefer not to answer.
2. Mini Cog is completed to measure cognitive function ~ 5 minutes. The Mini Cog is a commonly used cognitive test that consists of a quick mental screening.
3. Four Square Step Test - This is a standardized test used to assess balance and reaction time. The test requires the subject to complete a sequence of stepping forward, backward, and sideways in a clockwise direction, then reversed, over four 1/2-inch plastic pipes placed in a X on the ground. You will be instructed to step as fast as possible without touching the plastic pipes. The time to complete the activity is recorded. One demonstration and one practice trial are completed. FSST trials are completed until two successful trials are obtained. The test will be repeated with a subtraction task. Repeat trials may be necessary to achieve two successful trials. A safety gait belt will be used and a spotter present when performing the assessment. Your performance will be video recorded to help with accurate assessment. Time to complete is less than 10 minutes.

WHAT ARE THE RISKS OF THE STUDY?

There is a minimal risk of loss of balance with the Four Square Step Test. This test will be performed with a safety gait belt and spotter to prevent any falls. You may feel overly challenged by the cognitive portion of the test. If it proves too challenging, this portion of the test will be adapted or excluded. If, however, you become upset by task at hand, you may stop at any time or choose not to complete the task.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will be able to have your balance assessed at no cost. We also hope that, in the future, other people might benefit from this study because of the normal scores we find may help identify those with a risk of falling, so health care providers can provide interventions to prevent falls.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THE STUDY?

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.
CONFIDENTIALITY

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of only allowing researchers to look at identifying data and securing all data and forms in a locked office. All data will be coded and identifying information removed once all data is gathered. If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified. Any recorded video will be viewed by only researchers, used only for educational purposes, and will be erased following the completion of the study. The assessments will be performed in a private room.

IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate, or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your current or future relations with the University of North Dakota.

CONTACTS AND QUESTIONS?

The researchers conducting this study are Kristin Johnson Thomanschefsky and Meridee Danks. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Kristin or Meridee at 701-777-2831 during the day.

If you have questions regarding your rights as a research subject, you may contact The University of North Dakota Institutional Review Board at (701) 777-4279 or UND.irb@research.UND.edu.

- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking “Information for Research Participants” on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm
I give consent to be video recorded during this study.

Please initial: _____ Yes _____ No

I give consent for my quotes to be used in the research; however, I will not be identified.

Please initial: _____ Yes _____ No

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (Printed):

__________________________________________________________

Signature of Subject ________________________________________ Date ________________

I have discussed the above points with the subject.

__________________________________________________________

Signature of Person Who Obtained Consent _______________________ Date ________________

Approval Date: MAR 26 2018
Expiration Date: MAR 25 2019
University of North Dakota IRB
APPENDIX C

CDC FALL RISK CHECKLIST
Please Circle “Yes” or “No” for watch statement below. ( ) indicated # of points.

Yes (2) No I have fallen in the past year. If yes, how many time? ______
Yes (2) No I use or have been advised to use a cane or walker to get around
   *If yes, what assistive device do you use most often?
Yes (1) No Sometimes I feel unsteady when I am walk
Yes (1) No I steady myself by holding onto furniture when walking at home.
Yes (1) No I am worried about falling.
Yes (1) No I need to push my hands to stand up from a chair.
Yes (1) No I have some trouble stepping up onto a curb.
Yes (1) No I have lost some feeling in my feet.
Yes (1) No I take medication that sometimes makes me feel light-headed or more
tired than usual.
   *How many prescription medicines do you take per day?_________
Yes (1) No I take medicine to help me sleep or improve my mood.
Yes (1) No I often feel sad or depressed.

Total______ Add up the number of points for each “Yes” answer. Scores greater than 4 may indicate a higher risk of falling.
APPENDIX D

BASELINE QUESTIONNAIRE
Baseline Questionnaire

What is your age? ______ Gender? ______

Yes   No  Have you had any surgeries or major health issues in the past?
      If yes, please list;

Yes   No  Have you had a recent injury that has affected your ability to walk?
      If yes, explain.

Yes   No  Do you have difficulty with walking or balance?
      If yes, explain.

Yes   No  Do you exercise regularly (3x/week or more)?
      If yes, what type of exercise and how often do you perform it?

How would you rate your physical activity level? (Circle One)

Inactive   Minimally Active   Moderately Active   Highly Active
APPENDIX E

MINI-COG
## MINI-COG™

### Instructions

**ADMINISTRATION**

1. Get patient's attention and ask him or her to remember three unrelated words. Ask patient to repeat the words to ensure the learning was correct.

**SPECIAL INSTRUCTIONS**

- Allow patient three tries, then go to next item.
- The following word lists have been validated in a clinical study:1-3

<table>
<thead>
<tr>
<th>Version 1</th>
<th>Version 3</th>
<th>Version 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana</td>
<td>Village</td>
<td>Captain</td>
</tr>
<tr>
<td>Sunrise</td>
<td>Kitchen</td>
<td>Garden</td>
</tr>
<tr>
<td>Chair</td>
<td>Baby</td>
<td>Picture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Version 2</th>
<th>Version 4</th>
<th>Version 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daughter</td>
<td>River</td>
<td>Leader</td>
</tr>
<tr>
<td>Heaven</td>
<td>Nation</td>
<td>Season</td>
</tr>
<tr>
<td>Mountain</td>
<td>Finger</td>
<td>Table</td>
</tr>
</tbody>
</table>

2. Ask patient to draw the face of a clock. After numbers are on the face, ask patient to draw hands to read 10 minutes after 11:00 (or 20 minutes after 8:00).

- Either a blank piece of paper or a preprinted circle (other side) may be used.
- A correct response is all numbers placed in approximately the correct positions AND the hands pointing to the 11 and 2 (or the 4 and 8).
- These two specific times are more sensitive than others.
- A clock should not be visible to the patient during this task.
- Refusal to draw a clock is scored abnormal.
- Move to next step if clock not complete within three minutes.

3. Ask the patient to recall the three words from Step 1.

Ask the patient to recall the three words you stated in Step 1.

### Scoring

- **3 recalled words**
  - Negative for cognitive impairment

- **1-2 recalled words + normal CDT**
  - Negative for cognitive impairment
  
- **1-2 recalled words + abnormal CDT**
  - Positive for cognitive impairment

- **0 recalled words**
  - Positive for cognitive impairment

### References


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REFERENCES


