Single Leg Stance Intervention Protocol Summary

a. **Researchers:** Jeffrey Damaschke PT, DPT, OCS, CSCS; Tiffany Krebel SPT; Catherine Prince SPT; Monica Rangel SPT; Grant Robinson SPT.

b. **Title:** *The Effects of Balance Interventions on the Measure of Static Balance in a Normal Population: A Pilot Study*

c. **Purpose of Study**: To study the effect of balance training and commonly used interventions, including single leg stance with eyes open and eyes closed and single leg stance and the use of a Bodyblade, on static balance.

d. **Significance of study**: Findings from this research study can be useful in physical therapy practice when attempting to improve static balance. The balance training could be implemented as a therapeutic intervention to be used to improve static balance and reduce falls. The study could also provide insight to the validity of the interventions in clinical use.

e. **Hypothesis:** In a normal population (no neuromusculoskeletal conditions)**,** improvements in static balance, as measured by the SLST, will be noted in experimental groups, with the greatest improvements noted in static balance with the intervention using the Bodyblade.

f. **Study Design:** Randomized controlled trial; pilot study. One control group, one experimental intervention group using single leg stance as an intervention, and one experimental group using single leg stance and Bodyblade as an intervention.

g. **Sample Characteristics:** Inclusion Criteria: All Rosalind Franklin University students, staff and faculty between the ages of 18-65. Exclusion Criteria: Previous balance or vestibular problems, an injury to lower extremity in the past six months, and those who may be pregnant.

h. **Subject Recruitment:** Forty-five potential subjects will be used in this study. Fifteen subjects will be randomized into each group; control, single leg stance experimental, and single leg stance with Body Blade experimental. Flyers, e-mail and word of mouth will be used to recruit students, staff and faculty from Rosalind Franklin University of Medicine and Science.

i. **Financial Considerations:**
   1. Personnel-1 Primary Investigator, 4 Research Assistants - $0
   2. Equipment-(5) Bodyblades to use for intervention - $500.00 to 800.00; based on type of Bodyblade. Working with company.
   3. Facilities- Physical Therapy Lab at RFUMS- $0
   4. Supplies- Stop watch, paper for informed consent and data collection, scale and tape measure for weight, height and BMI of subjects- all supplied by Physical Therapy Department

j. **Risks to Subjects:** The physical risks are minimized to the participants by having a demonstration of the single leg stance test and having them practice for three trails. The researchers will stand by during the tests to insure safety of the subjects. Participants may experience emotional distress if they realize their measurements are not within normal range. This will be minimized for by blinding the participants to their results. In order to assure that no harm is done to anyone participating in our study we will exclude anyone who has a previous balance or vestibular problem, injury to lower extremity in the past six months, those who may be pregnant, and those who are not between the ages of 18-65. Participants may stop testing at any time during the study process. Coercion will be minimized by having the primary investigator not recruiting or testing student subjects.

k. **Benefits to Subjects/Society:** Society and subjects will benefit by gaining knowledge to the area of physical therapy. Depending on the results it may change or confirm the way physical therapists assess static balance which will improve how subjects are examined.

l. **Instruments:**
   1. The Single Limb Stance Test (SLST) is a diagnostic tool that requires nothing more than an individual with a trained eye and a stopwatch. Therefore, it is an ideal and inexpensive test to determine an individual's static balance performance in the clinical setting. It can be used to determine the effects of an intervention among groups of subjects and if the difference is large enough, monitor the functional improvement in patients with injuries to the lower extremities undergoing rehabilitation. The subjects will be instructed to stand barefoot on their non-dominant leg (determined by verbal questioning) on a level hard surface, within an outlined tape box on the floor. The dominant leg will be raised to the level of the knee on the contralateral leg but will not touch the contralateral leg. The arms will be crossed across the chest. The subject will focus on a mark located on the wall at eye level, 1m in front of the subject. The test will be assessed with eyes open and eyes closed. For eyes open timing till begin when the contralateral leg is raised to the level of the knee. For eyes closed, timing will begin once the eyes close. The subject will be instructed to stand as still as possible and to correct any sways in balance as quickly as possible. Prior to the test sessions, one practice round of 10 seconds will be made available. Testing will begin once the raised leg is in position for eyes open and once the eyes close for the eyes closed test. The subject will perform a maximal duration SLST up to 120 seconds. Rest periods of 30 seconds will be provided between each round. The test is terminated if the raised leg could not be maintained at knee level of the contralateral limb, the raised leg touches the floor, if the arms become uncrossed or move, if any part of the weight bearing foot moves onto the tape box, or if the eyes open

during an eyes closed test. Duration of the SLST will be recorded in seconds. Three test sessions for eyes open and three sessions for eyes closed will be taken with a rest break of 1 minute between each session eyes open and closed. The results from the three sessions will be averaged together.
2. This testing will take place prior to randomization into specific groups and then after 6 weeks of intervention.

m. **Procedure:**
1. Recruitment will be accomplished by advertisements through e-mail and flyers around Rosalind Franklin University. It will be voluntary and available to all RFUMS students, staff and faculty. A phone number and e-mail will be put on the flyer for subjects to call and set up an appointment time.
2. At the time of their appointment, the subjects will enter the Physical Therapy Lab at Rosalind Franklin University. They will first read and be explained about the informed consent document. After answering any questions, signing the informed consent and receiving a copy of the informed consent, the participants will fill out a demographic survey that will include variables of sex, age, weight and height and ask questions about inclusion and exclusion criteria. The weight and height will be used to calculate BMI.
3. Randomization will occur as to whether the subject performs the SLST with eyes open or closed will be randomized. This will be done by having the subject pick a piece of paper out of a hat. A black piece of paper means the subject performs the tests eyes closed first and white piece of paper means the subject performs the tests with eyes open first. There will be 20 pieces of paper. Half of each color and the piece of paper will be replaced into the hat after the subject draws.
4. The subject will then be shown how to properly perform the SLST for either eyes open or eyes closed, based on randomization. The subjects will be instructed to perform the timed single leg stance test. The participants will stand barefoot on their non-dominant leg, determined by verbal questioning, on a level hard surface within an outlined tape box on the floor. The dominant leg will be raised to the level of the knee on the contralateral leg but will not touch the contralateral leg. The arms will be crossed across the chest. The subject will focus on a mark located on the wall at eye level, 1m in front of the subject with eyes open, and timing will begin once the leg is raised in the correct position or once the eyes are closed, depending on the test. The subject will be instructed to stand as still as possible and to correct any sways in balance as quickly as possible. Prior to the test sessions, one practice round up to 10 seconds will be made available. A rest period of 30 seconds will be provided between each repetition. The subject will perform a maximal duration SLST up to 120 seconds. Duration of the SLST will be recorded in seconds. Three test repetitions with a rest break of 1 minute

between each repetition will be performed. The results from the three periods will be averaged. The single leg stance test will be terminated if the raised leg could not be maintained at knee level of the contralateral limb, the raised leg touches the floor, if the arms become uncrossed or move, if any part of the weight bearing foot moves onto the tape box, or if the eyes open.

5. A single tester for the timed SLST will be used and the tester performing the single leg stance test will be blinded to the numbers on the stop watch by having a piece of black paper covering the watch. One researcher will record these numbers to keep the tester blinded. The subjects will be blinded to the test results.

6. Assignment to one of three groups will be done randomly by pieces of paper out of a hat. Each piece of paper will be labeled "C" for control group, "SLS" for Single Limb Stance experimental group, and "SLSB" for Single Limb Stance Bodyblade experimental group.

7. The intervention phase of the study will be 6 weeks in duration.

    a. Subjects in the SLSB experimental group will use the Bodyblade. The subject will hold the body blade in front of them in one hand while producing rhythmic oscillated movements. The subject will practice standing on one leg in the single limb stance position while producing the oscillating movements with the body blade. They will also practice for 6 sets total for up to 1 minute each, 3 sets with eyes open and 3 sets with eyes closed.

    b. Subjects in the SLS experimental group will practice the single limb stance. They will stand on one leg for up to 1 minute, practicing for 6 sets total, 3 sets with eyes open and 3 sets with eyes closed. Subjects will practice this intervention three times a week.

    c. Subjects in the control group will not participate in any intervention.

8. Subjects will follow step 4 of the procedure for the post-test.

n. **Data Analysis:** Demographics will be analyzed using central tendencies, including age, gender, height, weight, and Body Mass Index. Control and experimental groups will be analyzed to insure there are no differences between groups prior to intervention. Groups will then be analyzed and compared to look for differences in outcomes due to interventions.

o. **Timetable**
    1. Jan-Feb 10-Collect Data
    2. Feb-Nov 10- Analyze data and write research paper
    3. Nov 10- Internal RFUMS Platform Presentation, Fall 2010 Illinois Physical Therapy Association Conference

p. **Confidentiality of Data-** All information regarding test records will be identified by using an assigned identification number. Records linking an individual to his/her identification number will be kept separate from test results on a password protected computer. Confidentiality of records identifying the participants will be maintained and safeguarded.

q. **Study Limitations-** The study is only taking place at Rosalind Franklin University. Therefore; this information is not representative of the whole world population. Also the results will only be applicable to healthy individuals between the ages of 18-65.

r. **Personnel:**
   1. 1 Primary Investigator: Jeffrey Damaschke, PT, DPT, MS, OCS
   2. 4 Research Assistants
      1. Tiffany Krebel SPT; CITI Trained in Human Research, BS; Exercise Science major
      2. Catherine Prince SPT; CITI Trained in Human Research, BS; Kinesiology Major
      3. Monica Rangel SPT; CITI Trained in Human Research, BS; Movement Sciences Major
      4. Grant Robinson SPT; CITI Trained in Human Research, BS; Exercise Science Major

s. **References:**

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