

Title of Project: Exercise intensity during interactive video games and standard of care of individuals post-stroke

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1. Purpose/Specific Aims

1.1 Objectives

To compare exercise intensity and enjoyment for persons post-stroke using customized video games (VSTEP), off-the-shelf video games (Kinect) and standard of care.

1.2 Hypotheses

We hypothesize that for persons post-stroke, exercise intensity, performance and enjoyment will be superior when participating in the VSTEP games, followed by standard of care and off-the-shelf games.

2. Background and Significance

The levels of physical activity among individuals post-stroke in the chronic phase rarely meet the recommendations of physical activity to promote health and for cardiovascular fitness. There is some evidence that activity-promoting video game (AVG) technologies promote physical activity. Off-the-shelf AVG consoles like the Microsoft Xbox with the Kinect sensor have been shown to enhance body movement and energy expenditure for healthy individuals and recent research has shown promise for individuals post-stroke. (Kafri, 2014) Off-the-shelf games are not designed for rehabilitation and often are too difficult for persons post-stroke. The VSTEP, consists of a series of mini games developed in the RIVERS lab for rehabilitation for balance, mobility, coordination, and fitness. They are customized to the users abilities and therefore may be better suited for persons post-stroke. This study will determine the differences in exercise intensity, performance and enjoyment levels while individuals post-stroke use the VSTEP compared to the off-the-shelf Xbox Kinect games and standard of care.

3. Research Design and Methods

Overview of study design: The proposed study will use an experimental cross-sectional design. It will be conducted in one session. During the first part of the session participants will be familiarized with the games. The second part of the session will have participants play interactive video games and perform mobility tasks. During this session data of energy expenditure and enjoyment of activity will be collected.

3.1. Duration of Study

Each subject will participate for approximately 2 hours.

3.2 Study Sites

RIVERS Lab SSB 723 or SSB 920

3.3 Sample Size Justification

This is a pilot trial and therefore will enroll 15 subjects. This number is comparable and in fact exceeds published articles in the neuro rehabilitation field.

3.4 Subject Selection and Enrollment Considerations

3.4.1 Inclusion Criteria

Participants will be men and women who will have sustained a stroke at least six months before enrolling in the study and will be between 19 and 80 years old. They will be able to ambulate 100 feet without physical assistance but allowed to use assistive devices and orthotics, and able to stand for 3 minutes. They will be screened for inclusion with the PARQ.

3.4.2 Exclusion Criteria

1. A history of severe heart disease, heart attack, valve replacement or coronary artery bypass surgery, severe lung disease, uncontrolled diabetes, traumatic brain injury or neurological disorder other than stroke.
2. Are unable to follow directions.
3. Do not have adequate vision and hearing ability (either aided or unaided with glasses, contacts or hearing aids)
4. Are unable to sign a consent form.
5. Unstable medical condition or musculoskeletal disorder such as severe arthritis, knee surgery, hip surgery, or any other condition that the investigators determine would impair the ability to perform the required stepping for the games presented.
6. Any other medical condition contraindications to exercise.

3.4.3 Subject Recruitment

Participants will be recruited by flyers and contacting previous participants in the RIVERS Lab studies who have agreed to be contacted for future studies. Recruitment flyer has been uploaded separately for ease of stamping. The email will be sent once the IRB approval is obtained to participants, both clinicians and persons post-stroke who have been involved in previous studies and expressed an interest in being contacted for future studies.

3.4.4 Consent Procedures

The study will be explained to the potential subjects by the Principal Investigator or co-investigators, the consent will be read, and the potential subject's questions will be answered. If they wish to enroll, the subjects will sign the consent form. The study staff obtaining consent will also sign and date the consent form, and a copy will be given to the subject.

3.4.5 Subject Costs and Compensation

There is no cost for participating this study. A \$30.00 honorarium will be provided for participation.

3.5 Chart Review Selection There are no charts to review.

4. Study Variables

4.1 Independent Variables or Interventions

The independent variable is type of exercise with four levels: VSTEP(random), VSTEP (repeated) Kinect and Standard of Care.

- VSTEP: a custom designed video game that utilizes the motion sensor hardware of the Xbox Kinect to track the movements of the user whose feet are represented on the game screen. The object of the game is for the subject to step from a center square to another target square that appears around the perimeter using the appropriate foot. A variation of the game consists of the user marching in place to “kick” soccer balls that appear on screen. The VSTEP is game paced but calibrated to the user as the targets will switch at a rate customized to the subject. It will be played in two modes
 - VSTEP random
 - VSTEP repeated
- Kinect: A mini game called "Light Race" from the off the shelf game for the Xbox Kinect titled “Your Shape: Fitness Evolved.” The game consists of one minute rounds in which the user steps on lighted tiles. The user is represented on screen as standing in the middle of a circle of tiles that light up, which the user must step on with their avatar before they disappear. Subjects will also perform stepping tasks interspersed between rounds of gameplay.
- Standard of Care (SOC): A stepping task designed by the authors to represent a practical, comparable intervention that may be used by clinicians to treat patients with stroke in a rehabilitation setting.

4.1.1 Drug or Device Interventions: N/A

4.2 Dependent Variables or Outcome Measures

The dependent variables will include measures of exercise intensity, performance, and enjoyment for each of the types of exercise. Additional measures will be taken to determine readiness for physical activity and to characterize lower extremity sensorimotor function.

- Exercise Intensity: HR, VO₂, Rate of Perceived Exertion (RPE)
- Performance: Accuracy (Kinect and VSTEP), Total Steps (SOC)
- Enjoyment: Physical Activity Enjoyment Scale (PACES)
- Fugl-Meyer Assessment of Lower Extremity Function

4.3 Risk of Harm

There is minimal risk associated with participating in this study. You may experience neuromuscular fatigue or loss of balance. There will be a clinician who is part of the study team on site to decrease the chance of any harm.

4.4 Potential for Benefit

There is no direct benefit from participating in this study. However, the information gained may be used to develop relevant and useful games for rehabilitation.

5. Data Handling and Statistical Analysis

Statistical analysis on the data gathered will be performed using a Repeated Measures ANOVA to compare differences in energy expenditure (METs) and a Friedman test to compare participant feelings' of enjoyment in each subject for the three interventions. An alpha level of .05 will be set for all analyses. There may also be blocked comparisons between VSTEP repeated and SOC, and VSTEP random and Kinect. These will employ paired t-tests.

6. Data and Safety Monitoring: Study is minimal risk.

7. Reporting Results

7.1 Individual Results

Data collected on the individual will be summarized into a table for easy to read purposes with a brief narrative of their results. On selected occasions there may be instances where a single subject is of great interest and that data may be represented as a case report.

7.2 Aggregate Results

Aggregate results will be shared in the form of a summary paper with all the participants via email.

7.3 Professional Reporting

Data from this study will be communicated in poster format and then in a paper format and at a virtual reality society or rehabilitation meeting.

8 Bibliography:

Kafri M, Myslinski MJ, Gade VK, Deutsch JE. Energy expenditure and exercise intensity of interactive video gaming in individuals poststroke. *Neurorehabilitation and neural repair*. 2014;28(1):56-65.

Kafri M, Myslinski MJ, Gade VK, Deutsch JE. High metabolic cost and low energy expenditure for typical motor activities among individuals in the chronic phase after stroke. *Journal of neurologic physical therapy : JNPT*. 2014;38(4):226-232.