Utilizing Gaming Mechanics to Optimize Telerehabilitation Adherence in Persons With Stroke

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Data Analysis Plan

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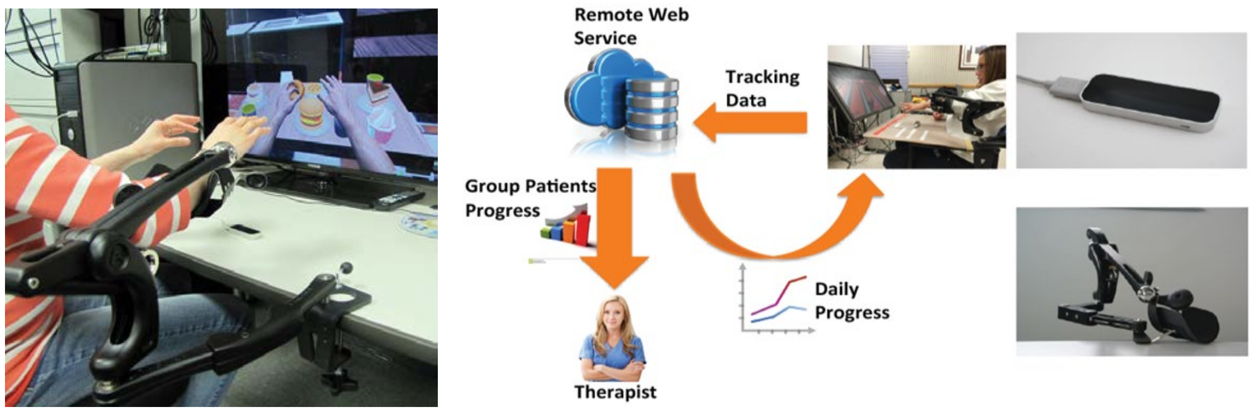


Figure 4. Left: Home-based Training system NJIT HoVRS. Hand tracking and real-time interactions with virtual environments are provided by the LEAP that is replacing two data gloves in the NJIT-RAVR system while the arm support is used as a substitution for the Haptic Master robot in the NJIT-RAVR system. Right: NJIT HoVRS architecture design. Upper right corner: Leap Motion Controller. Lower right corner: Armon Edero arm support.

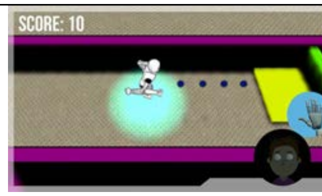
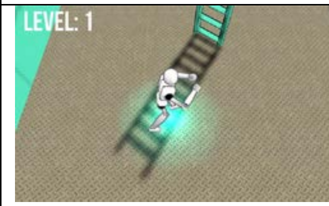
RESEARCH DESIGN AND METHODS

Description of Home Based Exercise System: To date, telerehabilitation of the upper extremity has been accomplished by custom built systems designed for rehabilitation. These systems can accommodate a wide variety of impairments but they require extensive assistance for persons with impaired hand function to set up and their cost prohibits broad implementation. Off the shelf gaming systems provide a meaningful alternative for many populations but none of these systems capture finger angles with the accuracy required for rehabilitation. We have developed the New Jersey Institute of Technology – Home Virtual Rehabilitation System (NJIT-HoVRS) to address this limitation and facilitate intensive, hand focused rehabilitation in the home. The system integrates a Leap Motion controller, a passive arm support and a suite of custom designed hand rehabilitation simulations. Novel technologies like the commercially available Leap Motion allow for an affordable and easy-to-use solution to several home based rehabilitation issues that has not existed previously. The Leap Motion provides accurate, camera based measurement of finger angles, allowing for integrated virtual arm and finger activities without an expensive, cumbersome wearable apparatus. If the patient's arm is severely impaired and he/she cannot support the hand against gravity above the Leap Motion Controller (LMC), a spring compensation system (such as the Armon™ Edero or Saebo™ Mobile Arm Support) can be provided to the subject. (Figure 4) This system consists of a forearm orthosis that counter-balances gravity to provide graded support to the arm during activity. These orthoses will be calibrated to provide the least support necessary to complete a simulation within a pre-determined bandwidth of success (usually 70% - 85%. The orthoses will be adjusted (and eventually removed) as patients improve their motor abilities.

Using the Unity Game Engine, we have developed a library of interactive games, each designed to focus on training a specific hand movement such as wrist rotation or finger individuation. (see Table 2 below). 3D assets were created using 3DS Max and the interactions were programmed using C#. A comprehensive calibration procedure is used to measure each subject's active range of motion within the LMC visual area and this range is scaled to fit into the video game virtual environment. Motor skills required to accomplish the rehabilitation games are introduced gradually in different game levels. Therefore, as patients progress in game level, they will be training and gaining new motor skills. Therapists can change and save game settings to individualize the games, as ability will vary between patients and the ability level for each patient will vary by day. This configuration and reconfiguration can be performed in the patients' home or remotely by study personnel. Subjects will be able to communicate with study personnel directly via ZOOM, a free, HIPPA-compliant web-conferencing system (Fig 5).

Treatment Protocol: Both groups will use the NJIT-HoVRS system and play a series of computer games

Table 2. Rehabilitation Games

Description	Enhanced Game	Enhancements	Un-Enhanced Game
Speed Bump Player controls speed of car by opening and closing their hand. Supination / pronation changes lanes. **Scoring:** Coins collected		Leaderboard Level-scaled graphics Level Scaled scoring Avatar purchases for career scores	
Gesture Flying: Player controls roll, pitch and yaw of the plane flexing and extending wrist **Scoring** # of Spheres captured		Leaderboard Level-scaled graphics Level Scaled scoring Avatar purchases for career scores	
Maze Runner Direction of runner with horizontal plane reaching. Jumping controlled with hand opening **Scoring:** # Spheres captured		Leaderboard Level-scaled graphics Level Scaled scoring Avatar purchases for career scores	

targeted to train movement of their shoulder, elbow and fingers. The physical therapist will set up the apparatus in their home and visit them once or twice in the first week to train them how to use the system and how to play the games. After this training period they will then continue to practice in their homes independently with on-line support from the therapist and in-person or on-line assistance from the study-engineer as needed. Both groups will be instructed to perform all three of the simulations assigned to them for at least twenty minutes, daily for twelve weeks.

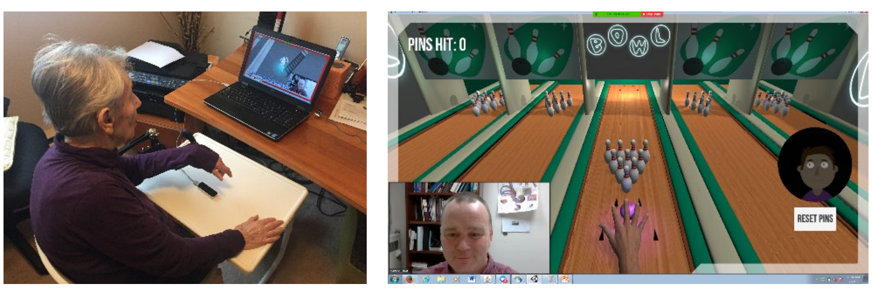


Figure 5. Left: Patient home system setup with the passive arm support, hand tracking device and computer. Right: Patient is able to talk to and see therapist (lower left corner) and while playing games, patient's game screen is shared with therapist at the same time as well.

The enhanced motivation (EM) group will train using three simulations (See Table 2). These simulations will all provide the user with eight to twelve levels of gradually increasing difficulty and complexity. There is a screen announcing each level change and the graphics for each new level change substantially. Scoring opportunities increase at each new level as well. When a simulation is completed, for the day, a leaderboard displays the user's score for the day, their total points scored for the entire training period (career score) on that simulation, and the top ten career scores for the entire program (including other subjects). When users achieve a milestone career score (1 million points, two million points, three million points), they will have an opportunity to choose a new avatar for future play. This opportunity is provided at the beginning of gameplay.

The unenhanced control (UC) group will perform the same three simulations. Difficulty will increase utilizing an adaptive control algorithm that increases difficulty based on performance. Difficulty changes are extremely incremental making them imperceptible for most subjects. Graphics and scoring will not change as difficulty level changes. Total score for the day will be displayed after each simulation for the day is completed, but no leaderboard displaying past performances, career scores or the career scores of other subjects will be displayed. UC subjects will use the same avatars for the entire experiment.

Description of Simulations: For this study, we have developed a library of 3 task-based simulations that train hand manipulation and arm transport. These simulations include activities such as flexing and extending fingers to move a car, fly a plane with wrist movement and control a man running in a maze using reaching movements. Please see Table 2 for description of each game, scoring, and motivational enhancement techniques used.

Experimental Design and Training Protocol

Aim 1: To test the impact of motivation enhanced, game-based interventions on <u>intrinsic motivation</u> to perform a telerehabilitation exercise program in persons with strokes.

Rationale: Low levels of motivation are cited as the primary barrier to adherence to home based rehabilitation programs. Designing rehabilitation activities that elicit the highest levels of intrinsic motivation is critical to overcoming this barrier and optimizing the effectiveness of home based interventions.

Hypotheses: We predict that subjects in the motivation enhanced (ME), game-based intervention group will report higher initial levels of motivation as measured by the Intrinsic Motivation Inventory than those performing un-enhanced control (UC) interventions. We further predict that IMI scores for the ME group will remain higher than those for the UC group.

*Subjects***:** This will be a randomized, blinded study. The same subjects will be utilized for all three aims. Upon IRB approval 30 persons with chronic strokes will be recruited from the outpatient rehabilitation department of JFK Medical Center, its hospital based fitness center program for persons with stroke and its stroke support group. **Inclusion criteria** are a) 25-85 years old, b) unilateral stroke, c) score of 24 or greater on the Folstein Mini-Mental Status Exam(52), d) Score of 1 or better on extinction and inattention portion of NIH Stroke Scale (NIHSS)(53), e) Fugl-Meyer (FM) between 30-60/66 (54), f) Score of 1 or better on language portion of NIHSS, g) intact cutaneous sensation (e.g. ability to detect <4.17N stimulation using Semmes-Weinstein nylon filaments(55). **Exclusion criteria are:** Orthopedic issues that would limit the ability to perform regular upper extremity activity. **Randomization:** Because level of impairment may affect (a) compliance with training regime, (b) intrinsic motivation, (c) adherence, and finally (d) measures of effectiveness, it is crucial (especially in a study with limited n) to balance the treatment and control arms. Because simple randomization of subjects to arms may not result in a balanced design, and because the ability to statistically adjust for baseline arm differences in these two characteristics is likely to be limited, we will use the following strategy to ensure arm equivalency. Subjects' initial scores on our measurement of motor control impairment caused by the stroke the (UEFMA) will be dichotomized into low/high. Subjects are then classified into the cell corresponding to their impairment level. Subjects in each cell (n1, n2) are provided random IDs (to prevent an ID by case recruitment association), and an investigator blinded to the randomization process then randomly assigns the first case in each cell to treatment or control arm. Each following subject within the cell is then assigned sequentially to the alternate arm. This is done for all cells to balance the source of variability between arms. **Blinding: Subjects** will be blinded to the purpose of the study and group assignment. They will also be blinded to their previous self-reported scores and their previous performance on objective tests. **Research assistants** performing outcomes measures will be blinded to group assignment and blinded to previous performance on all tests.

Outcomes Measures: (See Table 4 for a summary of all measures and Figure 6 for a data collection Schedule). The impact of game mechanics on motivation to perform the simulation that is specifically related to the experience of using the simulation not the general motivation to improve their hand function or increase their independence, etc. will be measured utilizing the Intrinsic Motivation Inventory (IMI) (58). IMI data will be measured following the first training session (Collection 2) to measure the subjects' initial reaction to the system and simulations as well as after the twelfth session (Collection 3) and after the final training session (Collection 4) to chart subjects' responses to repeated use.

Statistical Analysis: (See Table 5 for a summary of all planned comparisons) Our primary outcome measures will compare differences in IMI scores after the initial exposure to the training program. Data will be evaluated for normality and transformed if necessary for evaluation. Baseline group equivalence will be evaluated via t-test. The within-and-between group interaction will be examined to evaluate differences in change between groups.

Aim 2: To test the impact of intrinsic motivation on adherence to a telerehabilitation exercise program in persons with strokes.

Table 4 Outcome measures

Motivation Measure	
Intrinsic Motivation Inventory	Measurement of emotional response to an activity.
Adherence Measures	
Number of interventions days	Recorded by system
Total intervention time	Recorded by system
Average intervention day time	Recorded by system
Clinical Measures	
Upper Extremity Fugl-Meyer Assessment (66)	A 33 item battery which evaluates reflexes, movement patterns in and out of synergy, grasp, and coordination (impairment level)
Action Research Arm Test (62)	19 item battery which tests the ability to handle items of different size, shape and weight (activity level)
Box and Blocks Test (67)	Standardized dexterity test with well-established benchmarks for persons with CVA and age-matched healthy populations
Quality of Life Measure	
Stroke Impact Scale (69)	Patient reported assessment of multiple activity and participation level domains post stroke including hand function, activities of daily living and social participation.
Kinematic/Kinetic Measures	
Hand opening/closing range of motion	Sum of maximum angular excursions of the paretic metacarpo-phalangeal (MCP), proximal inter-phalangeal(PIP) and distal inter-phalangeal joints (DIP) joints.
Hand opening velocity	Peak angular velocity during hand opening
Hand trace RMSE	Ability to control hand opening as subject moves a cursor tracking a sine wave. Reported as root mean square error (RMSE) comparing target position and cursor position.
Wrist Trace RMSE	Ability to control wrist flexion and extension as subject moves a cursor tracking a sine wave. Reported as root mean square error (RMSE) comparing target position and cursor position.
Horizontal shoulder and elbow trace RMSE	Ability to control shoulder and elbow as subject moves a cursor tracking a sine wave. Reported as root mean square error (RMSE) comparing target position and cursor position.

Rationale: Very few rehabilitation studies examine the interaction between motivation and adherence quantitatively. Utilizing knowledge of this interaction to inform design of rehabilitation simulations should advance the field of home based rehabilitation substantially.

Hypothesis: We predict that intrinsic motivation related to game play will predict adherence more effectively than patient readiness alone.

Subjects: The same subjects will be utilized for all three aims.

Outcome measurements: will include number of sessions as well as total intervention time and average session time. Time signatures from the telerehabilitation system will be used to overcome overestimation effects associated with patient self-reports of actual exercise time (59).

In an attempt to expand our understanding of the interaction between motivation (as measured by the IMI) and adherence to the autonomous home rehabilitation program, we will perform an in depth qualitative analysis focusing on subjects' unique perceptions and understandings of their participation in the proposed rehabilitation program. Using a Grounded Theory approach (60, 61), data collection and analysis will follow these steps: 1) A trained interviewer will ask open-ended questions in telephone interviews, allowing participants to reflect on and describe their experiences. 2) Investigators will read participants' narratives to develop a general sense of the subjects' experiences and attitudes toward the rehabilitation program. 3) Investigators will identify emerging narrative themes in participants' experiences and attitudes toward the program. 4) Finally, an iterative coding process will be used to refine initial findings and synthesize these themes.

Statistical Analysis: (See Table 5 for a summary of all planned comparisons.) Linear regression will be used to evaluate the effects of IMI (From Data Collection 1) on total time (Collected during training sessions).

Aim 3: To test the impact of motivation enhanced, game-based interventions on the effectiveness of a telerehabilitation exercise program in persons with strokes.

Rationale: Studies of clinic based interventions targeting hand function in persons with stroke have produced measurable changes in hand function that do not substantially reduce hand related disability. Study of a long term, home based program emphasizing adherence will inform the development of sustainable alternatives to costly clinic based interventions that fall short of the ultimate goal of rehabilitation.

Hypothesis: We predict that subjects in the ME group will demonstrate larger improvements in hand function as measured by the Action Research Arm Test (ARAT) than those performing UC interventions. We further predict that subjects in the ME group will demonstrate larger reductions in impairment and larger improvements in measures of motor control and quality of life than UC group subjects.

Subjects: The same subjects will be utilized for Aims 1-3.

Outcome Measures: (Please see Table 4 for the full listing and description of the proposed clinical and quality of life measures.) A trained RA, blinded to group assignment will collect all outcome measures described in Table 4 immediately prior to training, immediately after training and 3 months after training (Data Collections 1 and 2). The RA will be blinded to previous test scores during post testing and retention testing.