Assessing Feasibility, Efficacy, and Acceptability of visual feedback during HR monitoring in rehabilitation

NCT05273801

February 11, 2022

STU#: 00216223

PROTOCOL TITLE: *Assessing Feasibility, Efficacy, and Acceptability of visual feedback during HR monitoring in rehabilitation*

PRINCIPAL INVESTIGATOR:
Miriam Rafferty PT, DPT, PhD
APTA Board Certified Neurologic Clinical Specialist
Shirley Ryan AbilityLab
312-238-7233
mrafferty@sralab.org

VERSION DATE: 2.11.2022

STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	Heart Zones System **https://heartzones.com/heart-zones-system-technical-documents/**
IND / IDE / HDE #	
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	90
Funding Source	SRAlab/PMR Department
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

OBJECTIVES:
The purpose of this investigation is to determine if knowledge of heart rate (HR) and target HR zones (HRzone), with visual feedback vs no feedback of HR or HRzone improves patient exercise intensity during rehabilitation. The central hypothesis for this study is with visual feedback of HR and target HR zones with instruction about exercise intensity and targets will increase patient HR intensity during sessions within a safe range set by their medical team. For purposes of this study, patients will be monitored in group and individual settings throughout the rehabilitation continuum of care sites including: inpatient rehabilitation, day rehabilitation, and

community fitness and will be inclusive of all individuals with chronic health conditions. Physical activity and exercise guidelines recommend everyone, including those with chronic health conditions, strive for 150 minutes of moderate intensity aerobic exercise per week.[1] This study will contribute to the knowledge of how patients achieve recommended individual HR and moderate-high intensity zones during exercise.

Aim 1: Measure the extent to which monitoring and education regarding intensity is provided (1) before HR monitoring intervention, (2) when providers know HR monitoring is occurring but without visual feedback, and (3) with visual feedback of HR monitoring.
We hypothesize providers will modify their behavior in the number of times they ask about intensity, adjust session intensity or provide education regarding intensity when visual feedback is provided compared to no feedback, which will be further increased from pre-study baseline levels.

Aim 2: Determine the efficacy of using HR with visual feedback during rehabilitation to reach target intensity.
We hypothesize participants will have higher mean HR and increased time in their individualized target HR zones when given visual feedback compared to no feedback during group sessions.

Aim 3: Determine the safety of using Heart Zones technology in rehabilitation for increasing participant exercise intensity.
We hypothesize the technology will be safe without an increase in number of adverse events throughout their rehabilitation stay.

Aim 4: Assess patient acceptability, exercise self-efficacy and confidence following use of Heart Zones technology in rehabilitation sessions.
We hypothesize use of Heart Zones technology in group settings with feedback will increase participant self-efficacy and confidence in reaching higher exercise intensities, and will be well accepted. Furthermore, we hypothesize the use of Heart Zones will be feasible in at least 75% of patient's group sessions.

Aim 5: Explore the feasibility of submax exercise testing when completed 2 times to establish individualized training targets for individuals receiving inpatient rehabilitation.
We hypothesize submax exercise testing will be feasible to perform, safe and informative to clinicians to establishing individualized heart rate zones. We believe there will be a change pre to post in submax testing indicating improvement in patient's condition.

Aim 6: Assess provider opinions regarding the feasibility, acceptability, and appropriateness of using Heart Zones technology in rehabilitation.
We hypothesize providers will find the Heart Zones feasible, appropriate and easy to incorporate into therapy sessions.

BACKGROUND:

One of the important components in regards to successful aerobic exercise is that it needs to be intensive. This has been described as one of the key active ingredients to improve walking function in those with chronic neurological diagnoses along with that the task is specific, and provided in high repetition.[2, 3] Neurophysiologically, exercise performed in an intensive manner drives BDNF factors, increase brain blood flow and neuroplasticity for recovery post stroke as well as is thought to be one of the most important components with regard to safety and effectiveness of an aerobic endurance training program.[4, 5] Exercise and intensity are thought to

play an integral role in quality of life, and reduced risk of secondary sequelae for individuals with cardiovascular, Parkinson's and other chronic disease conditions.[6, 7]

However, there is a misalignment in the application, selection, and actual execution of appropriate intensity exercise for aerobic endurance, both in rehabilitation and in the community. Formulas such as Hunt and Karvonen that provide guidance for clinicians when determining target HR zones based on age, or age/resting HR, and suggested adjustments based on cardiotropic medications such as beta-blockers.[8,9] Ratings of perceived exertion (RPE) such as the BORG 6-20 or modified BORG 1-10 scales are long accepted and validated scales used to help patients achieve appropriate intensities and should correlate with HR. Despite these measures, some studies have raised concerns for safety due to individual variability and inconsistencies between these measures of intensities in individuals in cardiac rehab as well as post stroke.[10, 11] Furthermore, these concerns are heightened with the knowledge that often in rehabilitation, HR zones and RPE is utilized without performance of a submax exercise test due to cost containment challenges.[12] Thus, the target range for patients may be inaccurate or inappropriate for the patient's current condition. HR monitors commonly used in rehabilitation have allowed for instantaneous readings of HR, without a full log of session HR and are readable only by the therapist. This presents several gaps: decreased ability to use standard formulas to establish accurate HR zones in complex medical populations in the rehabilitation setting, and unknown utilization/application of intensity recommendations in standard rehabilitation, in particular group therapy.

Group exercise with HR monitoring has previously shown to be successful in healthy adults. These studies have found higher mean HRs, greater percent of time spent above 70% of HR max when individuals are given visual feedback in a group exercise setting compared to individual sessions with feedback or no feedback.[13] Also the majority of subjects preferred the group condition with feedback.[13] Another study found that subjects were able to maintain their time in higher intensity zone even after feedback was removed.[14]

Our previous pilot work in Parkinson's Disease and others with chronic conditions confirmed similar results previously stated with healthy individuals as well as identified the need for individualized HR zoning. This work was completed in 14 individuals, 9 of whom had Parkinson's Disease and 5 others with other chronic conditions in a community based fitness setting. In fitness class focused on large amplitude movements addressing 4 areas frequently affected by PD: antigravity extension, weight shifting, axial mobility, and transitional movements. Data was collected for a total of 7 sessions and visual feedback of HR was provided every other session while the exercise physiologist provided education about HR and zones. We found that when visual feedback was provided it motivated participants to workout at a higher intensity and resulted in increased time spent in higher intensity zones, higher peak HR and average HR compared to the first class when feedback was not provided to participants. Average peak HR was 146 bpm with visual feedback compared to 101 when no feedback was provided. Participants reached higher intensity zones and were able to sustain the effort longer, as noted by longer duration in higher intensity zone in the class with feedback compare to the class without feedback. One limitation noted during this preliminary work was the difficulty of participant's to reach targeted zones when calculated off percentage of age predicted max because some individuals never reach the target of 60% HR max, despite reporting higher RPE values.

Provided this result in our preliminary data and prior evidence that chronic health conditions and comorbidities can affect an individual's ability to reach target intensity, it is important to provide individualized HR zones based on submax exercise testing for this study. Submax exercise

testing is a predictive test to estimate maximal aerobic capacity, however is consider safer, less labor intensive, and requires less patient motivation to complete compared to a maximal exercise test thus lending it to be more feasible and applicable in clinical settings.[15]

Clinical providers have many options for submaximal (submax) aerobic capacity testing, although they are rarely used outside of cardiac rehabilitation. The 6 minute walk test which have been studied in a range of populations including heart failure, end stage lunge disease, COPD, chronic renal failure, and older individuals.[15] The recumbent stepper test has been shown to be able to predict VO2 peak in healthy adults.[16] For individuals with limited ambulatory or lower extremity motor function, an alternative to determine aerobic capacity is to use the arm crank ergometer.[17]

This study will facilitate the understanding of feasibility and safety of moderate to vigorous aerobic endurance exercise, based on individually set aerobic intensity zones carried out in a rehabilitation setting. It will also study if the behavior of the provider or participant changes when provided visual feedback of HR during sessions.

STUDY ENDPOINTS:

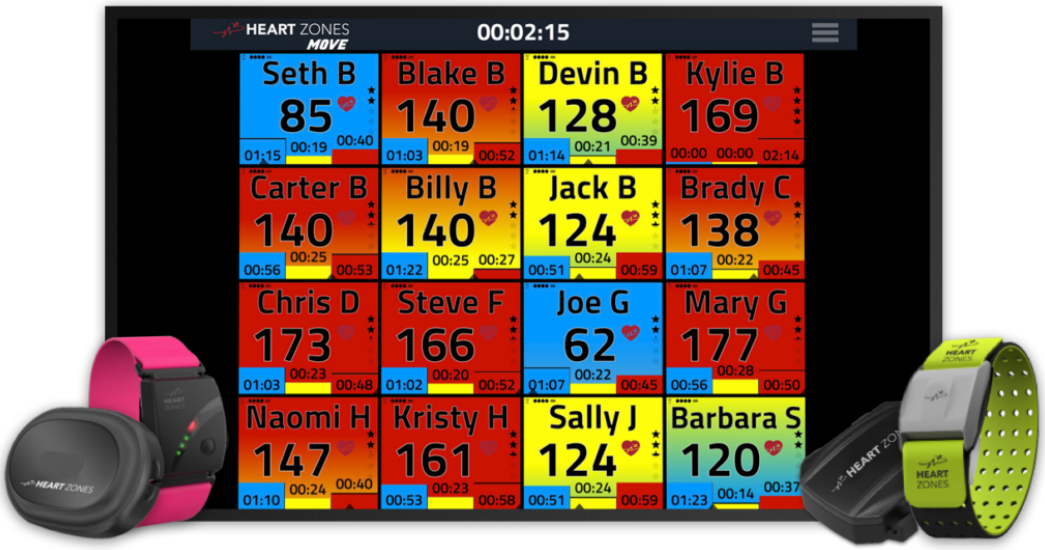
- To evaluate the safety of using Heart Zones technology in a rehabilitation model across the rehabilitation continuum by recording the incidence of adverse events.
- To demonstrate the feasibility of using Heart Zones during group sessions by measuring the incidence of session usage to missed sessions.
- To demonstrate the efficacy of using visual feedback of HR monitoring to achieve greater intensities during sessions compared to no visual feedback of HR.
- To analyze the effect of HR monitoring with visual feedback on therapist perception of acceptability, feasibility and appropriateness as well as participant exercise self-efficacy and confidence.
- To assess feasibility of submax exercise testing in the inpatient setting to establish individualized target training intensities and assess the change in submax testing when completed at 2 times points.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

Heart Zones is a commercially available software platform that integrates feedback from several different commercially available HR sensors. The software platform displays HR and provides continuous biofeedback with ability to provide individualized programs to maximize individual and multi-person sustained effort. It has the capability to record session data for later review and analysis.

We are not evaluating safety or effectiveness of the Heart Zones software, rather assessing the effect of monitoring HR with visual feedback in a group setting.

STU#: 00216223



We will be using commercially available non-invasive, wireless HR monitors, such as the Scosche forearm monitor or other monitors with Bluetooth capability to pair with the Heart Zones platform. Scosche has a sensor with Velcro strap armband that is able to be cleaned with standard hospital cleaning procedures (Cavicide) between patient uses, yet is affordable, accessible and easy to use. Multiple heartrate monitors can be paired simultaneously and paired with a display such as an Apple IPad or other screen. Through visual display of multiple HRs in real time, it is feasible to use the Heart Zones application during a group rehabilitation session. The display monitors, HR monitors and Heart Zones platform will be stored in a locked cabinet accessible to research personnel for authorized use with this study.

PROCEDURES INVOLVED:
AIM1:
This will be conducted prior to enrollment of subjects into active phases of the study in order to understand baseline provider behavior regarding education to patients regarding intensity, monitoring of intensity and progression/modification of session intensity.

Observation of 15 sessions of each of the following conditions (total of 1500 minutes/condition):

1. Condition 1: Baseline Provider Behavior (prior to study beginning)
2. Condition 2: HR monitor on, no visual feedback
3. Condition 3: HR monitor on, visual feedback

Record number of instances in session the following occur:
-Provider provides education regarding HR/RPE/intensity
-Provider monitors HR/vitals
-Provider ask for RPE from patient
-Provider mentions target RPE/HR range
-Provider modifies task to reach target RPE/HR range

AIMS 2-5:
Screening Procedures & Consent

1. Potential subjects will be recruited from multiple settings across the continuum of rehabilitation as they are admitted.

2. Once informed consent is obtained, screening will be performed to ensure inclusion criteria for study are met
3. Medical clearance for participation from supervising physician through online REDCap form.

2. Baseline
    1. Participants will complete submax exercise test with licensed physical therapist in order to establish individualized HR intensities and zones.
        i. Based on participant capability and timing, we will perform one or more of the submax tests or HR zone calculation methods for the individual based on clinical presentation and functional capacity.
            1. A formula using HR reserve: Based on individual factors and timing, target HRR may be calculated instead of using a formal submax exercise test. 40-60% HRR is considered moderate intensity and 60-80% HRR is considered vigorous intensity.[18] The appropriate range between moderate and vigorous will be used for each participant.
            2. Clinical discretion to establish zones based on medical parameters: depending on recent medical procedures and precautions, occasionally patients will have strict guidelines to HR for exercise. The utilization of this is anticipated to be more of a rare occasion, however establishing zones for these patients will be based on set medical safety guidelines.
            3. 6 minute walk test: the participant is asked to walk as far as they can in 6 minutes with standard encouragement given every 1 minute. If a rest break is needed, it is permitted. Vitals including pre, during and post HR monitoring is performed. Peak VO2 can be estimated based on distance walked on 6MWT.[19]
            4. Seated Stepper: this test is a progressive test using a seated stepper, called Nustep, in which the resistance is increased every 3 minutes until participant fatigues or until 85% HR max is achieved while maintaining a target stepping cadence of 100 steps/minute. HR is recorded at the end of the 2nd and 3rd minute of each stage, and if within 5 bpm of each other, participants progressed to the next stage. If the difference was greater than 5 bpm, an additional minute is performed to ensure a steady-state. The amount of resistance added is measured through wattage output and is based on HR response in prior stage. Upon completion of the exercise test, the individual continued to step at a comfortable self-selected speed for 2 minutes or until HR returned to near baseline levels.[16]
            5. Arm Crank Test: This test is performed in sitting for 6 minutes, up to 10 minutes. It uses the upper extremities to cycle at a constant cadence of 55-65 revolutions/minute, and resistance starts at 25W and increases for the first 3 minutes by 5W. It is then is held constant for the remainder of the test until completion or a percentage of your max HR is reached. The aim is to reach a steady state of HR in minutes 5 and 6, with maximum fluctuation of 5 bpm between 60-85% HR max, if this was not achieved, the test is extended up to 10 minutes to achieve steady state.[17]
    2. Baseline measures and information will be collected from patient and medical record which include demographic information including gender, DOB, height, weight, co-morbidities, prior level of function, medical complications or concerns (pressure injuries, falls etc), precautions, admission level of function based on QI mobility items

and outcomes measures in electronic medical record, reason for admission to rehabilitation.

3. Intervention:
    1. Group and individual physical or occupational therapy sessions that are focused on endurance training (using upper and/or lower limb activities) which is a part of standard care for appropriate patients.
    2. The only addition to usual standard care is the addition of a HR monitor that syncs with the Heart Zones software platform with or without visual feedback. Subjects will wear the HR monitor on their less sensory/motor impaired upper extremity.
    3. There will be a continuous rolling enrollment, so some participants will receive HR feedback first while others will receive it on their second week.
    4. Timing
        i. Inpatient: 1 week of visual feedback of HR during group sessions and 1 week they will receive no feedback on their HR/zones.
        ii. Day rehabilitation or community fitness: 2 weeks of visual feedback of HR and 2 weeks of no feedback due to fewer sessions per week.
    5. Session Monitoring and Feedback
        i. We will ask participants to rate their level of perceived exertion by using the Borg RPE Scale (6-20) at baseline, mid, and post each group session.
        ii. Participants will answer 2 self-efficacy and confidence questions at the end of each session, rated from 0-100%.
        iii. Subject's HR data from each session will be transferred for storage on a password protected computer accessible by approved lab staff only in order to perform summative data analysis, including peak HR, time in target HR zone, and average HR for whole session and for endurance training portion of the session.
    6. We will monitor for occurrence of adverse events during sessions by assessing physiologic response to exercise, incidence of falls, etc.
4. Midpoint
    1. We will collect information from their electronic medical record including new medical complications or concerns, their current functional level based on QI mobility items and outcome measures completed.
5. Post
    1. At the end of the study, we will ask participants to answer one summative quality improvement question regarding their participation in the study.
        i. If discharged unexpectedly, we will attempt to reach out to participants via their preferred contact method (phone or email) in order to allow them to provide feedback.
    2. We will collect information from their electronic medical record including new medical complications or concerns, their current functional level based on QI mobility items and outcome measures completed and ask the participant regarding discharge destination.
    3. If the submax exercise test was completed at baseline, we will complete the same test a second time at least 3 days later.

AIM 6:

a. We will ask for provider feedback and perceptions at the end of the study by their completion of the Acceptability, Appropriateness and Feasibility Questionnaire.
b. Given the potential for covering providers, we will only ask participation from participating providers who are core staff/covering for a long term placement at each of the study locations.

SHARING RESULTS WITH PARTICIPANTS

Given the nature of the study design, participants will receive immediate continuous feedback of their heartrate for a portion of the study. Individual study results may be provided once the study is completed if the patient requests. Results will be shared in written or verbal means, depending on participant's preference.

STUDY TIMELINES

The participant will be in the study for up to the duration of their length of stay in inpatient rehabilitation or day rehabilitation. We anticipate that it will take up to 8 months to enroll all study participants and primary analyses will be completed by September 2022.

INCLUSION AND EXCLUSION CRITERIA

Participant Criteria:

Inclusion:

- Age 18-90 years
- Admitted to inpatient rehabilitation, day rehabilitation or participant in community fitness
- Qualifies for group therapy based on diagnosis and insurance reimbursement
- Physician clearance for participation

Exclusion:

- Unable to provide informed consent due to cognitive impairment
- Inability to communicate with investigators
- Sternal Precautions
- Individuals with LVADs
- Pregnant women
- Uncontrolled Hypertension
- Serious and unstable cardiac arrhythmias
- Loss of bilateral upper extremity sensation
- At high risk for skin breakdown due to poor skin integrity (open wound, fragile skin, etc)
- Previous participation in this study while in another level of care in the last 6 months

Provider Criteria:

- Occupational therapist, physical therapist, assistant or exercise physiologist
- Core staff at locations of study or flex staff on long term placement (~3 months)
- Willing to participate in structured feedback via questionnaire

PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local	0	120	90

Study-wide	0	120	90
Total:	0	120	90

RECRUITMENT METHODS

Participant:

1. Trained research staff who have access to medical records will review the data to identify all persons with recent admission to the strength and endurance (floors 19 and 20) at Shirley Ryan AbilityLab who may be eligible to participate in this study during inpatient rehabilitation or during day rehabilitation at Streeterville. A research team member will approach in person potential participants and introduce the study. If the patient is interested in hearing more about the study, a team member will describe the project in detail. The team member will have recruitment flyers and a copy of the consent available for review. Per potential participants' preference and continued availability, consenting procedures may occur at this time or a later time. If the patient agrees to participate in the study, the team member will obtain written documentation of informed consent from the patient.
2. Referrals from SRAlab healthcare providers involved in patient's care who receive patient's verbal permission to pass along their name to research staff regarding interest in the study.
3. In addition, we will update our website (www.sralab.org) to include this research project under current clinical trials and studies.
4. We will distribute flyers to the community fitness center associated with Shirley Ryan AbilityLab to facilitate recruitment from this setting.

Provider:

1. Will work with management to identify core and registry staff assigned provide group therapy in inpatient, day rehabilitation, and fitness center.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Participants will receive a total of $50 via Clincard, $25 after medical clearance is received and and $25 following completion of final summative feedback question.d.

WITHDRAWAL OF PARTICIPANTS

Participants may be withdrawn from the study without their consent if they are transferred to the MACU for higher level monitoring or discharged from rehabilitation care due to acute hospitalization for a change in medical status lasting greater than 72 hours or if they no longer meet inclusion criteria for the study.

RISKS TO PARTICIPANTS

The possible adverse events or risks from the study procedures may include, but are not limited to:

- Discomfort or pressure caused by armband: temporary, minor risk associated with direct usage during the session. Adjustment will be provided if patient provides feedback that it is too tight.

- Risk of skin breakdown due to armband pressure will be minimized by excluding people with sensory loss. Adjustments will be provided if the patient provides feedback regarding discomfort. If redness lasts greater 15 minutes after the session, patient may be placed on hold from further study participation at the discretion of the research PT and clinical teams.
- Fatigue, or Muscle Soreness: these risks are associated with usual care and are associated with exercise. We do not anticipate an increased incidence of these occurring due to participation in this study. To minimize this risk, subjects will be closely monitored throughout sessions by their provider and given rest breaks as needed.
- Chest Pain or Shortness of Breath: this is a potential risk of exercise, particularly for those with underlying medical conditions. We do not anticipate an increased incidence of this occurring due to participation in this study. To minimize this risk, subjects will be closely monitored throughout the sessions by their provider and provided rest breaks as needed.
- Falls: this risk is associated with participation in exercise and is not increased by use of the heart monitor. To minimize this risk, participants may be asked to wear a gait belt around the waist or a harness for safety or use an assistive device like a cane or walker per the discretion of the PT/OT/exercise physiologist.
- Loss of confidentiality of HR Intensity: because this study involves using HR in a group setting with feedback, the participants' HRs and zones will be viewable to other participants of the group. Subjects will be able to self-identify/choose a nickname for the monitor during group training.
- Risk of loss of confidentiality will be minimized by not including personal identifying information on forms (participant will be assigned a research study number) and by conducting data collection in a private setting.

POTENTIAL BENEFITS TO PARTICIPANTS

There is likely no direct benefit to participants. Participation in this study will help researchers understanding if the use of visual feedback of HR in a group setting is feasible, efficacious and acceptable as care provided in a group model is a standard in rehabilitation.

DATA MANAGEMENT AND CONFIDENTIALITY

The analytic plan follows from the aims and the hypotheses. Descriptive statistics will be used to describe the participants and the data. Statistical tests will be utilized to assess for differences in individual outcomes baseline, mid and post through paired t-tests or appropriate non-parametric tests in consultation with a statistician. Data regarding the aims below may be analyzed for group sessions, individual sessions, and combined.

Aim 1: The null hypothesis is that there is no different in therapist behaviors to monitor/progress intensity prior to study, without visual feedback, or with visual feedback of participant's HR.

Aim 2: The null hypothesis is that there will be no difference in participant's ability to reach target intensity between sessions in which visual feedback of HR is provided and sessions where there is no visual feedback.

Aim 3: The null hypothesis is that there will be no increase in number of adverse events related to the use of Heart Zones with and without visual feedback.

Aim 4: The null hypothesis is that there will be no difference in participant exercise self-efficacy and confidence in reaching appropriate intensity when using visual feedback to no visual feedback during sessions.

Aim 5: The null hypothesis is that there will be no difference between submax exercise tests completed at baseline compared to post.

Aim 6: The null hypothesis is that the providers will not feel the technology is appropriate, acceptable or feasible to use in a rehabilitation setting.

Data will be transferred to and stored on Shirley Ryan AbilityLab's REDCap system.
All personal information (names, addresses, email or phone numbers, etc.) gathered for this study that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by an alphanumeric code. The "master list" linking personal information to the alphanumeric code will not be shared, and will be kept by the study PI in a secure location.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS
Every possible precaution will be taken to protect the privacy interests of subjects. To begin with participation in this study is completely voluntary. Trained research personnel will explain the purpose of the study and intended use of subject's personal health information and precautions taken to keep the study information and data confidential. Sessions will occur as a part of participant's usual rehabilitation, it is important for the research team to know information about the care they received while in the rehabilitation, including things such number of sessions, progress, medical history and adverse events and thus access to their medical record is paramount. Participants will be asked on consent if they are ok with research personnel accessing their medical record as a part of this study.

Subjects have the right to refuse to answer to any questions they feel uncomfortable answering and the research team will mark these questions as unanswered. Furthermore, participants can refuse other objective tests in the protocol or during their care however if the participants refuse the majority of tests which affect the overall implementation of the study, the participants will be offered to withdraw from the study.

COMPENSATION FOR RESEARCH-RELATED INJURY
The participant is required to promptly notify the PI of the study about the illness or injury. The hospital [Researchers, SRAL, Northwestern University and all affiliated clinical sites] will not pay for medical care required because of a bad outcome resulting from participation in this research study. However, this does not keep subject from seeking to be paid back for care required because of a bad outcome.

ECONOMIC BURDEN TO PARTICIPANTS
There are no additional costs as a result to participation in this study as it occurs during their usual care. Compensation is provided for their time to complete the additional brief surveys throughout the study with a terminal payment at the end of the study.

CONSENT PROCESS
Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. The consent process will take place at the Shirley Ryan AbilityLab in the patient's room or in a private treatment space. Trained research personnel will guide the subject through consenting process. Subject will be given detailed explanation of the purpose, time line, commitment, procedures, data handling, privacy and confidentiality of information pertaining to the study. Participants will be allowed to ask as many questions as they have regarding the study and its procedures prior to proceeding. Once this essential information has been provided to the patient and the study team member is assured that the patient understands the

implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB approved consent form. The written informed consent form must be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

Should there be amendment made to the consent form after the initial signature of the original, the subject will be required to sign a new consent form at their next visit. A researcher will review the changes and discuss the implications of the change.

NON-ENGLISH SPEAKING PARTICIPANTS
For patient's whose primary language is Spanish, an interpreter will be provided for their rehabilitation sessions through Shirley Ryan AbilityLab interpreter services. Research consent and questionnaires will be translated to Spanish for utilization during the study.

WAIVER OR ALTERATION OF CONSENT PROCESS – NA

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)
Subjects records will be kept completely confidential: Every possible precaution will be taken to protect the privacy interests of subjects. Participation in this study is completely voluntary. Trained research personnel will explain the purpose of the study and intended use of a subject's medical information and the precautions taken to keep the study information and data confidential. Data will be collected and kept confidential and compliant with HIPAA standards.

Participants will be assigned an alphabetical or numerical study ID. Identifying data will be kept in locked cabinets and password protected servers completely separate from de-identified data. Research data will be de-identified and stored in locked cabinets in the lab accessible only by authorized research personnel. Electronic data will be de-identified and kept on secure, password protected servers at the Shirley Ryan Ability Lab. Only authorized research staff will be able to access any of the formerly mentioned data. De-identified data will be kept indefinitely. Study documentation will be collected and stored and kept confidential and compliant with HIPAA requirements. Identifying data will be held for 7 years after the study is completed and published.

All personal information (names, addresses, email or phone numbers, etc.) gathered for this study that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by an alphanumeric code. The "master list" linking personal information to the alphanumeric code will not be shared, and will be kept by the study PI in a secure location. All personal information linking participants to their data will be destroyed after 7 years following the completion of the study.

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE
Shirley Ryan AbilityLab is a 226 bed rehabilitation hospital with up to 68 beds on the Strength and Endurance Floors, which is site of focus for recruitment for inpatient rehabilitation. 90% of patients would be eligible for participation in inpatient rehabilitation. Streeterville Day rehabilitation at Shirley Ryan AbilityLab is a day rehabilitation site with appropriately 200,000 patient units per year, approximately 80% of the patients at day rehab would be eligible for the study based on receiving group based rehabilitation as a part of their care. Because of the study design with rolling admission into the study, we anticipate being about to recruit the number of subjects needed from inpatient and day rehab with 2-3 months each. There will be medical

resources including a resident on call and nursing staff available 24 hours a day if needed in case of an emergency. All our treadmills have overhead harnesses for additional safety during training.

The PI of this study, Miriam Rafferty, is a research scientist at the Shirley Ryan AbilityLab. Adequate dedicated office space is available for private meetings with potential subjects, performing physical evaluations, explaining the study protocol and obtaining study consent, performing data analysis, and writing manuscripts.

1. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. *Jama*. Nov 20 2018;320(19):2020-2028. doi:10.1001/jama.2018.14854
2. Holleran CL, Straube DD, Kinnaird CR, Leddy AL, Hornby TG. Feasibility and potential efficacy of high-intensity stepping training in variable contexts in subacute and chronic stroke. *Neurorehabil Neural Repair*. Sep 2014;28(7):643-51. doi:10.1177/1545968314521001
3. Hornby TG, Reisman DS, Ward IG, et al. Clinical Practice Guideline to Improve Locomotor Function Following Chronic Stroke, Incomplete Spinal Cord Injury, and Brain Injury. *Journal of neurologic physical therapy : JNPT*. Jan 2020;44(1):49-100. doi:10.1097/npt.0000000000000303
4. Ploughman M, Austin MW, Glynn L, Corbett D. The effects of poststroke aerobic exercise on neuroplasticity: a systematic review of animal and clinical studies. *Translational stroke research*. 2015;6(1):13-28.
5. Whaley MH, Forsyth G. The value of traditional intensity feedback for self-regulation of initial exercise training. LWW; 1990.
6. Thornton JS, Frémont P, Khan K, et al. Physical activity prescription: a critical opportunity to address a modifiable risk factor for the prevention and management of chronic disease: a position statement by the Canadian Academy of Sport and Exercise Medicine. *Br J Sports Med*. 2016;50(18):1109-1114.
7. Wieringa FP, Broers NJH, Kooman JP, Van Der Sande FM, Van Hoof C. Wearable sensors: can they benefit patients with chronic kidney disease? *Expert review of medical devices*. Jul 2017;14(7):505-519. doi:10.1080/17434440.2017.1342533
8. Eston R, Connolly D. The use of ratings of perceived exertion for exercise prescription in patients receiving beta-blocker therapy. *Sports medicine (Auckland, NZ)*. Mar 1996;21(3):176-90. doi:10.2165/00007256-199621030-00003
9. Karvonen MJ, Kentala E, Mustala O. The effects of training on heart rate; a longitudinal study. *Ann Med Exp Biol Fenn*. 1957;35(3):307-15.
10. Joo KC, Brubaker PH, MacDougall A, Saikin AM, Ross JH, Whaley MH. Exercise prescription using resting heart rate plus 20 or perceived exertion in cardiac rehabilitation. *Journal of cardiopulmonary rehabilitation*. May-Jun 2004;24(3):178-84; quiz 185-6. doi:10.1097/00008483-200405000-00008
11. Wu T, Dong Y, Hu X, Li J, Shi Z-H. Exercise intensity criteria for routine rehabilitation therapy for stroke patients. *J Phys Ther Sci*. 2015;27(3):645-647. doi:10.1589/jpts.27.645
12. Brubaker PH, Ross JH, Joo KC. Contemporary Approaches to Prescribing Exercise in Coronary Artery Disease Patients. *Am J Lifestyle Med*. 2016;12(2):130-139. doi:10.1177/1559827615625482

13. Reynolds KA. *Impact of visual feedback on exercise intensity and motivation*. Illinois State University; 2016.
14. Shaykevich A, Grove JR, Jackson B, Landers GJ, Dimmock J. Auditory feedback improves heart rate moderation during moderate-intensity exercise. *Medicine and science in sports and exercise*. 2015;47(5):1046-1051.
15. Noonan V, Dean E. Submaximal Exercise Testing: Clinical Application and Interpretation. *Physical Therapy*. 2000;80(8):782-807. doi:10.1093/ptj/80.8.782
16. Billinger SA, E VANS, McClain M, Lentz AA, Good MB. Recumbent stepper submaximal exercise test to predict peak oxygen uptake. *Med Sci Sports Exerc*. Aug 2012;44(8):1539-44. doi:10.1249/MSS.0b013e31824f5be4
17. Bulthuis Y, Drossaers-Bakker W, Oosterveld F, van der Palen J, van de Laar M. Arm crank ergometer is reliable and valid for measuring aerobic capacity during submaximal exercise. *J Strength Cond Res*. Oct 2010;24(10):2809-15. doi:10.1519/JSC.0b013e3181e31242
18. American College of Sports Medicine RDEJKLGMM. *ACSM's guidelines for exercise testing and prescription*. 2018.
19. Ross RM, Murthy JN, Wollak ID, Jackson AS. The six minute walk test accurately estimates mean peak oxygen uptake. *BMC Pulm Med*. May 26 2010;10:31. doi:10.1186/1471-2466-10-31