INTENSITY OF USUAL CARE THERAPEUTIC INTERVENTIONS IN INPATIENT REHABILITATION – A PILOT STUDY

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CHAPTER I

INTRODUCTION

Stroke and spinal cord injury (SCI) are debilitating injuries that have broad lasting effects on patients' functional abilities, mental health, independence, overall quality of life, and even risk of increased medical morbidity in the future.[1,2] Rehabilitation is a longstanding, primary resource utilized in recovering function, strength, and independence after injury onset.[2,3] However, while the impetus to standardize the provision of healthcare grows, the scientific evidence behind the efficacy of different rehabilitation approaches has lagged due to the heterogeneity of its delivery and assessment in terms of setting, clinician, type, dose, patient diagnosis, and timeliness.[2,4,5] One key dosing parameter affected by these discrepancies is that of intensity, which has been defined by frequency, type, duration, volume, and cardiorespiratory measures in order to research, test, and prescribe exercise to improve health.[6(p179)]

Exercise is crucial after a deconditioning neurologic injury and has beneficial effects on various physical, mental, and social aspects of both SCI and stroke.[7,8] Additionally, recent technological advances in robotic exoskeletons and functional electrical stimulation (FES) show promise in addressing early rehabilitation needs in deconditioned patients or those with lower extremity paresis.[9,10] However, inconsistent evidence, variable intervention descriptions, poor documentation, low powered studies, and the nature of rehabilitation have made it difficult to discern which treatment modality of exercise training imparts maximum health benefits or if

exercise guidelines can be met though other physical activities that are not considered exercise, especially during inpatient rehabilitation.[11,12] Achieving the desired or recommended intensity of therapy during inpatient rehabilitation is challenging. The present study aims to determine objective and subjective measures of intensity using heart rate and a modified Borg's Rated Perceived Exertion scale (RPE), respectively, for usual care therapeutic activities undergone in inpatient rehabilitation.

This study was conducted over a six-month internship at the Baylor Scott & White Institute for Rehabilitation (BSWIR), a 92-bed inpatient rehabilitation hospital with 1468 discharges in 2018, as a part of a quality improvement initiative. Dr. Cameron Millar (faculty member at the University of North Texas Health Science Center (UNTHSC)) served as major professor overseeing the completion of the work. On-site at BSWIR, Dr. Chad Swank served as mentor for the subject area, in tandem with Ms. Librada Callender. Both served as advisors and assigned tasks in concert with the purposes of the Clinical Research Management practicum.

CHAPTER II

PROBLEM AND HYPOTHESIS

During usual care therapy at BSWIR, clinicians have no practical or objective way of assessing the level of intensity realized by the patient during each therapy activity. Therapeutic activities often differ in nature. For instance, neuromotor exercises, aerobic exercises, and functional activities all have different purposes with unique ultimate goals. However, each of these activities require similar amounts of time. Clinicians use problem-solving, patient assessments, and patient goals to inform their choice of therapy activities to pursue during a patient's short length of stay (LOS) in inpatient rehabilitation. When clinicians choose a specific activity during the limited stint of inpatient rehabilitation, there are often opportunity costs involved, in that certain activities do not stress the heart adequately enough to confer cardiovascular benefits, while those that do, preclude increases to patient independence or proficiency in functional tasks. These are important determinations to make as current evidence indicates transfer to inpatient rehabilitation and the subsequent course of treatment is most beneficial the earlier it occurs after a patient incurs SCI or Stroke.[13,14] By identifying which activities reach certain thresholds of intensity, physical therapists can optimize patient outcomes and limit opportunity costs.

In recent years, clinicians have seen the brisk introduction of robotic exoskeletons and FES into usual care rehabilitation practices. These new technologies potentially open doors for

more intense, consistent, and timely rehabilitation to severely deconditioned patients, and if implemented early in the inpatient rehabilitation setting, EksoGT, an FDA-approved brand of robotic exoskeleton, could prove to be beneficial.[9] However, no evidence-based guidelines currently exist. There is a lack of evidence regarding the physiological response to overground robotic gait training (RGT) in terms of cardiorespiratory intensity and its efficacy, particularly during the sub-acute phase of recovery. With the possible advantages of RGT in the form of early mobilization, consistent repetition, spasticity improvements, cardiopulmonary improvements, psychological benefits, and improvements to bowel and bladder continence, it is essential to discern the measurable impact it has on patients.[15] Recently, EksoGT was successfully implemented in the inpatient facility, followed by a clinician-initiated case study that reported RGT as having higher intensity at 55% maximal heart rate (HR_{max}) compared to 51% HR_{max} and 49% HR_{max} for functional exercises and functional electrical stimulation (FES) cycling, respectively. Based on the need to define inpatient intensity dose, substantial EksoGT utilization[9], the subacute cervical tetraplegic SCI preliminary data, and prior studies in chronic thoracic SCI[16-18] we propose to address the following aims:

Aim 1: Describe physiological response as measured by intensity [heart rate reserve (HRR) and rate of perceived exertion (RPE)] in patients with subacute SCI and stroke undergoing inpatient rehabilitation therapy activities. From physiological measures, a determination will be made as to the exercise intensity of each usual care therapeutic activity according to American College of Sports Medicine (ACSM) HRR recommendations.

Hypothesis 1a: Despite the variability in patient diagnoses and the differences in therapist approaches, we hypothesize HRR and RPE will correlate consistently between therapy activities in inpatients.

Hypothesis 1b: We hypothesize EksoGT RGT will meet recommended intensity goals in this setting.

Aim 2: Describe potential differences in treatment and intensity realized in inpatient rehabilitation across different diagnoses and severities of SCI and stroke for each activity.

Hypothesis 2: We hypothesize that we will observe differences in intensity in patients across diagnoses of SCI and stroke due to the extent and type of pathology, as well as the activity types performed.

CHAPTER III

BACKGROUND

For healthy individuals, physical therapists approach exercise prescription under the guidelines of the ACSM, modifying aspects of exercise in terms of Frequency, Intensity, Time, Type, Volume, and Progression (FITT-VP). Exercise is ideally prescribed individually, after assessing the characteristics of each individual patient, such as health status, age, and patient goals. While the ACSM[6(p375)] proposes exercise prescription guidelines based on systematic reviews for SCI, these fall under the scope of chronic injury and as such do not directly address inpatient rehabilitation. Billinger et al.[10] propose exercise across the continuum of stroke care, noting the importance of cardiovascular fitness in maintaining health post injury and increasing functional outcomes, however they acknowledge the need for further research in regard to maximizing the beneficial effects of aerobic conditioning in patients. Exercise guidelines proposed by the ACSM also identify mitigating post-injury sequelae as a primary indication of exercise prescription necessity but do not address exercise volume or type required to meet desired rehabilitation outcomes post-injury.[6(179-180)] This dose-response relationship in inpatient rehabilitation is an actively researched subject area in patients with SCI and stroke.[19,20] In consideration of guidelines as limits or as goals to meet, the BSWIR physical therapists aim to identify where usual care therapy activities align in terms of intensity.

For patients who have experienced significant neurologic injury, the primary objective in inpatient rehabilitation is recovery of function. However, inpatient rehabilitation is often limited by factors such as LOS and medical acuity. As such, therapists are often forced to choose a course of therapy activities at the exclusion of other potentially beneficial interventions. These clinical decisions often incur opportunity costs.[21] In SCI, possible opportunity costs have been identified in inpatient rehabilitation, where patients are not meeting the minimum recommended guidelines for improved physical fitness of two sessions per week of moderate to vigorous intensity for 20 minutes each[20,22]. This is a clear area for improvement in the implementation of inpatient rehabilitation practices, in that therapists can target recommended volumes of vigorous activity more accurately in patients with SCI. While this targeted area of intensity has clear benefits on cardiovascular fitness, it may also encourage neural plasticity.[20]

For inpatients with stroke, increasing intensity of therapeutic training undergone during rehabilitation, estimated by volume (quantity of sessions, session length), is potentially beneficial in reducing the LOS of inpatients and improving outcome measures such as in increased Functional Independence Measure (FIM) scores and increased performance on activities of daily living (ADL).[19,23,24] Most approximations of inpatient stroke rehabilitation have relied on the commonly-reported parameters of quantity of training sessions, or scheduled time per patient, whereas the lesser-reported parameters of frequency of repetitions, or the length of active time, would represent the ideal.[19] As stated by Kwakkel et al.,[23] time spent in therapy represents a rough estimation of actual energy and effort expended during therapy. Recent findings have indicated that early aerobic activity, after 6 days and up to 6 months since stroke occurrence, positively impacts improvements in walking distance capacity, and other functional outcomes.[7] In addition to the benefits of increased cardiovascular fitness on promoting functional outcomes

and mitigating post stroke comorbidities in general, recent studies in a rat model describe possible beneficial effects of high-intensity interval training (HIIT) in the acute to subacute phase of recovery on neuroplasticity, grip strength, and aerobic fitness when compared to moderate intensity training.[25] In addition, Crozier et al.[26] also proposed the use of HIIT in lieu of currently recommended moderate intensity training, in order to elicit a greater increase in neuroplastic effects, as well as in functional recovery end measures. However, they stressed the need to delineate intensity in terms of HRR more accurately in order to assess these training modalities' effects on recovery. Recent findings on the proposed benefits of increased intensity and limited assessments of intensity in subacute stroke rehabilitation infer a need for more precise measurements during rehabilitation activities.[27]

Cardiorespiratory fitness (CRF) is assessed preeminently by maximal oxygen uptake per unit time (VO_{2max}), which is a product of maximum cardiac output and the arterial-venous oxygen difference. When studying populations with chronic disease, this gas exchange analysis can be limited by local muscle wasting, atrophy, or the inability to achieve maximal cardiac output.[6(p119)] This measurement would also require additional skilled staff and expensive, clinically impractical spirometers, both of which are not feasible across the subacute inpatient population or rehabilitation setting.[28] When directly measuring VO_{2max} is limited, physical therapists can use submaximal measures (e.g., HRR, RPE, VO_{2R}) to prescribe and measure exercise intensity.[6(p120)] A reserve is a measure of the difference between a maximum and resting value. Percentage of reserve estimates are used to more accurately prescribe exercise by the ACSM since maximum exercise intensities and basal metabolic rates differ between patients, whereas HR in beats per minute is assumed to increase linearly with exertion and does not account for individual variability. Percent HRR (%HRR) has been shown by a majority of

researchers to approximate to Percent Reserve Oxygen Uptake (%VO_{2R}), which is a viable alternative used in prescribing exercise intensities in unhealthy populations. Therefore, %HRR and %VO_{2R} are used interchangeably by the ACSM to prescribe and estimate exercise intensity.

However, Solheim et al.[29] demonstrated some deviation of the assumed consistency of HRR to VO_{2R} across all levels of intensity in healthy athletic populations and concluded that caution should be used when utilizing HRR alone. Conversely, HRR is a valid end measure for delineating exercise intensity in patients with paraplegia due to SCI.[30] Since patients with neurological injury can have chronotropic limitations and differences in pathophysiology, the relative measurement of HRR is suited for measurement in SCI and stroke populations in a pilot study and is possibly made more accurate by continuous monitoring during the course of therapy activities. In patients with incompetent chronotropic responses, HRR can be defined by the difference between age-predicted maximal HR and resting HR, divided by the observed HRR to correct for the actual portion of HRR used.

Following the findings of Solheim et al.[29] and the exercise testing guidelines of the ACSM,[6(p120)] RPE was used in addition to HRR. RPE is a well-validated self-report indicator that correlates with exercise intensity. The submaximal measure of RPE can also be used to assess peak exercise intensity in unhealthy individuals.[31] A modified Borg RPE category-ratio scale from 1 to 10 was used instead of the original Borg from 6 to 20, but the scales can be used interchangeably.[32] However, some limitations exist in the RPE scale's comparability between individuals and physical activity modalities.[6(p122)] These breakdowns of the association of RPE to intensity have been identified in the population with stroke at vigorous intensities[33], across varying ADLs[34], and between patients with SCI based on level of injury who were found to be influenced more strongly by peripheral limb exertion than by extent of dyspnea.[35] Despite these

limitations, RPE is still widely used in prescribing exercise, monitoring exertion, and for submaximal exercise testing in deconditioned or impaired populations in inpatient rehabilitation.[6][122] While RPE is not suggested to be used to compare multiple therapeutic modalities, it is commonly used to gauge intensity in usual care rehabilitation therapeutic activities.

RGT and the feasibility of implementing an RGT system such as EksoGT RGT (See Figure 1) in the inpatient rehabilitation setting has only recently been explored. Additionally, there exists the issue of adequate training for therapists, which, in its current form, has been criticized as being inefficient. Due to barriers to successful implementation of EksoGT RGT in the inpatient setting, there have been no formal studies to date of overground RGT in patients with acute or sub-acute SCI. Thus, it is important to further explore overground RGT in the desired patient population and setting to bolster previous *ad hoc* indicators that RGT may result in positive outcomes from strength increases to psychosocial benefits.[9]

Figure 1. EksoGT by Ekso Bionics

EksoGT is a robotic exoskeleton that is powered at the hip and knee by individual motors. EksoGT can be used under a variety of different settings, offering considerable assistance with gait for patients with severe motor limitations or providing resistance for higher functioning patients. EksoGT is unique in its function in that it offers no body weight support like many exoskeleton-treadmill hybrids. It also actively involves patients by utilizing sensors in the foot plates to detect weight shifts in order to initiate steps.

Significance

Between 1990 and 2015 neurological disorders were the primary contributor to global disability, where nearly half of this burden was accounted for by stroke. In 2015, Stroke led to approximately 6,326 deaths of every 100,000 people and left nearly 627 in 100,000 people disabled.[36] In 2016, an estimated 13 SCIs occurred for every 100,000 people globally, while approximately 368 of 100,000 people lived with associated disability. SCIs accounted for 9.5 million years of life lived with disability (YLDs) in 2016.[37] Despite signs of a technologically and medically-driven amelioration of mortality rates in stroke and SCI, expanding populations, population aging, and the subsequent increased risk of injury threaten to impede progress and demand significant increases in resources devoted to the specialized care and rehabilitation associated with neurologic injury.[37,38]

The economic burden of these chronic conditions can impact both society and patients. Stroke and SCI costs are accumulated from the continuum of treatment, medications, hospitalization, and loss of productivity.[39] A stroke in the US has estimated costs of $15,597, $17,201, and $25,782 per capita in non-Hispanic white, Hispanic, and African Americans, respectively. Additionally, stroke is projected to cost the United States more than 2.2 trillion dollars by 2050.[40] While SCI incidence is lower, estimated average first-year costs were $523,089 and the following yearly costs were $79,759 although costs vary widely based on injury severity.[41] In light of this extreme quality of life and economic burden, early and effective rehabilitation is needed to maximize functional outcomes and limit the risk of secondary health conditions that promote long-term and increased utilization of healthcare resources.[42,43] This study intends to set a foundation for greatly needed high-quality studies on efficacy and assist clinicians in meeting current exercise recommendations in early inpatient rehabilitation.

CHAPTER IV

METHODS

Design

This is an observational, longitudinal cohort pilot study that began on July 11, 2019. Convenience sampling was used to recruit patients. The study objective was to investigate the cardiorespiratory intensity associated with usual care therapy activities performed in an inpatient rehabilitation facility for patients with SCI and stroke by observing patient response in HR and RPE.

Subjects

Patients newly admitted to the inpatient rehabilitation facility at BSWIR in Dallas, Texas with a diagnosis of SCI or stroke were recruited by their treating physical therapists. Patients with SCI were not excluded from the study based on level or etiology of their injury. Likewise, patients with stroke were not excluded based on type or location of stroke. Neither groups of patients were excluded based on severity of injury alone. Patients were included as long as they were cleared for participation in inpatient rehabilitation by their physician. Patients were recruited if they were in the sub-acute window of their injury and the expected LOS based on their Case Mix Group (CMG) in inpatient rehabilitation allowed for at least two weeks of data collection. Due to slow patient turnover and low total number of admissions, no special

consideration given to meeting minimum subsets regarding extent of disease in SCI or stroke. Initially, we intended to include recordings of a minimum of 5 sessions of each category of therapy activity; however, due to the nature of inpatient rehabilitation and the large variation in patient functional abilities, frequency of each therapy activity type performed was highly variable. Patients were excluded from the study if:

- Their injuries were chronic, i.e., greater than 1 year had passed since injury.
- They had cognitive deficits limiting participation including inability to follow commands or an inability to understand, agree, and knowingly participate in treatment based on clinician judgment.
- Their medical condition was unstable (e.g., uncontrolled autonomic dysreflexia, uncontrolled hypotension, hypertension, uncontrolled spasticity, untreated thrombus).
- They had wounds limiting contact with rehabilitation equipment.
- They had a cardiac demand pacemaker in place.
- They were pregnant.
- They were less than 18 years old

Further exclusions were applied to EksoGT utilization according to manufacturer criteria:

- Body habitus:
  - ~62” to 74” (1.58 m to 1.88 m)
  - Up to 220 lbs. (100kg)
- Range of Motion:
  - Hips: 135˚flexion to 20˚extension
  - Knees: 130˚flexion to 0˚extension

        - Ankles: 10˚flexion to 10˚extension
    - Continent of bowel and bladder or Foley catheter in place
    - Passed standing frame trial (e.g., tolerated upright standing position for 15 minutes without hypotensive episode).
    - Hip width <18”
    - Able to achieve neutral ankle dorsiflexion with <12˚of knee flexion
    - No more than 12˚hip flexion contracture
    - No thigh length discrepancy >0.5” and no leg length discrepancy >0.75”

This study received approval from the Baylor Scott and White Research Institute affiliated Institutional Review Board before any study procedures occurred.

Data Collection Procedure

Subject HR data was continuously monitored at 1-second intervals using Polar A370 Fitness Watches (Polar Electro Inc., Bethpage, NY USA; See Figure 2) worn by patients and operated by the therapist during therapy sessions. Patients were issued a smart watch for the duration of their hospitalization.

Figure 2. Polar A370 Fitness Watch (Face/ Sensor)

Polar Fitness watches use photoplethysmography (PPG) to measure heart rate. This technique illuminates the tissue of the forearm using a green LED. Light is reflected at different intensity based on the volume of blood perfusing the tissue, this volumetric change corresponds to the rhythmic contraction of the heart. Light sensitive diodes detect the rate of this change in light intensity, and the watch is then able to derive HR

Therapists were instructed to discretely record HR, activity type, and duration for all physical and occupational therapy sessions performed during the patients' hospitalization according to therapy activity type (See Table 1). Following the completion of each activity, patients were asked to rate their perceived exertion on the modified Borg scale (See Figure 3). Therapy activities were categorized based on similarities in clinical usage and desired outcomes by several clinicians experienced in inpatient neurologic rehabilitation (Table 1). For instance, gait training consists of overground gait, EksoGT, Treadmill, LiteGait, and gait trainer, which offer different versions of body weight support, assistance, or forced exercise to improve a patient's aerobic capacity or ability to ambulate. The functional skills category is composed of tasks or obstacles a patient will encounter in their daily lives, such as transferring to and from a wheelchair or developing strength and techniques to maneuver themselves in bed. Strength training activities include static and dynamic activities against body weight or added resistance. Aerobic training involves various apparatuses made to circumvent post-injury impairments and achieve a cardiorespiratory training intensity, such as the hand cycle or FES for those with lower extremity impairments, and recumbent steppers or combined upper and lower body ellipticals to compensate for various muscular deficits. The neuromotor task category includes repetitive tasks geared toward the affected limb or limbs, that train parts of a whole task, such as gait.

Patient demographics were retrieved from the medical record and were collected according to typical BSWIR protocol and inpatient rehabilitation facility classification requirements according to Medicare regulations. Demographics and patient characteristics included sex, ethnicity, race, date of birth, injury date, insurance type, diagnosis, mechanism of injury, paraplegia or tetraplegia, SCI injury level, ASIA Impairment Scale, type of stroke, presence or absence of hemianopsia, and FIM scores.

Procedure Limitations

While therapists were instructed to record every therapy session that was attributable to a study-specific activity, some sessions were not recorded due to issues with staffing or data recording logistics. Since participating therapists were involved in study design and execution, they were not blinded to the HR results or objective of the study. Patients were similarly unblinded.

Table 1. Therapy Activity Type

Code	*Category Description*	*Subcode*	*Activity Specification*
1	Gait training	*a*	Overground Gait
		b	EksoGT
		c	Treadmill
		d	Lite Gait
		e	Gait Trainer
2	Functional activities	*a*	Transfer practice (basic, toilet, car, etc.)
		b	Mat skills
		c	Stair practice
3	Strength training	*a*	Supine exercises
		b	Sitting exercises
		c	Standing exercises
		d	Stretching - any position
4	Aerobic	*a*	MotoMed
		b	NuStep
		c	RT300
		d	EasyStand Glider
		e	Hand Cycle
		f	UBE
5	Neuromotor tasks	*a*	Single limb stance/ pre-gait
		b	Static standing balance/ tolerance
		c	Dynamic standing balance activities
		d	Standing frame
6	Wheelchair propulsion	*a*	Wheelchair propulsion manual
		b	Wheelchair propulsion power

Data Analysis

Each patients' raw HR data for every therapy session was downloaded from their assigned smart watch to a computer. Data was processed initially for each patient's specific parameters using Excel (Microsoft Corp., Redmond, WA USA). Theoretical maximum HR for each patient was found using the Karvonen formula Hr_{max} = 220 – age (yrs), while customized regression equation estimates for HR_{max} exist, the former is still currently recommended by the ACSM for universal application.[44] Resting HR was found after patient discharge by searching nursing medical records for the lowest recorded HR, which is typically taken in the early morning before patients can be active. Using the HRR method for prescribing exercise intensity, zones of exercise intensity (very light <30%, light 30 - 39%, moderate 40 - 59%, vigorous 60 – 89%, near maximal >90%) were determined from the equation Target HR (THR) = [(HR_{max} – HR_{rest}) • % intensity desired] + HR_{rest} for each patient.[6(p186)] For each activity, frequency of each HR in 1-second intervals was determined for each %HRR zone and activity duration was used to determine the percentage of time spent at each intensity.

Data analysis was compiled using SAS (SAS Institute, Cary, NC USA). Data was stratified by injury type, SCI and stroke, severity, as well as therapeutic activity type. Continuous variables were summarized by mean and standard deviation or median and interquartile ranges depending on normality. Categorical variables were summarized using counts and percentages. Subjects' data was assessed to determine if ACSM recommendations for aerobic exercise were met during inpatient rehabilitation and to what extent each activity can be potentially used to meet aerobic exercise prescription needs. Intensity by diagnosis was compared using a mixed effect general linear model with individual subject as the random effect and diagnosis as the fixed effect, which accounts for repeated measures. RPE as a predictor of exercise intensity in

the subacute SCI and stroke populations was assessed using a partial correlation analysis, to account for subject effect, with percent time spent at each exercise intensity and the duration of each activity.

CHAPTER V

RESULTS

Demographics

Table 2. Summary of Patient Demographics and FIM scores

Patient Characteristics	**All (N = 28)**	**SCI (n=12)**	**Stroke (n = 16)**
Age (yrs)	56 (41, 65)	49.5 (30, 59)	60 (47, 65)
Male	14 (50%)	7 (58.3)	7 (43.8)
Hispanic Ethnicity	4 (14.3%)	0 (0%)	4 (25%)
Race			
Asian	2 (7.1%)	2 (16.7%)	0 (0%)
Black/African American	9 (32.1%)	3 (25%)	6 (37.5%)
White/Caucasian	17 (60.7%)	7 (58.3%)	10 (62.5%)
Time from Injury to Rehab (days)		25 (16, 200)	11 (6.5, 30.5)
Resting Heart Rate		62.17 ± 11.04	57.69 ± 5.49
FIM at Admission		**(n = 3)**	**(n = 11)**
Motor		23 ± 11.1	27.4 ± 13.3
Cognitive		28.7 ± 0.6	15.7 ± 4.4
Total		51.7 ± 11.7	43.1 ± 17.1
FIM at Discharge		**(n = 3)**	**(n = 11)**
Motor		66.3 ± 7.5	55.5 ± 18.3
Cognitive		34 ± 0	24.3 ± 3.4
Total		100.3 ± 7.5	79.7 ± 20.8

Only 3 SCI and 11 Stroke patients have FIM scores; All data entries cited as Mean ± SDM or median (Q1, Q3)

Of the enrolled patients, 16 suffered a stroke and 12 sustained a SCI and were admitted for inpatient rehabilitation at the facility for the study period. The study included equal numbers of male and female patients with 7 males in both populations. Average age of patients was 50.8

years. Of these patients, 14 and 5 patients with stroke and SCI, respectively, completed their rehabilitation and were discharged, resulting in only 11 and 3 patients with stroke and SCI having complete FIM score evaluations. Average time from injury to rehab was 25 days and 11 days for patients with SCI and stroke, respectively. Over the course of their hospitalization, average resting heart rate for patients with a SCI (57.69 bpm) was expectedly lower than that of patients with stroke (62.17 bpm). The study sample was predominately White/ Caucasian. Refer to Table 2 for the summary of patient demographics.

Table 3. Summary of Patient Diagnosis Characteristics

SCI Characteristics		**Stroke Characteristics**	
Mechanism of Injury		**Stroke Type**	
Motor Vehicle	1 (8.3%)	Left	5 (31.3%)
ATV/ATC/Go-Cart	1 (8.3%)	Right	7 (43.8%)
Gunshot Wound	1 (8.3%)	Bilateral	4 (25%)
Air Sports	1 (8.3%)	Unknown/Missing	1 (6.3%)
Fall	4 (33.3%)	**Hemianopsia**	
N/A Non-traumatic	3 (25%)	Yes	0 (0%)
Unknown	1 (8.3%)	No	15 (93.8%)
Para or Tetra		Unknown/Missing	1 (6.3%)
Paraplegic	5 (41.7%)		
Tetraplegic	7 (58.3%)		
SCI Level			
Cervical	7 (58.3%)		
Thoracic	5 (41.7%)		
ASIA Impairment Scale			
A (Complete)	2 (16.7%)		
B (Sensory Incomplete)	3 (25%)		
C (Motor Incomplete)	5 (41.7%)		
D (Motor Incomplete)	1 (8.3%)		
Unknown	1 (8.3%)		

3 of the 12 patients post stroke in the sample had total admission FIM scores less than 54, categorizing them as patients with severe disabilities due to stroke, while the other 9 were categorized as moderate.[45] The patients with SCI fell mainly into the higher severity ASIA Impairment categories (e.g., ASIA-A, ASIA-B, and ASIA-C), indicating that besides two patients, they had limited or absent motor function below the site of injury. 7 of the 12 patients with SCI suffered injury at the cervical level, whereas 5 had thoracic injuries. These two characteristics together indicate a severely disabled patient sample. Mechanism of injury was variable in our sample with the highest number suffering injuries from falls (See Table 3). Patients with stroke varied in the location of their stroke left (31.3%), right (43.8%), and bilateral (25%). None of the patients post stroke presented with hemianopsia as a result of their condition.

Table 4. Rehabilitation Therapy Activity by Diagnosis

Activity Type	SCI (n=124)	Stroke (n=342)
1a	17 (13.7%)	83 (24.3%)
1b	31 (25%)	32 (9.4%)
1c	0 (0%)	5 (1.5%)
1d	0 (0%)	12 (3.5%)
2a	5 (4%)	38 (11.1%)
2b	21 (16.9%)	0 (0%)
2c	0 (0%)	5 (1.5%)
3a	5 (4%)	37 (10.8%)
3b	8 (6.5%)	12 (3.5%)
3c	5 (4%)	11 (3.2%)
3d	5 (4%)	3 (0.9%)
4a	0 (0%)	26 (7.6%)
4b	0 (0%)	12 (3.5%)
4c	10 (8.1%)	0 (0%)
4d	1 (0.8%)	0 (0%)
4e	1 (0.8%)	0 (0%)
5a	1 (0.8%)	34 (9.9%)
5b	1 (0.8%)	12 (3.5%)
5c	0 (0%)	3 (0.9%)
5d	5 (4%)	1 (0.3%)
6a	4 (3.2%)	16 (4.7%)
6b	3 (2.4%)	0 (0%)

While chosen therapy techniques differ greatly depending on patient diagnosis, patient needs, and clinician preference, it is interesting to note the high usage of EksoGT in patients post SCI at 25% of therapy provided in comparison to its use in only 9.4% of sessions in patients post stroke (See Table 4). Additionally, functional mat skills (2b) were practiced 16.9% of the time in SCI but not at all in the stroke subgroup, likely due to extent of lower extremity disability differences between the two groups. Understandably, these treatment differences also apply to FES RT300 bike usage in SCI at 8.1% of the time, whereas it was not used in patients with stroke.

Heart Rate Reserve by Activity and Diagnosis

Table 5. Average Percent of HRR Across Activities in Patients Post SCI (n = 12)

Activity Type	**n**	**Average Duration (s)**	**Very Light**	**Light**	**Moderate**	**Vigorous**	**Near Max**
1a	3	1190±346	43±22	32±4	25±18	0±1	0±0
1b	6	1357±226	18±18	34±17	47±24	1±1	0±0
2a	3	1785±594	44±8	38±8	17±14	0±1	0±0
2b	5	1853±54	42±32	32±16	26±28	0±0	0±0
3a	4	2349±1728	88±23	11±21	1±2	0±0	0±0
3b	4	1481±475	81±27	12±14	7±14	0±0	0±0
3c	2	1103±25	30±27	55±17	15±10	0±0	0±0
3d	4	1938±725	73±27	23±24	4±9	0±0	0±0
4c	6	1647±740	63±36	27±25	7±12	0±0	3±8
4d	1	1165±0	71±0	29±0	0±0	0±0	0±0
4e	1	1803±0	3±0	41±0	46±0	10±0	0±0
5a	1	1554±0	52±0	32±0	16±0	0±0	0±0
5b	1	2136±0	99±0	1±0	0±0	0±0	0±0
5d	2	1768±75	28±12	40±21	31±33	0±0	0±0
6a	2	2041±27	38±11	45±27	15±15	1±2	0±0
6b	3	1750±635	40±53	11±19	13±22	36±55	0±0

n = number of participants who had at least one session of the given activity type; All data entries cited as Mean ± SDM

Table 6. Average Percent of HRR Across Activities in Patients Post Stroke (n = 16)

Activity Type	n	Average Duration (s)	Very Light	Light	Moderate	Vigorous	Near Max
1a	14	1035±317	38±30	25±10	29±24	7±12	0±0
1b	7	1095±151	30±35	17±10	28±24	24±29	0±0
1c	3	639±331	31±23	36±10	34±22	0±0	0±0
1d	4	934±165	26±28	25±20	34±16	15±30	0±0
2a	12	611±199	39±34	32±24	28±27	0±0	0±0
2c	2	556±71	17±0	37±11	46±12	0±0	0±0
3a	8	1508±711	56±35	18±12	26±33	0±1	0±0
3b	4	1242±205	65±37	18±16	17±23	0±1	0±0
3c	8	1009±608	38±33	21±20	23±21	18±25	0±0
3d	3	745±406	92±9	7±7	1±2	0±0	0±0
4a	13	870±536	37±36	27±20	32±30	4±13	0±0
4b	5	1434±285	49±26	27±18	13±16	10±22	0±0
5a	8	1066±428	43±33	27±27	12±17	18±35	0±0
5b	9	842±379	49±38	29±30	14±21	8±23	0±0
5c	3	1615±418	34±29	31±24	26±38	9±15	0±0
5d	1	1239±0	100±0	0±0	0±0	0±0	0±0
6a	9	567±315	45±25	22±13	31±28	3±6	0±0

n = number of participants who had at least one session of the given activity type; All data entries cited as Mean ± SDM

Tables 5 and 6 report the averages of patient average percent duration in each heart rate zone for each activity. Tables 5 and 6 were reproduced in Figures 4 and 5 to help detail the differences between activity. Not every activity designated in Table 1 was performed by the SCI and stroke patient subgroups. Additionally, no activity provoked a near maximal intensity in the patient samples, nor was vigorous activity elicited in any clinically significant fashion in patients with SCI. Extreme variability is clearly present within each activity type in terms of duration and intensity. Power wheelchair propulsion (6b) in Table 5 is also influenced by an outlier, as this activity in this patient required only the movement of a single upper extremity to control the direction of the wheelchair. While this outlier was identified clinically, no vitals or other monitoring occurred during the session to confirm this designation. The data in Table 5 indicates

the greatest amount of moderate intensity exercise was likely provided in SCI by EksoGT (1b; 47%), handcycling (4e; 46%), and the standing frame (5d; 31%). While in stroke moderate intensity was largely administered by stair practice (2c; 46%, n = 2) followed closely by gait training modalities (1a-1d), transfer practice (2a), supine exercises (3a), MotoMed (4a), dynamic standing balance activities (5c), and manual wheelchair propulsion (6a), which garnered moderate intensity responses greater than 25% of the time. Contrary to these activities' effects on patients after SCI, patients post stroke reached vigorous intensity performing several activities, but largely maintained vigorous activity through EksoGT (1b; 24%), standing strength exercises (3c; 18%), and single limb stance/ pre-gait training (5a; 18%).

Table 7. Average Percent of HRR in Broad Activity Type Categories in SCI and Stroke

All Activity	n	Average Duration (s)	Very Light	Light	Moderate	Vigorous	Near Max	Mod. -Vig.	Average RPE
1	22	1128±246	30±24	28±13	33±20	8±14	0±0	41	4.4±2.3
2	18	1038±635	43±30	32±20	25±23	0±0	0±0	25	3.5±1.3
3	20	1576±936	62±30	19±17	15±18	3±9	0±0	18	3±1.6
4	21	1176±639	49±33	27±19	20±23	4±11	1±3	18	3.3±2.1
5	15	1155±423	46±30	32±22	14±17	8±22	0±0	22	3.6±1.9
6	14	1031±740	43±29	23±18	25±26	10±26	0±0	35	3.6±1.5
SCI									
1	7	1306±272	24±16	35±15	25±27	1±1	0±0	26	5.7±2.8
2	6	1873±182	48±24	35±14	17±17	0±0	0±0	17	3.7±1
3	8	1979±1250	75±23	18±17	7±10	0±0	0±0	7	3.5±1.4
4	6	1684±726	64±36	25±21	8±15	1±2	2±6	9	4.3±1.3
5	3	1794±69	44±29	32±20	24±27	0±0	0±0	24	3.5±2.1
6	5	1866±477	39±38	25±27	14±17	22±43	0±0	36	2.6±0.6
Stroke									
1	15	1044±188	33±27	24±11	30±21	12±16	0±0	42	3.8±1.9
2	12	621±194	40±33	31±23	28±26	0±0	0±0	28	3.4±1.4
3	12	1308±568	53±32	20±17	21±21	6±12	0±0	27	2.7±1.6
4	15	973±491	43±31	28±19	24±25	5±13	0±0	29	2.9±2.3
5	12	995±297	46±31	32±24	12±15	10±25	0±0	22	3.6±2
6	9	567±315	45±25	22±13	31±28	3±6	0±0	34	4.2±1.6

Averages are weighted equally; All data entries cited as Mean ± SDM

For broad categories of activity type (See Table 7), gait training appears to be the therapy type that most efficiently trains patients at a moderate to vigorous intensity based on HRR. Across both diagnoses, moderate to vigorous activity was performed for approximately 41% of the duration of gait training activities. In patients with stroke, it appears that gait training is even more successful at 42%, while in patients with SCI gait training required exercise at moderate to vigorous intensity only 26% of the time when performing gait training therapies. The next most effective training type in patients post SCI was wheelchair propulsion training (36%) and mobility training (24%). For patients post stroke, all but one training type, mobility training, caused a moderate to vigorous exercise intensity greater than 25% of the time. Wheelchair propulsion activities showed a consistent pattern in both subgroups at 36% and 34% in SCI and stroke, respectively. It appears the least cardiorespiratory strain is evoked across both diagnoses during strength activities at about 18% of the time, but even more so in the SCI group alone at around 7%. This is remarkable due to its necessity in maximizing functional outcome measures in an inpatient rehabilitation program and its proposed synergism with aerobic activities.[46]

Table 8. Comparison of Average Percentage of Activity Duration by Intensity and Diagnosis

	SCI (n=124)	**Stroke (n=342)**	**p-value***
Duration (seconds)	1624.7±639.2	1013.2±637.8	**<0.001**
Percent of Duration in HRR zone			
Very Light	39±35	47±37	0.3482
Light	31±24	24±22	**0.0236**
Moderate	28±32	23±27	0.4001
Vigorous	1±9	6±18	**0.0484**
Moderate + Vigorous	29±33	29±34	0.9477
RPE	4.1±2.1	3.8±2.2	0.6358

The averages are calculated across all sessions for all patients; All data entries are cited as Mean ± SDM.

*A mixed effect general linear model with subject ID as the random effect and diagnosis as the fixed effect was used for analysis in order to account for repeated measures.

Using a mixed effect general linear model with Subject ID as the random effect and diagnosis as the fixed effect to account for repeated measures, there was a significant difference between time spent in activities in SCI and stroke ($p < 0.001$). Whether or not it is possible to correlate this clinically or to fatigability is undetermined. While a defined protocol existed, there was no guarantee it was followed precisely across therapists and patients, especially due to the logistics of the heart rate monitor and the prioritization of patient care over data collection. There were additional significant differences in time spent in light ($p = 0.0236$) and moderate ($p = 0.0484$) activity when comparing patients in the SCI and stroke groups. The SCI group appeared to spend more time in light intensity (31%), while patients post stroke spent a higher percentage of duration at vigorous intensity (6%). No significant difference was found between percentage of duration in intensity zones of Very Light, Moderate, Moderate + Vigorous, or in average RPE.

Rate of Perceived Exertion in Inpatient Rehabilitation in SCI and Stroke

Table 9. Comparison of RPE to Average Percent of Duration of Intensity (%HRR) in SCI

RPE	n	Duration	Very Light	Light	Moderate	Vigorous	Near Max
1	13	1517 ± 656	52 ± 38	23 ± 18	25 ± 31	0 ± 0	0 ± 0
2	13	1756 ± 450	63 ± 36	19 ± 20	18 ± 32	0 ± 0	0 ± 0
3	20	1752 ± 886	40 ± 36	32 ± 21	22 ± 25	6 ± 22	0 ± 0
4	17	1474 ± 669	33 ± 36	30 ± 27	36 ± 38	1 ± 4	0 ± 0
5	22	1495 ± 466	30 ± 31	37 ± 29	33 ± 37	1 ± 3	0 ± 0
6	9	1717 ± 336	22 ± 26	46 ± 20	30 ± 21	1 ± 3	0 ± 0
7	1	2070 ± 0	19 ± 0	77 ± 0	4 ± 0	0 ± 0	0 ± 0
8	9	1321 ± 540	32 ± 36	27 ± 23	41 ± 37	0 ± 0	0 ± 0
9	2	1533 ± 147	10 ± 1	8 ± 1	82 ± 0	0 ± 0	0 ± 0
10	1	1734 ± 0	3 ± 0	11 ± 0	85 ± 0	1 ± 0	0 ± 0
Partial Correlation		-0.09	-0.41	0.19	0.29	-0.01	NA
p-value		0.3607	**<0.0001**	0.064	**0.005**	0.9159	NA

*Note 17 sessions are missing RPE; All data entries are cited as Mean ± SDM.
*Partial Correlations adjust for subject effect

Table 10. Comparison of RPE to Average Percent of Duration of Intensity (%HRR) in Stroke

RPE	n	Duration	Very Light	Light	Moderate	Vigorous	Near Max
1	42	927 ± 489	58 ± 38	20 ± 21	18 ± 26	4 ± 16	0 ± 0
2	60	950 ± 584	48 ± 35	27 ± 23	20 ± 27	5 ± 17	0 ± 0
3	46	1024 ± 594	61 ± 34	23 ± 22	13 ± 23	1 ± 5	0 ± 0
4	44	861 ± 414	40 ± 39	23 ± 22	27 ± 28	10 ± 22	0 ± 0
5	36	1045 ± 554	45 ± 39	17 ± 17	27 ± 33	10 ± 24	0 ± 0
6	31	938 ± 501	35 ± 32	32 ± 23	28 ± 25	4 ± 15	0 ± 0
7	14	1041 ± 404	44 ± 40	13 ± 15	27 ± 26	16 ± 31	0 ± 0
8	22	1383 ± 1392	41 ± 34	24 ± 15	26 ± 20	9 ± 17	0 ± 0
9	2	816 ± 82	34 ± 48	25 ± 10	41 ± 58	0 ± 0	0 ± 0
10	1	256 ± 0	100 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
Partial Correlation		0.1	-0.17	0	0.08	0.2	NA
p-value		0.0865	**0.0036**	0.9896	0.2011	**0.0006**	NA

*note 44 sessions missing RPE; All data entries are cited as Mean ± SDM.
*Partial Correlations adjust for subject effect

Correlation coefficients were determined for RPE against duration and average percent of time spent within each intensity based on range of %HRR. Significant correlations were found for very light and moderate levels of intensity in the subgroup with SCI, which were moderate and low, respectively. In patients post stroke, significant but low correlations were found for very light and moderate levels of intensity. A negative correlation indicates a lower RPE was more likely based on a higher percentage of average duration in that zone. In patients with SCI, a significant ($p < .0001$) negative moderate correlation (-0.41) for very light intensity and a significant ($p = 0.005$) positive low correlation (.29) for moderate intensity were determined. In patients post stroke, a significant ($p = 0.0036$) negative weak correlation (-0.17) for very light intensity and a significant ($p = 0.0006$) positive weak correlation for vigorous intensity were found. The directionality of these significant correlations follows what would be expected as higher percentages of duration spent in lower intensities should result in a lower perceived exertion, which is shown in very light activity (See Figures 10 and 11). Similarly, as percentage

of duration spent in moderate and vigorous intensity increases, we would expect RPE to increase. No significant correlations were found between average duration or light intensity to RPE, and the only consistent relationship for both stroke and SCI subgroups was that of RPE to very light intensity activity.

Discussion

The aim of this study was to assess the cardiorespiratory demand of specific and usual care inpatient rehabilitation therapies (See Table 1) in the subacute SCI and stroke populations using HRR and RPE, as well as determine their usage and effect according to diagnosis and severity. Study observations indicated that 1) on average this population is capable of meeting intensity thresholds recommended to improve cardiorespiratory fitness, however the patients and therapy type vary considerably, 2) caution should be used when applying HRR and RPE across differing diagnoses, medical severities, and therapy modalities, and 3) EksoGT is possibly the most effective treatment at providing moderate to vigorous intensity across this high acuity, sub-acute population.

Estimating Intensity through Heart Rate Reserve

Primary goals of post stroke and SCI care and rehabilitation after injury are similar, including the recovery of function, independence in activities of daily living, and the reduction of post injury comorbidities.[1,7] These goals are met most quickly in the first 6 weeks after SCI and less time from injury onset to rehabilitation is seen as a similarly important factor in stroke recovery, denoting the importance of refining treatment and efficacy in the inpatient setting.[14,47] Current usual care rehabilitation therapies include activities with distinct goals, including strength, balance, endurance, and flexibility, which work best when applied together in a progressive, intensive, and task-based manner.[48] Despite the potential benefits of aerobic exercise, there is limited data on the dosage or type of intensity required and progression needed to derive maximal benefits in subacute SCI and stroke.[3,12,22,46,49,50]

The question as to how to effectively employ, measure efficacy, and consistently replicate effects, such as levels of cardiorespiratory strain is unanswered, but necessarily answered by thorough characterization across facilities, diagnoses, and therapeutic techniques in inpatient rehabilitation.[5] Given the 295 sessions in severe stroke (n = 13) to the 47 sessions in moderate stroke (n = 3), and the parallel sample of ASIA-A tetraplegics (n = 2; 21 sessions), the 2 tetraplegic and 1 paraplegic ASIA-B (n=3; 30 sessions), 3 tetraplegic and 2 paraplegic ASIA-C (n=5; 63 sessions, 49 of which are in patients with tetraplegia), and a tetraplegic ASIA-D (n = 1; 1 session), our sample is descriptive of a particularly high acuity population.

Current ACSM guidelines[6] suggest 30-60 min•d^{-1} (≥150 min•wk^{-1}) of moderate intensity (40-59% HRR) or 20-60 min•d^{-1} (≥75 min•wk^{-1}) of vigorous intensity (60-89%HRR) are recommended in healthy populations, but cardiorespiratory benefits have also been accumulated from light intensity (30-39%HRR) in deconditioned individuals. Updated guidelines[22] dictate a minimum required exercise recommendation 40 min•wk^{-1} performed over two days for SCI. In patients who sustained a stroke, minimum guidelines are higher, recommending 3 to 5 days of 20 to 60 minutes of moderate to vigorous intensity exercise.[7] However, a recent systematic review[51] also indicates physical activity performed in intermittent bouts regardless of time can be beneficial to health, and duration has even been identified as being negatively correlated to the odds of a good outcome.[52] Therefore, activities that were less than 10 minutes in duration are still potentially clinically relevant in parsing the dose of intensity and potential for benefit due to aerobic activities. Nevertheless, average activity duration, in patients with SCI and stroke, was 27 min and 4 seconds and 16 minutes and 53 seconds. Only two average activity durations, functional stair practice and wheelchair propulsion in patients with stroke, were less than 10 minutes at 9 minutes 16 seconds and 9 minutes 27 seconds, respectively.

Given the recommendations and the assumption of a representative sample of therapy recordings, 58.9% (SDM = 24.8%, range = 17-90.1%, median = 62.9%) of stroke and 48.9% (SDM = 21.9%, range = 0-73.5%, median = 56.6%) of SCI patient time on average in monitored therapy was spent at an intensity zone (30-89%HRR) conducive to eliciting physical fitness gains from aerobic activity. However, under the more stringent criteria (40-89%HRR) for healthy individuals, patients with stroke and SCI only spent 29% (SDM = 34%, range = 0.7-78.4%; median = 31.6%) and 29% (SDM = 33%, range = 0-40.6%; median = 24.2%), respectively, in the moderate to vigorous zones of intensity. If this percentage was applied to the scheduling goals of the facility (5 hours of PT per week), patients post stroke received 2.94 to 1.45 hours compared to SCI that received 2.45 to 1.45 hours of the targeted intensity, and in terms of total time at intensity, met minimum exercise guidelines for people living with stroke and SCI. However, this generalization is limited due to the nature of this pilot study, logistical issues, and therapists' commitment to maintaining usual care practices. As such, not every therapy session was recorded.

While similar studies[20,53,54] set out to describe inpatient rehabilitation, they are conflicting in the determination of whether or not inpatient rehabilitation provides adequate cardiorespiratory strain, demonstrating the large amount of variation between inpatient rehabilitation settings. Zbogar et al.[20] indicate only 11 of 87 patients with SCI met the 20-minute guideline when recording all of either PT or OT sessions in 2 days of inpatient rehabilitation, whereas Koopman et al.[53] indicate sufficient cardiorespiratory strain greater than 40% HRR for an average of 114 min per day for 75% of subjects but large variability in the per patient averages was mentioned. Interestingly, the former reports most patients that exceeded 20 minutes of activity at 40% HRR had AIS D motor incomplete injuries and were able to actively engage in

gait therapy, which was designated as being most likely to reach greater than 40% HRR for a clinically significant length. Under the updated, expanded minimum physical activity guidelines and EksoGT's ability to open up gait training for dependent ambulatory patients, our study showed increased likelihood that inpatient rehabilitation therapies can administer sufficient cardiorespiratory strain and encourage cardiorespiratory benefits in the severe and dependent ambulatory population. However, special attention should be paid to patient individuality, while the time spent in target zones of HRR should also be monitored to maximize cardiorespiratory fitness or provide future evidence of exercise induced neuroplasticity.[55,56]

When broadly considering the activity types performed in this group of patients, the majority (38.7%) of sessions involved some form of gait training. Strengthening activities and functional activities took place the other 18.7% and 14.8% respectively, which appears appropriate for maximizing the synergistic effects of a combination of resistance and aerobic training.[46] Interestingly, aerobic exercises were utilized at a lesser rate (10.7%) than all but wheelchair propulsion activities, possibly due to the known integration of aerobic exercise in gait training.[57] Gait training was prioritized in both stroke and SCI, while SCIs were treated at higher rates using functional activities (21.1%) compared to stroke (12%). Neuromotor tasks were used nearly three times as much in stroke (14.6%), focusing on single limb stance and pre-gait, as they were in SCI (5.69%), which used the standing frame instead.

By broad activity groupings, gait therapy led to higher levels of average moderate to vigorous activity across SCI and stroke (41%), as well as in stroke (42%) alone. In patients with SCI gait training was the second most intense therapeutic activity type. Strength training led to the least amount of time in moderate to vigorous levels of activity at 18% across both groups (See Table 7) but had a more intense effect on patients post stroke at 27% compared to SCI at

7%. Across the board, patients with a stroke diagnosis appeared to reach higher levels of cardiorespiratory strain than SCI with every activity providing moderate to vigorous intensity greater than 25% of the time, whereas SCI only reached similar levels in neuromotor, gait training, and wheelchair propulsion modalities. Surprisingly, patients post stroke can reach vigorous levels of intensity in several therapeutic activities, while patients with SCI rarely meet those thresholds.

Patients with SCI and moderate stroke patients potentially found vigorous levels of intensity difficult to reach compared to the sample of patients categorized as severe post stroke (See Figure 9), which could be attributed to the severity and location of injury in these study population. Patients with severe stroke (20%) spent significantly ($p = 0.0005$) less time performing light intensity activity compared to patients with moderate stroke (37%). While this time might have been spent in more vigorous intensities than patients with mild stroke, statistical significance was not reached between the two groups at vigorous intensities. There was some distinction, though not statistically tested, between the amount of moderate to vigorous activity reached based on activity. Some activities elicited twice the intensity as others in patients with SCI (See Figure 5), and in those with severe stroke, a distinction could be made between activities that promoted vigorous versus only moderate intensity. Through the more meticulous study of these differences in intensity, clinicians and researchers could tease out therapies to avoid or meet intensity to study these effects further in these populations or direct therapy in a more purposeful manner to promote cardiorespiratory fitness and neuroplasticity in neurologically injured patients.

Determining the intensity of commonly used exercise modalities in inpatient rehabilitation is the first step in guiding individualized, evidence-based treatments to maximize

recovery from neurologic injury. For instance, moderate intensity exercise implemented in the early phase of recovery might encourage the recovery of cognitive function. Variation in the intensity and duration of exercise have been linked to differential expression of protective and regenerative endogenous neurotrophins (e.g., BDNF, NGF, and GDNF), but have also been shown to have antagonistic effects depending on location of injury and recency of injury. The potentially harmful effects of this endo-pharmacologic environment dictated at least partially by exercise intensity emphasizes the need to thoroughly define exercise parameters of conventional therapies.[58]

Overground Robotic Gait Therapy Using EksoGT

Table 4 summarizes activities in the SCI and stroke groups, indicating EksoGT (1b), functional mat skills (2b), and overground gait (1a) were used over 10% of the time each, with EksoGT being the most employed treatment in the SCI population at 25%. This high usage of EksoGT holds true in both cervical (21.98%) and thoracic (34.38%) injury levels. However, EksoGT was not used in the patients categorized as ASIA-A complete. EksoGT was also used at a considerable rate in patients post stroke (9.4%) as the fifth most utilized therapy, following the most used therapy, overground gait training (24.3%).

Physical therapy is a field that is often informed first by experience and later by evidence,[5] and as such, it is important to note this notably high usage of EksoGT. In activities performed at least 5 times and in all severities of SCI, minus ASIA-A classified patients, EksoGT provided the most intense cardiorespiratory strain in terms of %HRR (See Figure 7), keeping patients in moderate intensity for 47% of the time, while overground gait, functional mat skills, and rt300 (FES) provided moderate intensity only 25%, 26%, and 7% of the time. The

SCI population was difficult to keep at a vigorous intensity, with no activity promoting vigorous activity longer than 1% of the time. performed at least a total of 5 times by patients including at least 2 stroke types EksoGT was similarly effective at providing moderate exercise intensity in stroke at an average 28% of the time, a similar intensity to wheelchair propulsion (31%), aerobic MotoMed (32%), overground gait (29%), Lite Gait (34%), and functional transfer practice (28%). However, EksoGT was apparently more effective at reaching vigorous levels of intensity at 24% of time, compared to the next most vigorous, neuromotor single limb stance/ pre-gait (18%) and standing exercises (18%). Overground walking only provided vigorous intensity activity 7% of the time. These findings highlight the manner in which EksoGT could help to meet cardiorespiratory needs more adequately in this deconditioned population.

Compared to prior studies[16-18] of the cardiorespiratory demands of overground robotic exoskeleton gait therapy our study differs due to the inclusion of all severities of SCI in the subacute phase of recovery, whereas prior studies assessed only chronic, thoracic SCIs. The potentially increased cardiorespiratory strain due to EksoGT in cervical SCI (58%) compared to thoracic (39%) was unexpected. However, between these groups, cervical SCI appeared to reach higher intensities overall, although statistical significance was not reached (See Figure 8).

Current theories of EksoGT's mechanism of action rests on the idea that it forces patients to activate trunk musculature, use upper extremities to maintain balance, and actively participate in initiating steps, contrary to rigid treadmill exoskeletons effect on patients.[16,59,60] Therefore, based on level alone, we would expect a further extent of paralysis to the trunk and torso limiting exertion in these individuals, especially since the majority of EksoGT sessions were performed by patients with severe motor deficits characterized as ASIA-B and C. However, recent evidence[61] outlines substantial sparing of abdominal musculature despite motor-complete high

thoracic and cervical injuries. Our findings support this potential sparing of musculature inferior to the level of injury as a possible mechanism through which EksoGT encourages moderate to vigorous exercise intensity. Identifying EksoGT as an adequate cardiorespiratory treatment in subacute SCI and stroke, begins to build evidence that EksoGT can be used in severely disabled patients as a way to administer early, high intensity, task-specific therapy in lieu of conventional gait therapies that can require extensive effort by therapists at this stage in recovery. Further research is required regarding the efficacy and dose of overground RGT.

Misguiding Intensity Through Generalized Use of Perceived Exertion

RPE does not appear to be a reliable guide or tool to monitor exercise intensity (e.g., very light, light, moderate, vigorous) across the variable treatments provided in inpatient rehabilitation or in these sample populations. While significant correlations of RPE to time spent in very light, moderate, and vigorous intensity were identified, they were low except for the relationship of RPE to very light intensity in patients with SCI (See Tables 9-10). The very light intensity range of target HRs extends from the state of being sedentary to an activity such as a leisurely walk in a healthy population. A moderate correlation may indicate a therapist's ability to discern the beginnings of cardiorespiratory training ranges (%HRR>30) as RPE increases, but the range itself (%HRR<30) is not recommended specifically for cardiorespiratory training. The correlation coefficients determined in patients with stroke were weaker than that in patients with SCI and therefore less reliable, mirroring findings in a similar setting.[53] However, we did not assess the statistical significance of this between group difference.

Our findings allude to the significant difficulty of gauging exercise intensity in these populations through subjective measures alone, especially as a consequence of the extreme

variability in patient pathologies and therapeutic activity types. However, these low to moderate correlations may echo RPE's validity in patients after SCI and stroke using typical aerobic exercises such as handcycle or wheelchair ergometers[62,63] but RPE was potentially influenced by the variety of rehabilitation therapies (e.g., functional, strength) involved in rehabilitation.[34] Since significant rehabilitation time is allotted for task-specific, unintentionally aerobic training directed at improving metrics of ADL and functional independence, further research should be directed toward determining an accurate, generalizable objective measure to assess administered cardiorespiratory strain in these treatment types. Broadly, our findings indicate the current usage of RPE with inpatients in our facility is a poor predictor of exercise intensity with little clinical applicability. However, further interrogation of how, when, and for which activity our clinicians deliver the question of RPE to patients is warranted based on the RPE scale's historical validity in practice and in research.

CHAPTER VI

SUMMARY AND CONCLUSION

Limitations

There are several possible limitations to this study. First, neither HRR or RPE are a perfect estimate of intensity.[29] HRR and RPE were selected as proxy measures for intensity because they provide both objective and subjective perspectives and are clinically feasible in the subacute population. HR data generalizability is also limited. Several unblinded therapists assisted in collecting HR and RPE data, potentially differing in how much effort they inspired in patients during therapy sessions. We also did not control for cognitive deficits in patient populations.

It is important to note, in this population, HRR is variable and in this case often influenced by medication (e.g., beta blockers) as 3 of the 5 patients post stroke prescribed beta blockers spent only 9.39, 5.13, and 0.66 percent of time in greater than 40% HRR zones, while the other 2 exhibited comparable levels of intensity to the rest of the sample. After correcting for the HR-reducing effect of beta-blockers using a regression equation for a similar population of patients with coronary artery disease[64], the same 3 patients spent 55.7, 68.6, and 34.8 percent of time in moderate to vigorous intensity. Omitting these medication corrections to HRR and estimating theoretical max according to the generalizable Karvonen formula in this study, is a conservative approach to estimate intensity, considering the often-dampened sympathetic

innervation of the heart in cervical and high thoracic SCI as well as the patients' limited ability to perform and maintain high intensity physical activity.[65]

Moreover, this study is dependent on the accuracy of commercial Polar fitness watches. While PPG is an accurate tool for HR monitoring during physical activity in healthy people and patients with coronary artery disease, it is untested in the rehabilitation setting.[66] Fitness watches are a simple method for recording HR that requires little overhead in terms of patient and clinician barriers to usage, and price. However, future studies to determine this specific model's accuracy in homogenous patient populations in the rehabilitation setting are needed as this study only establishes it as a feasible implementation. Finally, the study sample was relatively small and potentially more acute than typical inpatient rehabilitation populations, making significant inferential statistical analyses or generalizations unlikely.

Future Recommendations and Studies

In light of the significant differences in intensity experienced between and within neurologic injury diagnoses in this study and the impractical use of direct measures of exercise intensity, further studies are encouraged to first accurately assess individual peak exercise capacity using conventional methods maximal or submaximal exercise testing. Additionally, more detailed clinician notes are encouraged to assess patient affect and stress during therapy sessions to account for possible clinically identifiable outliers. In a similar vein, the way in which RPE is obtained should be assessed and possibly modified to more accurately assess cardiorespiratory strain in nonspecifically aerobic activities involving muscular fatigue.

This study serves mainly to expose potential areas of study in inpatient rehabilitation utilizing cardiorespiratory strain as an outcome measure, however, our assertions are dependent

on commercially available fitness watches. Therefore, an assessment of their accuracy and a determination of the error rate against more accurate ECG-type devices is encouraged to lend clinical credibility and generalizability to findings.

Future Directions

In light of the feasible implementation of inexpensive, low effort HR monitoring in the inpatient population, large prospective and randomized control trials are possible and needed to determine the optimal dose of intensity to improve cardiorespiratory fitness and potentially inspire neurological recovery during the subacute phase of recovery in stroke and SCI. Additionally, special attention should be paid to patient cardiorespiratory response in order to assure guidelines are being met. However, RPE should be used with caution in this setting. In pursuit of meeting ACSM recommendations for exercise intensity, clinicians can look to EksoGT as a potentially efficient aerobic training tool in the sub-acute phase of recovery for deconditioned and dependent ambulatory patients in the sub-acute phase of recovery who have suffered stroke and SCI.

CHAPTER VII

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CHAPTER VIII

INTERNSHIP EXPERIENCE

As a Research Intern at the Baylor Scott & White Institute for Rehabilitation, I worked on several other projects in addition to the quality improvement project from which this thesis work stems. These projects included the Group Lifestyle Balance (GLB) studies with TBI and Stroke subjects, the Workout on Wheels Internet Intervention Randomized Controlled Trial (WOWii), the Spinal Cord Injury Energy Expenditure and Activity study (SEEA), Traumatic Brain Injury Model Systems (TBIMS) and a qualitative study on clinician experiences with the robotic exoskeleton. For the GLBCVA, GLBTBI, WOWii, and SEEA studies, tasks included preparing mailings except for in SEEA, data entry, assisting with intervention class sessions, coding and tracking patient recruitment, participation in internal audits, and construction of a CRF for actigraphy data. For GLB studies, I managed subject activity monitoring devices, including initialization, downloading, repairing, cleaning, shipping, and SOP production for the devices.

Tasks involved with the Clinical Experiences with Robotic Exoskeleton Use study included analysis of focus group data, assistance with manuscript production, abstract production, abstract submission, and figure or data table creation. The majority of tasks were associated with the intensity study, including: literature study and review, data collection, data entry, data abstraction from medical records, database management and creation, interpretation

of findings, creation of standard operating procedures, management of patient monitoring devices, data analysis, and organization of tracking systems.

Journal Summary

Initially, my time was spent with onboarding tasks, attending meetings, reviewing good clinical practice, being checked off as capable of delivering and receiving informed consent, and catching up on pertinent literature regarding ongoing studies. After onboarding, I took responsibility for the bimonthly birthday card mailers for the TBIMS study and managing Actigraphs for the GLB studies. Once I had written my proposal, received IRB approval, and helped work out the issues in the intensity study we began collecting data. Every Friday I would synchronize the Polar watches and update the patient CRFs, the RedCap database, and the tracking sheets. Throughout the week, I would keep in touch with the therapy teams and start new patients on watches when they became available. Throughout this time, Coulter and I analyzed data and helped to draft an abstract for the Lessons Learned with EksoGT study, which was accepted to ACRM this November as a poster presentation. We also submitted the subsequent manuscript for peer-review in September. The rest of my time was filled with various data management and data entry tasks, as well as various meetings and trainings with the Research Department.

APPENDIX

APPENDIX A

FIGURES

Figure 3. Modified Borg Rated Perceived Exertion

Rate of Perceived Exertion (RPE)	
How hard do you feel like your body is working during this activity? *¿Qué tan duro sientes que tu cuerpo está trabajando durante esta actividad?*	
So Tired, I Can't Go Anymore *Tan cansado, no puedo ir más*	**10** **9**
Really Tired *Muy cansado*	**8** **7**
Tired *Cansado*	**6** **5**
A Little Tired *Un poco cansado*	**4** **3**
Not Tired at All *No estoy cansado en absoluto*	**2** **1**

Figure 4. Therapeutic Activity Intensity and Frequency in Patients with Stroke

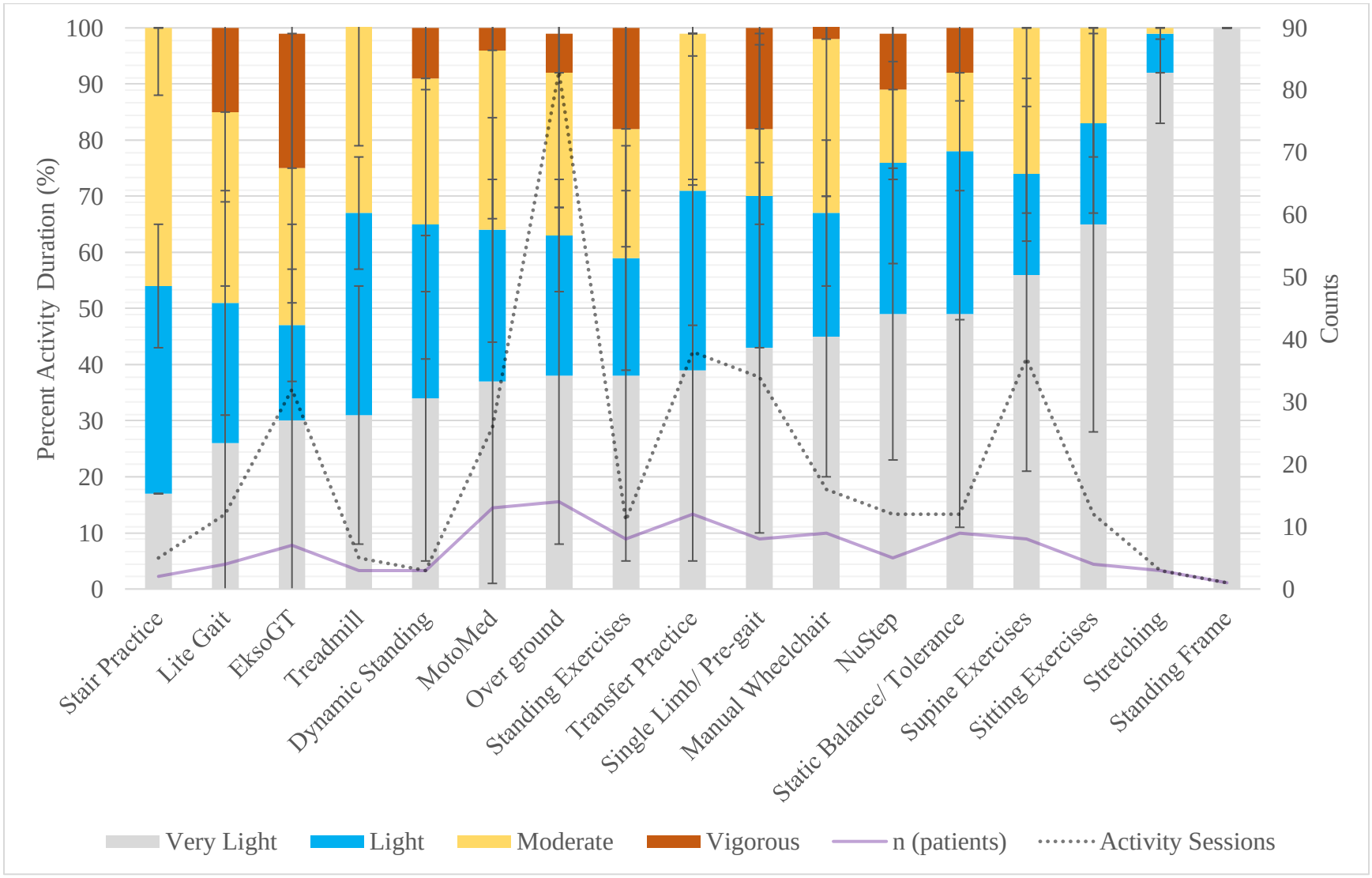


Figure 5. Therapeutic Activity Intensity and Frequency in Patients with SCI

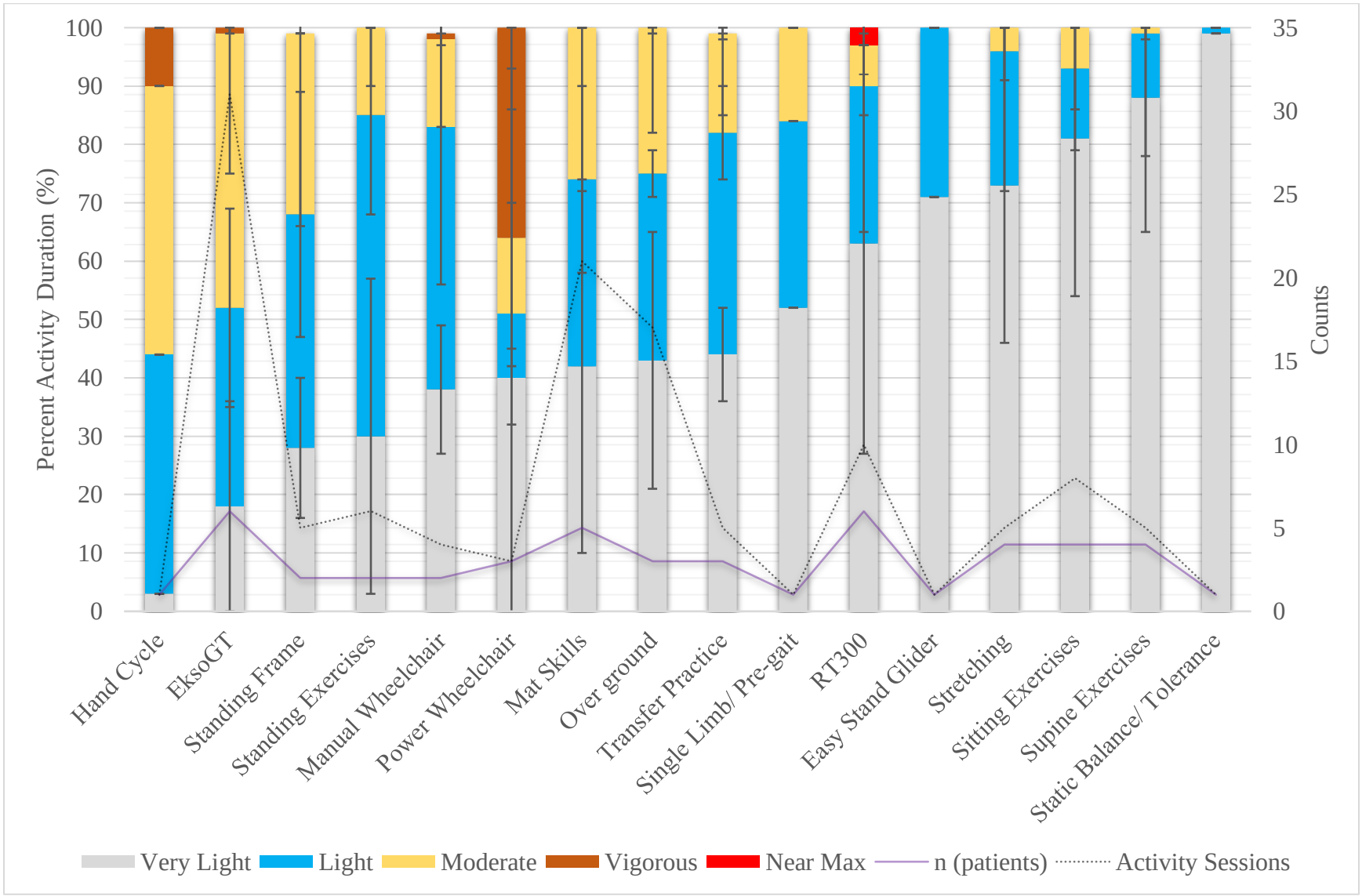


Figure 6. Widely Used Stroke Therapeutic Activities and Associated RPE

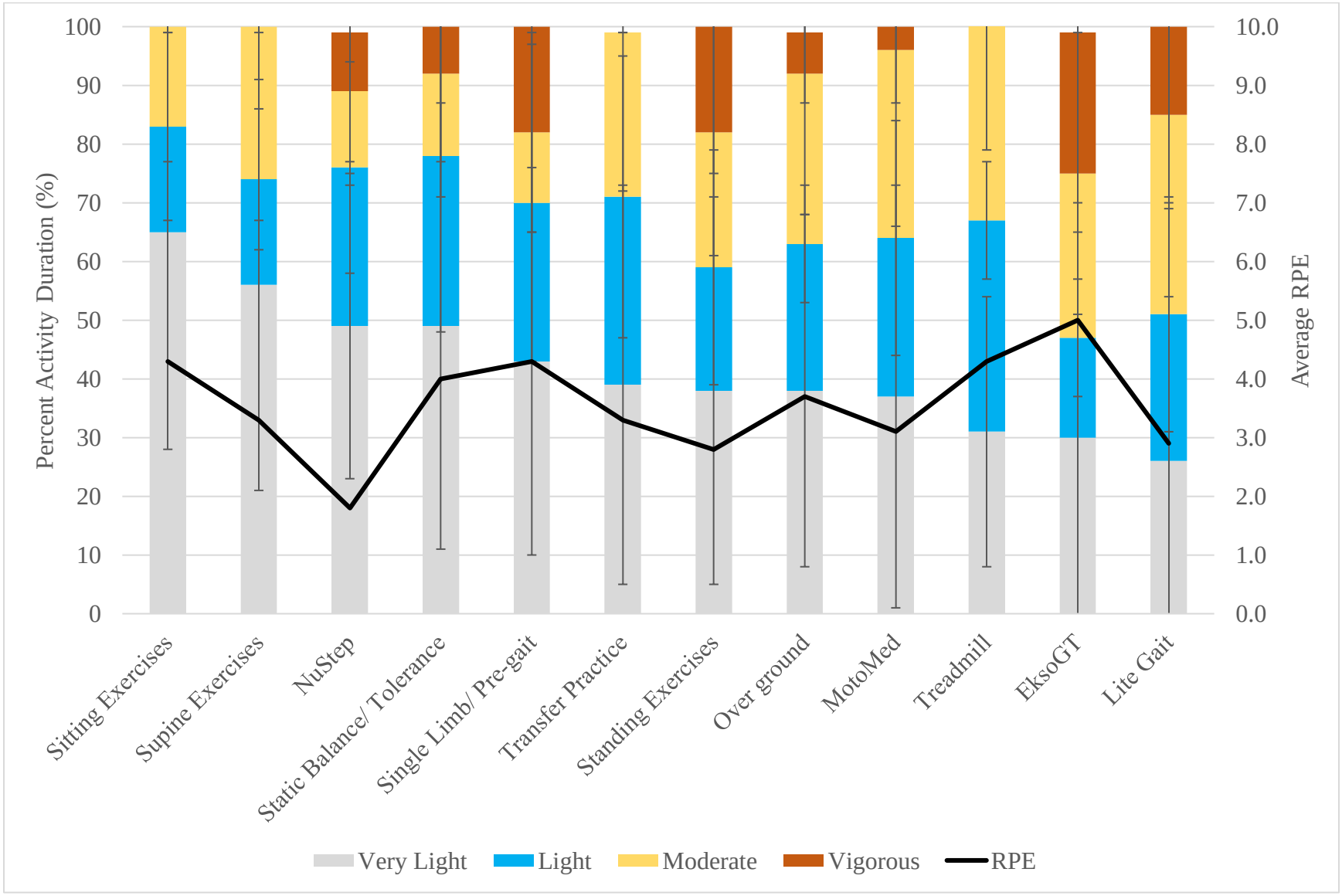


Figure 7. Widely Used SCI Therapeutic Activities and Associated RPE

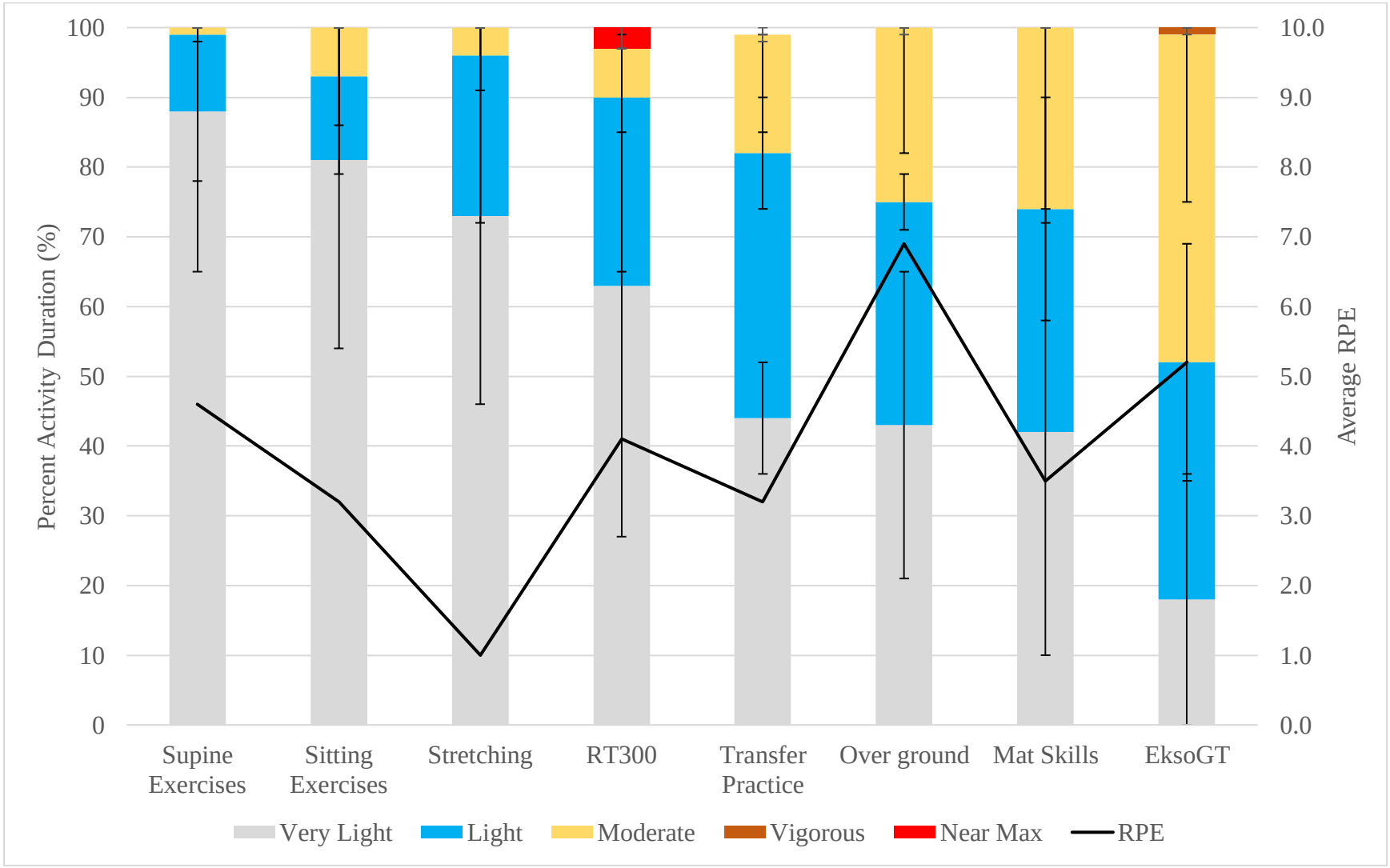
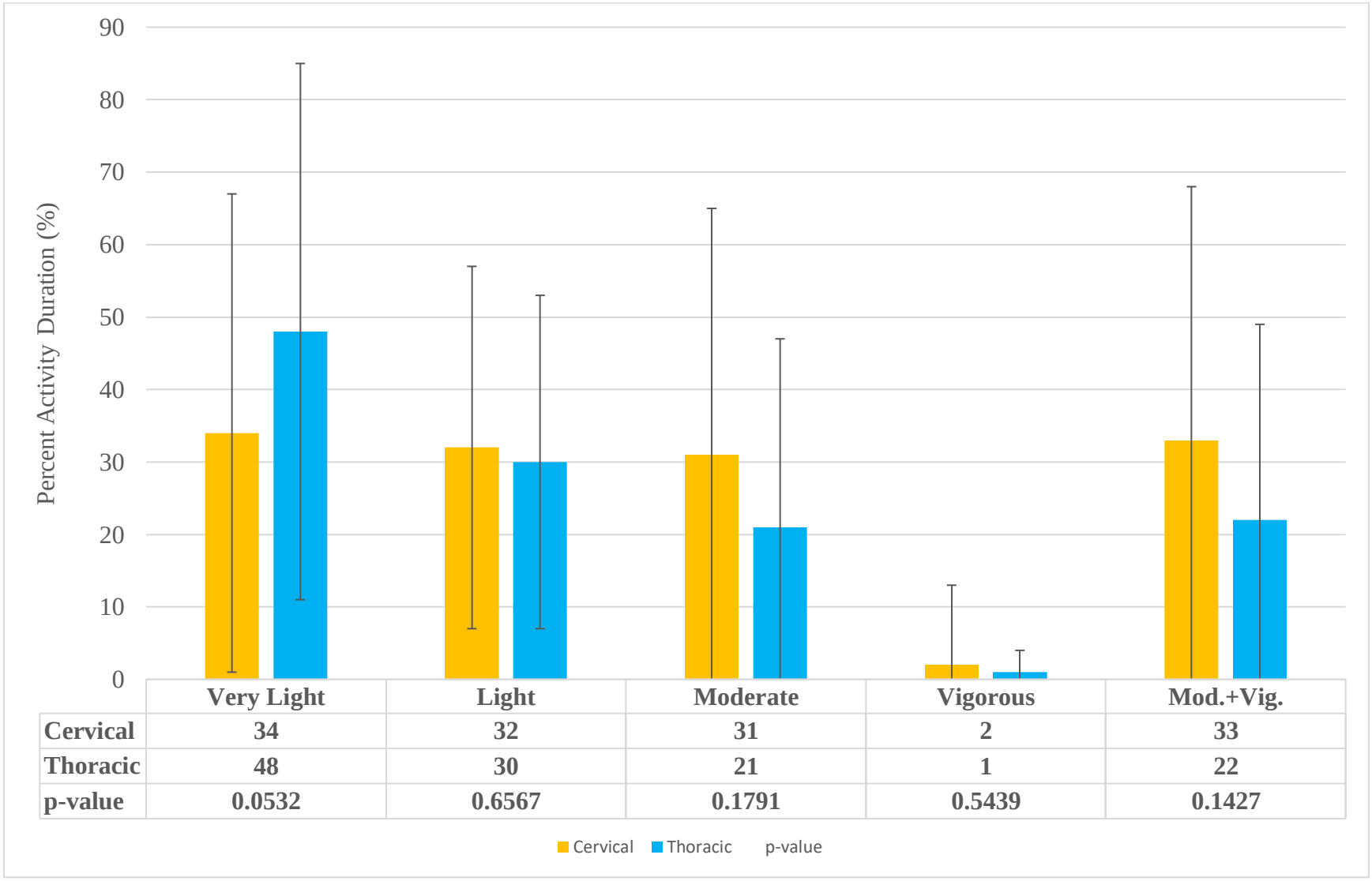
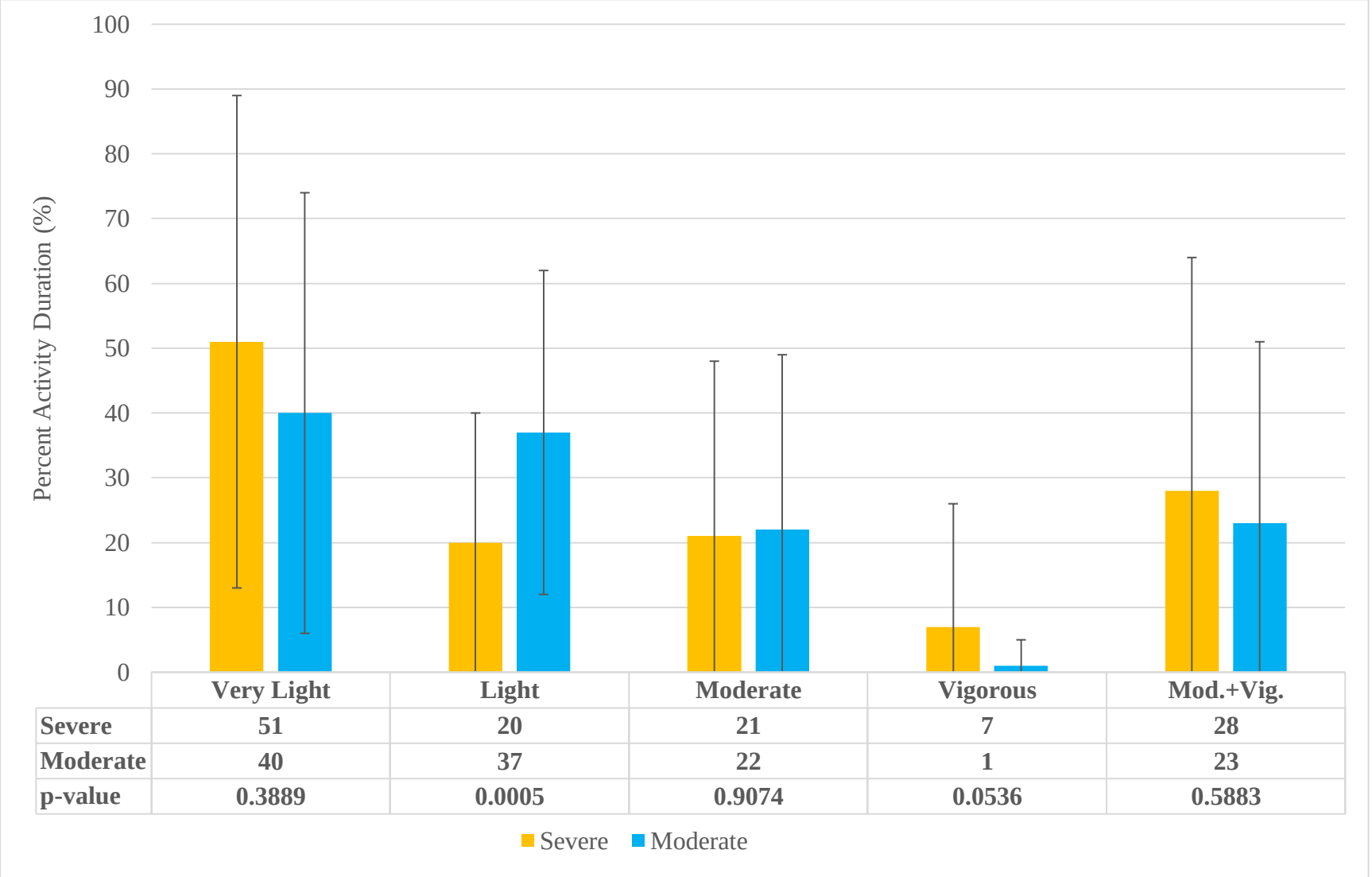


Figure 8. Average Intensity of Patients with Cervical and Thoracic SCI



	Very Light	Light	Moderate	Vigorous	Mod.+Vig.
Cervical	34	32	31	2	33
Thoracic	48	30	21	1	22
p-value	0.0532	0.6567	0.1791	0.5439	0.1427

Figure 9. Average Intensity of Patients with Moderate and Severe Stroke



	Very Light	Light	Moderate	Vigorous	Mod.+Vig.
Severe	**51**	**20**	**21**	**7**	**28**
Moderate	**40**	**37**	**22**	**1**	**23**
p-value	**0.3889**	**0.0005**	**0.9074**	**0.0536**	**0.5883**

*Moderate (<54 FIM score at admit) and Severe (≥54 FIM score at admit)

Figure 10. RPE and Associated Percent in HRR Intensity Zone for SCI Patients

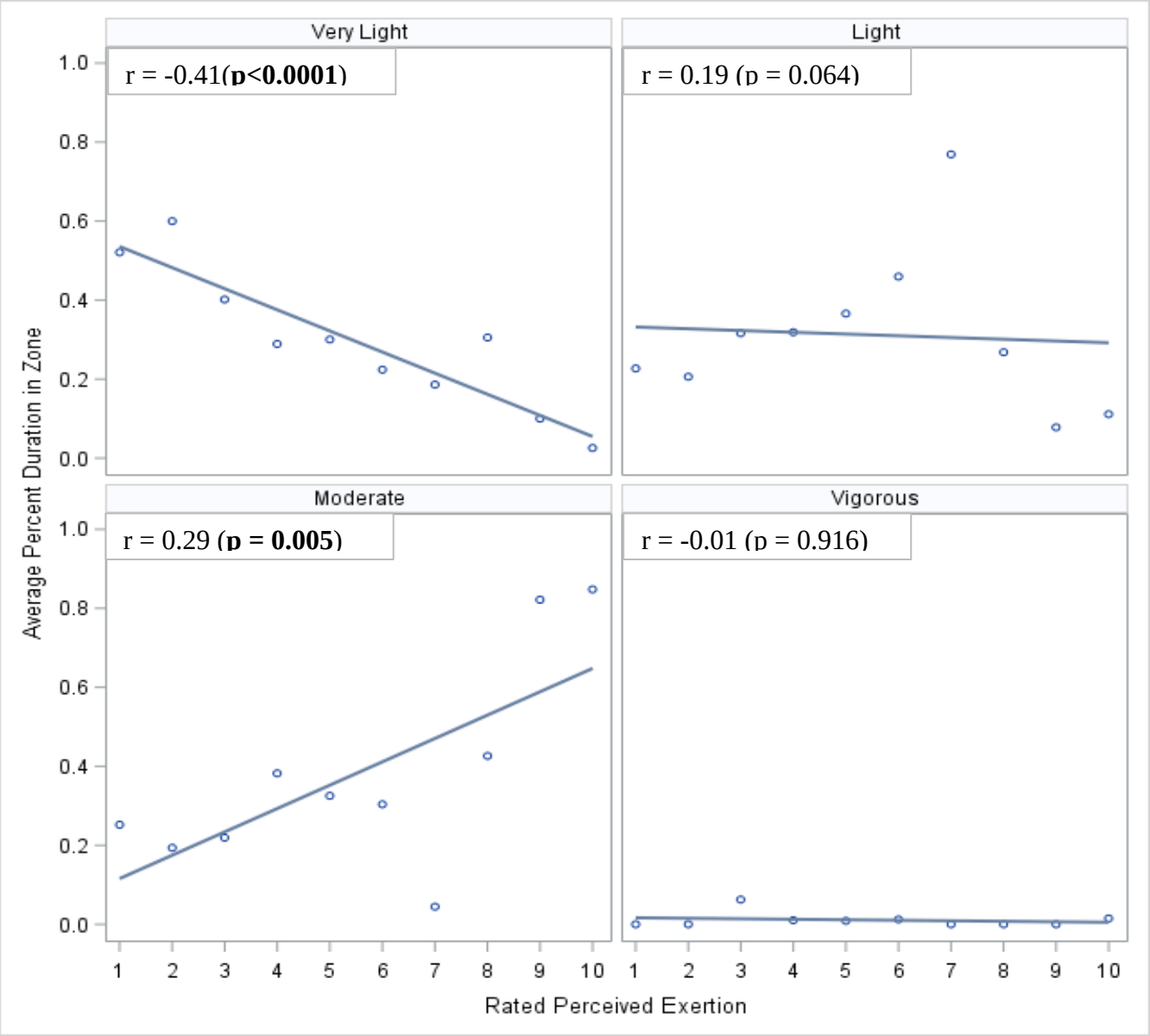
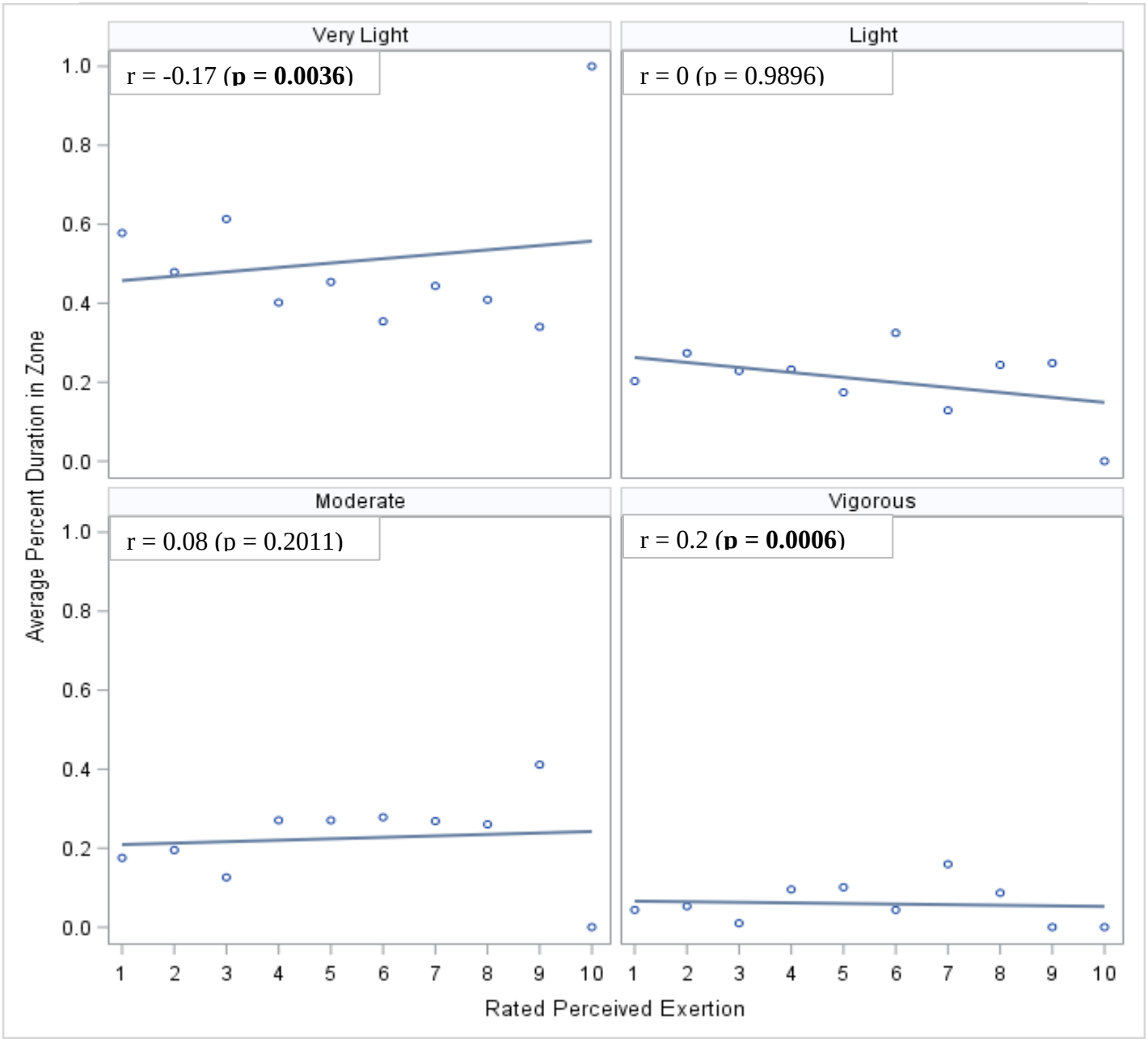


Figure 11. RPE and Associated Percent in HRR Intensity Zone for Stroke Patients



APPENDIX B

DAILY INTERNSHIP JOURNAL

Clinical Research Management Practicum Journal

May 28, 2019

Baylor Institute for Rehabilitation (BIR) Orientation:

- Training:
  - Read International Conference of Harmonization
  - Read and signed off on Protocol and Procedures of BSWH Research Institution

Group Lifestyle Balance Cerebrovascular Accident Study:

- Observed 6-minute walk and 10m walk done by Dr. Swank, recorded average distance and time, respectively.

EksoGT Feasibility Study:

- Read Dr. Swank's manuscript on feasibility of the EksoGT exoskeleton for use in Robotic Gait Therapy (RGT)

May 29, 2019

Baylor Institute for Rehabilitation Orientation:

- Training:
  - Read International Conference of Harmonization
  - Read and signed off on Protocol and Procedures of BSWH Research Institution

Group Lifestyle Balance Cerebrovascular Accident Study:

- Read relevant literature GLBCVA study

EksoGT Feasibility Study:

- Read relevant literature

May 30, 2019

Baylor Institute for Rehabilitation Orientation:

- Training:
  - Read International Conference of Harmonization
  - Read and signed off on Protocol and Procedures of BSWH Research Institution

Group Lifestyle Balance Cerebrovascular Accident (CVA) Study (GLBCVA):

- Read relevant literature GLBCVA study

EksoGT Feasibility Study:

- Read relevant literature

BIR Miscellaneous Tasks:

- Stamped mail cards, printed stickers, cut stickers, for mail out birthday cards to study participants.

EksoGT Intensity Study:

- Met with Dr. Swank regarding EksoGT project, possible practicum project/study.
- Set meetings with Physical Therapist teams from each floor (Traumatic Brain Injury (TBI), CVA, Spinal cord injury (SCI))

May 31, 2019

BIR Miscellaneous Tasks:

- Meeting of Research Department with CEO of BIR regarding downsizing, customization of space, and future construction.
- Stuffed birthday cards for study participants

EksoGT Intensity Study:

- Began exploratory literature search

June 3, 2019

EksoGT Intensity Study:

- Continued literature search
- Met with physical therapist teams, Dr. Swank, and Libby to discuss intensity and usual care at BIR and in inpatient rehabilitation in general
- Discussed possible questions regarding meeting with therapists over Intensity Study next week.
- Discussed possible measures during patient usage of EksoGT (steps, distance, type of injury, Heart Rate (HR), Heart Rate Reserve (HRR), RPE)

June 4, 2019

GLBCVA:

- Observed another walk test with Dr. Swank, recorded average time for 10m walk test and recorded distance for 6-minute walk test

GLBTBI:

- Attended weekly meeting for intervention cohort in GLB study, participated in yoga and breathing exercises alongside study participants.
- Listened to recovering TBI victim speak on stress prevention and management and life after TBI

EksoGT Intensity Study:

- Read relevant literature, continued literature search regarding usual care inpatient rehabilitation, intensity, and RGT methods.
- Discussed potential topics with Dr. Swank for Wednesday committee meeting with The University of North Texas Health Science Center (UNTHSC)

June 5, 2019

BIR Orientation:

- Attended full day BIR employee training from 7:30-3:00
    - Learned of warning signs of aspiration, Personal Protective Equipment (PPE), layout of BIR, safety training (fire, active shooter), and aspiration risk inpatient meal types.

EksoGT Intensity Study:

- Met with physical therapist teams and discussed usage of Polar A370 fitness watch, identifying outstanding issues and possible solutions
- Discussed need for categorical delineation of therapeutic activities for research purposes and data collection

BIR Miscellaneous:

- Meeting with Mr. Fullinwider, regarding proper use of library resources by BIR Research department.
- Learned proper method to conducting methodical literature search through databases

June 6, 2019

SCI Retrospective Study:

- Created new excel spreadsheet, compiling data for patients with SCI, including therapies, timeline, quantity, price. All-day task

June 7, 2019

SCI Retrospective Study:

- Created new excel spreadsheet, compiling data for patients with SCI, including therapies, timeline, quantity, price. All-day task

June 10, 2019

SCI Retrospective Study:

- Finished new excel spreadsheet, compiling data for patients with SCI, including therapies, timeline, quantity, price

EksoGT Intensity Study:

- Wrote first draft of the Standard Operating Procedures (SOP) and sent to Dr. Swank for edits
- Then revised version with Dr. Swank's edits

Clinical Experiences with EksoGT Study:

- Began thematic analysis of therapist focus group data.

June 11, 2019

Clinical Experiences with EksoGT Study:

- Met with Coulter regarding thematic analysis documents and to verify individual counts for each theme.
- Met with Coulter and Dr. Swank to revise thematic analysis and plan to write abstract for American Congress of Rehabilitation Medicine (ACRM) Conference at end of year.
- Abstract Due date June 18, 2019.

Baylor Scott and White Research Institute (BSWRI) Training:

- Attended day long research institute orientation at top floor of Sammons Cancer Center building.

June 12, 2019

BSWRI Training:

- Attended day long Research Focused Employee Orientation at Sammons Cancer Center building.
- Learned of regulations and guidelines for good clinical practice as clinical research personnel.

The University of North Texas Health Science Center (UNTHSC) – MS Clinical Research Management (CRM):

- Committee meeting with Drs. Swank, Ranjan, Millar, and Mathew, as well as, with Librada Callender.
- Determined Proposal topic and course project, being the EksoGT Intensity Study

GLBCVA:

- Sat in on auditing meeting

Clinical Experiences with EksoGT Study:

- Met with Coulter over codifying analysis and limiting themes to sub-groups
- Met with Dr. Swank subsequently to further constrain thematic analysis

June 13, 2019

Clinical Experiences with EksoGT Study:

- Worked on cleaning and making accurate the prior thematic analysis
- Verified counts

June 14, 2019

BIR Miscellaneous Tasks:

- Created personal collage for team building meeting on Wednesday.
- Finished birthday cards to be sent out for the month of June
- Organized office cabinets

Clinical Experiences with EksoGT Study:

- Passed revisions to Abstract back and forth between Dr. Swank, Coulter, and I
- Finalized version of Abstract for submission next week

June 17, 2019

Clinical Experiences with EksoGT Study:

- Worked with Coulter to finalize number of sub-sections and revise inclusion criteria for each sub-section

GLBCVA:

- Coulter taught me how to initialize the Actigraph hardware to be used in the GLBCVA trial

EksoGT Intensity Study:

- Learned to use EndNote and began to compile resources for proposal to be written by Monday next week

- Literature search for relevant articles across TBI, SCI, and Stroke, as well as, for information on usage of Heart Rate Reserve and Rated Perceived Exertion as end measure for intensity

June 18, 2019

GLBCVA:

- Initialized Actigraphs for two patients for the following week
- Learned to download and store data after patients return Actigraphs from home

Clinical Experiences with EksoGT Study:

- Submitted Final Draft of Abstract to Dr. Swank, Libby, and Dr. Driver
- Received approval and stayed late to submit abstract to ACRM before deadline
- Submitted abstract

June 19, 2019

GLBCVA:

- Practiced process of obtaining informed consent from patients during assessments for the GLBCVA study.
- Received Check-off/ Approval from Michelle Acker Director of Clinical Research at BSWRI for my performance in obtaining informed consent from patients
- Downloaded more data from patient-returned Actigraph hardware

BIR Miscellaneous:

- Team building staff meeting
- Learned of new data management plan for implementation in future studies

EksoGT Intensity Study:

- Met with physical therapist CVA team and took minutes while they discussed troubleshooting current issues in trial run of monitoring HR during usual care therapeutic activities at BIR.
- Finalized CRF
- Finalized watch tracking method
- Determined route of patient data from clinician records to research
  - Patient data begins in EPIC EMR and therapists transfer data to CRF.
  - Then Erina or I upload polar watch data, and subsequent recording in CRF will be done by either therapists or me.
  - I will then collect and enter data into RedCap
- Set date to finalize version of SOP for Intensity Study

June 20, 2019

EksoGT Intensity Study:

- Continued literature search for Proposal due Monday to Dr. Millar

GLBCVA:

- Finally enabled SELECT access and downloaded nine patient-returned Actigraphs for further analysis

UNTHSC:

- Rearranged CRM Journal to this point, adapting from excel spreadsheet

June 21, 2019

GLBCVA:

- Initialized Actigraph for CVA subject next week
- Troubleshot non-communicating Actigraph, emailed support, and arranged for safe return and data extraction

EksoGT Intensity Study:

- Read American College of Sports Medicine's Guidelines for Exercise Testing and Prescription chapter on framework and clinical decision making for exercise prescriptions
- Met with Dr. Swank to help guide writing for CRM proposal

June 24, 2019

EksoGT Intensity Study:

- Arrived at 8 AM and continued working on first draft of study proposal for intensity study. Met with Libby to discuss roles as a research intern, to include in the research proposal.
- Sent rough draft to Dr. Swank for review and guidance on practicum and project material.

June 25, 2019

EksoGT Intensity Study:

- Immediately went to work at finalizing SOP's for EksoGT Intensity Study
- Filled coffee carafe with water
- Edited CRF to include various patient characteristics that the therapists wanted to add

BIR Miscellaneous:

- Attended meeting with Libby over investigator-initiated studies

June 26, 2019

Clinical Experiences with EksoGT Study:

- Finalized thematic analysis with Coulter
- Identified quotes to capture overarching themes of each sub-section.

EksoGT Intensity Study:

- Finalized SOP's for EksoGT Intensity Study after Dr. Swank and Molly's edits
- Added FIM Motor Instrument to the CRF for use to characterize the patient population under study.

June 27, 2019

Clinical Experiences with EksoGT Study:

- Began work on manuscript by reading rough draft created by Dr. Swank

GLBCVA Study:

- Sent back two broken Actigraphs to Actigraph in Florida with RMA forms attached.
- Separated the patient-returned Actigraphs, cleaned thoroughly, and began charging them for data transfer.
- Set reminder to send status update on Actigraph progress to Dr. Driver, Evan, and Stephanie.

BIR Miscellaneous:

- Sat in on meeting with CCRCs regarding formalized goals and management software.
- Sat in on CCRC presentation regarding a leadership book, "This is not what we do here!" and opportunities for class auditing through edX.org.

FES/ EksoGT Therapist Initiated Case Study:

- Took minutes at meeting between Dr. Swank and Ashley, regarding edits to manuscript.

June 28, 2019

Clinical Experiences with EksoGT Study:

- Met with Dr. Swank prior to leaving for shadowing, discussed potential abstracts and meetings next week with Molly.

Shadowing:

- Had the opportunity to shadow Dr. Couch in the Surgical Critical Care Intensive Care Unit
- Witnessed the care of several very sick patients.
- Observed the placement of a central line, intubation, extubation, Butterfly IQ US use to determine presence of pleural fluid
- Rounded with the pharmacist, ICU nurses, general surgery resident, and Dr. Couch
- Sat in on Friday conference regarding the proper use of antibiotics available at BSW

July 1, 2019

EksoGT Intensity Study:

- Took pictures of the EksoGT-GT and polar A370 Fitness watch to input in Proposal document.
- Finalized second draft of intensity study proposal document, added pictures/descriptions, amended explanation of HRR vs VO2, fixed bibliography.

GLBCVA:

- Prepared patient binders to be used for meeting material
- Uploaded data of one of the Actigraphs and created a tracking sheet for Actigraphs and the corresponding patients.

July 2, 2019

Clinical Experience with EksoGT Study:

- Wrote a couple of paragraphs for manuscript
- Met with Coulter and distributed aspects of the manuscript.
- Determined due date for manuscript edits on July 8th

EksoGT Intensity Study:

- Emailed finalized document to Dr. Millar for final approval
- Finalized Intensity Proposal minus confirmation on statistical approach to data analysis.

GLBCVA:

- Finished preparing patient binders

July 3, 2019

Clinical Experience with EksoGT Study:

- Continued working on manuscript, finished first draft.
- Met with Coulter on manuscript writing and edited manuscript.

GLBCVA:

- Initialized Actigraph for study participant to be seen on the weekend.

EksoGT Intensity Study:

- Finalized Research Proposal and sent out to committee for evaluation and approval

July 5, 2019

EksoGT Intensity Study:

- Worked on editing and reformatting proposal to fit final practicum format

Clinical Experiences with EksoGT Study:

- Continue working on manuscript, edited table quotes to use more precise language and improve brevity.

July 8, 2019

GLBCVA:

- Initialized Actigraph to be used in Fort Worth today.
- Downloaded data from two patient-returned Actigraphs
- Organized food tracking notebook for GLBCVA participants

Clinical Experiences with EksoGT Study:

- Spoke with Dr. Swank about manuscript edits and additions
- Sent him first draft and received edits and critiques

BIR Miscellaneous:

- Decorated birthday cards.
- Assembled birthday cards
- Labeled birthday card
- Stamped postage on birthday cards

July 9, 2019

GLBCVA:

- Initialized several Actigraphs for the week and downloaded data for one.

EksoGT Intensity Study:

- Looked over pilot study proposed data collection methods by the therapists and troubleshooted discrepancies in recording methods by individual therapists.
- Helped realize method to properly track each watch with each subject.
- Met with Erina to start up A370 watch for a subject.
- Met with Dr. Swank over findings of CRF accuracy and collection methods.

GLBTBIMS:

- Looked over Garmin data and learned to extract and organize for next week's meeting on current results of the study.

July 10, 2019

BIR Miscellaneous:

- Punctured tire on the way to work, went to fix tire.
- Attended monthly auditing meeting and discussed current SOP and future goals.
- Discussed past revisions and completion deadlines

Clinical Experiences with EksoGT Study:

- While waiting for Discount Tire to repair my left front tire, I searched for representative quotes as additions to the results in the manuscript.
- Met with Dr. Swank and Coulter about finalizing a version of the manuscript to send to Dr. Driver for revisions.

July 11, 2019

EksoGT Intensity Study:

- Met with Dr. Swank and Molly to discuss proper data collection techniques and possible meeting to onboard the SCI team with the operating procedure.
- Requested Polar FlowSync application on laptops from IT

GLBTBIM:

- Recorded step data for Garmin watches according to each appointment date.
- Created excel spreadsheet to prepare data for quick entry into RedCap

GLBCVA:

- Met with Stephanie to plan how to clean up data that outlined her efforts in patient recruitment by calling by phone instead of flyer.
- Discussed need to clean up active vs inactive addresses for potential subject population.

Clinician Experiences with EksoGT Study:

- Finalized third draft of manuscript for Dr. Swank, Molly, Dr. Driver edits.
- Finalized table, and representative quotations.

July 12, 2019

EksoGT Intensity Study:

- Uploaded Polar A370 watch data.
- Transcribed polar heart rate, duration, and activity data into Case Report Forms (CRF)
- Met with Dr. Swank and Molly about troubleshooting current data collection procedures and meeting with the therapist teams.
- Printed and annotated various CRFs containing data collection errors.

GLBCVA:

- Codified Stephanie's recruitment first attempt phone records to better visualize and understand the effort and results of her efforts.
- Met with Libby over proper coding techniques and analyses
- Sent Actigraph updated tracking sheet to Dr. Driver, Evan, and Stephanie.

July 15, 2019

EksoGT Intensity Study:

- Met with Dr. Swank prior to meeting with therapists to determine important aspects of study and procedure to educate therapists on.
- Discussed data collection methods with therapists outside of the stroke team.
- Presented on issues with CRF and current issues with data collection methods.

GLBCVA:

- Updated Actigraph tracking sheet data with up to date screening dates.
- Finished codifying Stephanie's recruitment phone attempts and tabulated the data, creating method to tally future coding of phone recruitment attempts.

BIR Miscellaneous:

- Rearranged and organized research office cabinets.

July 16, 2019

Clinician Experiences with EksoGT Study:

- Edited manuscript and addressed corrections and suggestions offered by Dr. Driver.
- Read sections on qualitative analysis from *Program Evaluation: An Introduction to an Evidence-Based Approach* to help address the usage of qualitative and quantitative analysis in the study design.
- Met with Dr. Swank after finishing edits.

GLBCVA:

- Downloaded data from 2 Actigraphs and updated tracking sheet.

EksoGT Intensity Study:

- Tallied up the number of sessions per patient per type of therapeutic activity.

July 17, 2019

BIR Miscellaneous:

- Went through returned mail and marked as vacant or wrong address on recruitment spreadsheet to prevent sending aberrant recruitment flyers
- Monthly meeting 12:00 – 1:00 PM:

- Discussed continuing audit plan
- Volunteered to help rotate poster presentations in BIR.
- Ate carrot cake for a birthday

GLBCVA:

- Tested parking badges for GLBCVA participants
- Organized packets for lesson on healthy eating for the next GLBCVA class

Clinician Experiences with EksoGT Study:

- Edited manuscript further, after meeting with Dr. Driver.
- Decided on which journal to attempt publication through
- Read up on the various submission guidelines of the American Journal of Physical Medicine and Rehab
- Corrected figures with Coulter.

July 18, 2019

GLBCVA:

- Resent Actigraphs in for repair to Actigraph after postmarked at a less than required rate to weight requirement
- Uploaded data from returned Actigraph

EksoGT Intensity Study:

- Continued to gather literature sources and compile literature review matrix to help in producing the final paper.
- Decided to further determine the actual accuracy of wrist photoplethysmography and the various models of fitness watch monitors.

July 19, 2019

EksoGT Intensity Study:

- Worked on updating watches from the week and determining their current patterns of use in monitoring patients.
- Also, looked to see if minimum number of activities were monitored by the therapists for recently discharged patients.

Swank EksoGT SCI Intensity Grant Proposal:

- Began to compile data from specifically SCI patients, determining the best way to present the current results in the proposal.

July 22, 2019

Swank EksoGT SCI Intensity Grant Proposal:

- Began literature review specifically regarding outcomes due to EksoGT, dosing parameters, and intensity versus conventional therapeutic methods used in inpatient rehabilitation.

BIR Miscellaneous:

- Completed SELECT employee training modules online, took the morning to complete.

July 23, 2019

Swank EksoGT SCI Intensity Grant Proposal:

- Continued literature review specifically regarding outcomes due to EksoGT, dosing parameters, and intensity versus conventional therapeutic methods used in inpatient rehabilitation.

GLBCVA:

- Taught Coulter how to download Actigraph data to the Select computer.
- Downloaded three Actigraphs.

EksoGT Intensity Study:

- Synced a new patient on a preexisting watch.
- Spoke with Molly about their current decision making on whether to record a patient activity or not.
- Identified reasons for missing consecutive data in CRF and Polar Watches

July 24, 2019

Swank EksoGT SCI Intensity Grant Proposal:

- Continued literature review specifically regarding outcomes due to EksoGT, dosing parameters, and intensity versus conventional therapeutic methods used in inpatient rehabilitation.

GLBCVA:

- Worked on calculating initial Framingham 8-year diabetes risk for the baseline appointments of patients
- Also calculated metabolic syndrome severity scores for baseline appointments and survey information provided by the patients.

July 25, 2019

GLBCVA:

- Worked on calculating initial Framingham 8-year diabetes risk for the baseline appointments of patients
- Also calculated metabolic syndrome severity scores for baseline appointments and survey information provided by the patients.
- Synced more Actigraphs
- Recovered lost Actigraph data from Actigraph corp.
- Initialized Actigraph for Fort Worth appointment

Swank EksoGT SCI Intensity Grant Proposal:

- Continued literature review specifically regarding outcomes due to EksoGT, dosing parameters, and intensity versus conventional therapeutic methods used in inpatient rehabilitation.
- Tried to clean up and filter out relevant articles with relevant information

July 26, 2019

EksoGT Intensity Study:

- Synced the Polar watches after this week of therapy activities.

- Updated polar activity tracking sheet to the current date for each patient.
- Updated therapist-patient tracking sheet and current status of the watches for therapist reference
- Updated each patients' CRF to the current date.
- Confirmed discharge of two patients and updated a watch for a new patient to start in the pilot study.
- Discussed current recording practices with Molly and updated her on the status of Polar accounts

GLBCVA:

- Downloaded more patient-returned Actigraphs
- Updated Actigraph tracking sheet

Clinician Experiences with EksoGT Study:

- Met with Dr. Swank to discuss Dr. Driver's and Dr. Sikka's edits and further updates to the manuscript

July 29, 2019

BIR Miscellaneous:

- Stamped, decorated, stuffed 36 birthday cards for patient birthday's and updates for the August 1-15th period.

Clinician Experiences with EksoGT Study:

- Edited manuscript to address Dr. Driver's suggestions

GLBCVA:

- Cleaned and downloaded patient-returned Actigraph.

July 30, 2019

GLBCVA:

- Contacted Actigraph and received instructions to resolve issues with broken Actigraph.
- Will download recovery software through BSW IT in the near future.

BSW Miscellaneous:

- Sat in on training for surgical critical care fellows.
- Learned about the On-Q pain relief system and methods for installation across multiple rib fractures
- Observed placement of fenestrated delivery system across the ribs of a pig model.
- Played the model for ultrasound demonstration and practice for the fellows in cardiac imaging, IVC respirophasic changes, FAST exams, and other venous imaging

July 31, 2019

Swank EksoGT SCI Intensity Grant Proposal:

- Continued literature review specifically regarding outcomes due to EksoGT, dosing parameters, and intensity versus conventional therapeutic methods used in inpatient rehabilitation.

GLBCVA:
- Cleaned and downloaded Actigraph for GLBCVA study
- Met with Stephanie regarding SOP to clean and handle returned Actigraphs.
  - Decided to move tracking document that I created to the shared research drive to allow others to track status of Actigraphs during trials.

Clinician Experiences with EksoGT Study:
- Met with Dr. Swank over manuscript revisions

August 1, 2019

WOWii:
- Initialized eight Actigraphs for study participants.
- Cleaned watchbands, stuffed envelopes (charging dock/cord, watch, wristband) for mailing to out of state participants

Clinician Experiences with EksoGT Study:
- Edited manuscript to better align with goals of describing sustainability in EksoGT implementation.
- Edited discussion and results.

GLBCVA:
- Downloaded and cleaned a couple of Actigraphs.
- Another one is broken, will download repair software at some point in the near future.
- Parsed the cities from my GLBCVA tracking sheet and distributed into their respective files on the L drive for the team to see and edit.

August 2, 2019

GLBCVA, WOWii, BIR Miscellaneous:
- Wrote SOP for cleaning GT9X Link Actigraphy devices and watch bands.
- Sent to Coulter for suggestions

EksoGT Intensity Study:
- Synchronized watches with Polar Flow.
- Updated CRFs to current date.

Swank EksoGT SCI Intensity Grant Proposal:
- Continued literature review specifically regarding intensity dosage and rehabilitation.

August 5, 2019

EksoGT Intensity Study:
- Cleaned up data from current subjects and created Excel documents to better visualize and organize data for meeting.

- Met with Dr. Swank, Libby, and Molly regarding current sampling practices
- Discussed current data and need to develop a RedCap database to manage the data in the future

August 6, 2019

EksoGT Intensity Study:

- Started watch for new stroke subject
- Updated tracking sheets and placed in each team's binder.
- Created RedCap database for the study.

GLBCVA:

- Met with Coulter and discussed Actigraph cleaning SOP and planned a time to sanitize the watches.

August 7, 2019

Clinician Experiences with EksoGT:

- Wrote letter to the editor/ cover letter for manuscript publication submission.
- Wrote "What is known, what is new" blurb for journal submission.
- Met with Dr. Swank and Coulter over manuscript revisions.

EksoGT Intensity Study:

- Met with Libby, Coulter, and Christa regarding redcap database and need for repeated measures instrument.

BIR Miscellaneous:

- Department meeting and conference call, meditated, discussed upcoming abstracts, discussed rotating downstairs poster presentations.

August 8, 2019

- Out of office for interview

August 9, 2019

BIR miscellaneous:

- Found TBI model systems documentation to fax to project coordinator at BIR.

EksoGT Intensity Study:

- Synchronized active watches with cloud software.
- Started new patient on a watch early in the morning so that the therapists would be able to catch today's sessions.
- Updated tracking sheets for therapist use
- Updated SCI overground vs EksoGT therapy excel sheet to present to Dr. Swank at next week's meeting.

GLBCVA:

- Recovered data from Actigraphs having Actigraph-Actilife software issues.
- Downloaded data recovery tool in order to recover Actigraph data.
- Updated tracking sheet and updated Actigraph download status to Complete.

Clinician Experiences with EksoGT:

- Met with Dr. Swank regarding manuscript and idea to include a more detailed description of the therapist's methods for facilitating off-label EksoGT therapy

August 12, 2019

BIR miscellaneous:

- Pulled contact information for the clinical research assistant for study participants of Comparison of Sleep Apnea Assessment Strategies to Maximize TBI Rehabilitation Participation and Outcome (C-SAS)
- Refiled folders
- Added to list of Key Study Personnel for the C-SAS study.

EksoGT Intensity Study:

- Updated the CRF so that it now has the complete FIM instrument for admission and discharge. Not just the FIM Motor sub score.

Swank EksoGT SCI Intensity Grant Proposal:

- Sent Dr. Swank literature review matrix for SCI dosage, intensity, and EksoGT related outcomes.

August 13, 2019

GLBCVA:

- Downloaded 2 Actigraph devices and updated master tracking sheet
- Updated individual city tracking sheets on the research shared drive
- Repaired the coded phone and contact recruitment log

EksoGT Intensity Study:

- Entered 200+ data points into Redcap for first 8 participants.
- Troubleshot and corrected the database when needed.
- Filled out FIM scores for each of the 8 participants using ERehab data.
- Tracked missing data in the CRFs and noted what needed to be done to complete each subject's record.
- Updated 'Intensity Matters' tracking sheet and registered the last available watch to another participant.

BIR Miscellaneous:

- Met with therapists and Dr. Swank regarding a potential abstract from therapy being done at BSWIR.

August 14, 2019

C-SAS:

- Pulled secondary contact information for subjects in the C-SAS study for the clinical research assistant.

WOWii:

- Entered data into redcap, identified error in CRFs and postponed data entry until database developer could address the identified errors issues.

Clinician Experiences with EksoGT:

- Met with Dr. Driver and Dr. Swank on some final editing issues and critiques regarding the flow of the manuscript.

BIR Miscellaneous:

- Decorated, stuffed, labeled, and postmarked 36 birthday/ address update return cards

August 15, 2019

GLBCVA:

- GLBCVA debrief meeting, planning and addressing efficiency and practicality issues for follow-up appointments
- Presented on progress of Actigraph devices and current tracking methods

Clinician Experiences with EksoGT:

- Reviewed manuscript for journal guidelines
- Reviewed manuscript edits regarding sustainability project/ process

EksoGT Intensity Study:

- Took a look at the data for the first 10 participants and created tables and charts to get an idea of the current data for possible use in a grant proposal

WOWii:

- Discussed disorganized first cohort exit survey CRFs with Christa

August 16, 2019

GLBCVA:

- Downloaded Actigraph device and retrieved missing biometric data from the GLBCVA files
- Updated tracking logs

Clinician Experiences with EksoGT:

- Prepared manuscript for submission by reading and addressing discrepancies with the journal submission guidelines.
- Met with Dr. Swank to go over the minor revisions to the author declarations, format, and figure legend

EksoGT Intensity Study:

- Created 5 new patient records in RedCap and filled out patient information
- Filled out CRFs with the week's additional recorded activity sessions.
- Synchronized patient watches and watch activities.

August 19, 2019

WOWii:

- Met with Christa to review WOWii exit survey edits.
- Completed data entry of the WOWii Exit Surveys into RedCap

EksoGT Intensity Study:

- Entered FIM data for an Intensity Matters subject

- Met with Dr. Swank and Libby regarding EksoGT study and current number of active and discharged participants
- Discussed extracting SCI patient data for use in grant proposal

August 20, 2019

Out of office for Interview

August 21, 2019

BIR Miscellaneous:

- Attended monthly meeting
- Discussed upcoming audit of the GLBSCI study

EksoGT Intensity Study:

- Met with Molly and discussed current recruitment strategy for stroke patients.
  - Due to the nature of inpatient rehabilitation, stroke patients will typically be in the severe impairment category regarding FIM score and recruitment is not going to focus on different stratifications of FIM severity
- Synced watch and data from discharged patient, updating CRF and RedCap
- Began an additional stroke patient on available watch
- Pulled resting HR data and outlined intervals of exercise intensity compared to percentage of max heart rate

August 22, 2019

Clinician Experiences with EksoGT:

- Prepped final manuscript and figures for submission.
- Met with Dr. Swank over minor final revisions and corrections to formatting and point of view.

GLBCVA:

- Met with Stephanie and discussed missing Actigraphs not yet returned or lost in the mail.

August 23, 2019

Clinician Experiences with EksoGT:

- Submitted original research article "Lessons Learned from Robotic Gait Training during Rehabilitation – therapeutic & medical severity considerations over 3 years" to the *American Journal of Physical Medicine and Rehabilitation*

GLBCVA:

- Sterilized and scrubbed Actigraph devices and watchbands according to newly made SOP, prior to redistribution at the 3-month assessments for the first cohort.

EksoGT Intensity Study:

- Met with Molly and allotted new patients for available watches
- Synchronized watches
- Set up two newly admitted patients for watches.

BIR Miscellaneous:

- Replaced the poster presentation in the display case downstairs and placed new recruitment flyers as well.

August 26, 2019

UNTHSC:

- Completed Active Shooter Compliance Training
- Completed HIPAA Training.

EksoGT Intensity Study:

- Compiled SCI data from RedCap database and formatted for meeting this afternoon
- Created Excel sheet to consolidate and determine fraction of exercise activity that is performed at each level of intensity (very light, light, moderate, vigorous, near maximal) from the raw HR data

August 27, 2019

BIR Miscellaneous:

- Helped rearrange office for upcoming consolidation of research staff in the upstairs office

EksoGT Intensity Study:

- Finished Excel sheet to calculate fraction of exercise activity spent in each level of intensity and analyzed a second patient's data
- Updated watches for SCI patients
- Collected demographic data from therapists for patients with missing data in the CRF
- Updated RedCap and pulled raw data for grant proposal
- Created new record in RedCap for additional patient

Clinician Experiences with EksoGT:

- Worked with Dr. Swank to resubmit manuscript with journal's suggested edits to formatting.

August 28, 2019

EksoGT Intensity Study:

- Calculated HRR and levels of intensity for the additional SCI patients using the raw HR data
- Aggregated current SCI HRR intensity percentage per activity and met with Dr. Swank over the results from the averages of each activity in each patient
- Met with Molly and enrolled the final participant in the Stroke arm of the pilot study and retrieved resting HR for the SCI participants

UNTHSC:

- Completed Protecting Minors on Campus 2019 through the learnHSC Bridge site.

BIR Miscellaneous:

- Installed new computer in Libby's office

August 29, 2019

GLBCVA:

- Met with Stephanie and Libby regarding screening call log for GLBCVA recruitment and need to enter screened patients into RedCap
- Created records in RedCap for people contacted through the screening process and the reasons they were determined to be ineligible for the study.

BIR Miscellaneous:

- Met with Aimee and was shown where and how to locate the birthdays of contacts in the Microsoft Access database
- Created query and table to print out labels for mailing address updates and birthday cards
- Stuffed and mailed birthday envelopes for BSW contacts with birthdays in the month of September

August 30, 2019

EksoGT Intensity Study:

- Synchronized Polar watches from the 10 active patients
- Updated CRFs for the stroke and SCI team
- Updated RedCap database from the CRFs
- Added a stroke patient to a watch for next week

BIR Miscellaneous:

- Took out the recycling bins with Alex

GLBCVA:

- Continued entering the data from the screening call log into RedCap for ineligible participants
- Edited codes on recruitment screening call log to include additional detail regarding ineligibility and the associated circumstances

September 3, 2019

EksoGT Intensity Study:

- Updated HRR Intensity SCI spreadsheet data to include first case study subject and additional activities from the week of August 26 – August 30
- Updated RedCap

GLBCVA:

- Met with Coulter and discussed plans and time frame for initializing patient monitoring devices for GLBCVA assessments

BIR Miscellaneous:

- Participated in the Walk and Roll with a Doc event
- Updated the Walk and Roll with a Doc event participation tracking log for employees and patients
- Labeled training manual for incoming employee

September 4, 2019

BIR Miscellaneous:

- Monthly research staff meeting, welcoming new post-doc employee to BIR.
- Icebreaker
- Organized research drawers
- Made stop signs from construction paper

EksoGT Intensity Study:

- Met with Dr. Swank to discuss thesis deadlines and current state of data collection
- Discussed issues with completing data collection for TBI participants and possible exclusion from thesis, deciding to focus only on stroke and spinal cord injury
- Continued to compile HRR data for participants and set a future meeting with Libby and Dr. Bennet to discuss data and analysis methods.
- Began drafting thesis

Clinician Experiences with EksoGT:

- Reformatted manuscript for submission to a journal within the scope of the study findings

GLBSCI:

- Created private Facebook group for GLBSCI participants

September 4, 2019

GLBCVA:

- Initialized Actigraphs for next week's 3-month assessments
- Updated tracking sheet for newly initialized Actigraphs, and created separate worksheet to track 3-month assessments
- Packaged and stamped Actigraphs and device accessories for return in two weeks by the patients.
- Prepared Actigraph, stamps, envelopes and other items for Coulter to initialize and package tomorrow while I am out of the office

EksoGT Intensity Study:

- Synchronized some polar watches, and updated tracking sheet.

BIR Miscellaneous:

- Emailed retailer of the care partner/ bomxy pedometers

Left for interview.

September 5, 2019

Out of Office:

Interview

September 9, 2019

GLBCVA:

- Initialized Actigraph for 3-month assessment and verified that Actigraphs were in order for this week of assessments

EksoGT Intensity Study:

- Synchronized Polar watches and updated tracking sheet

- Spoke with SCI and Stroke teams about recently discharged patients
- Updated CRFs with current data
- Updated RedCap with current data
- Met with Dr. Swank and Molly for the weekly Intensity Matters meeting
- Started four new spinal cord injury patients on watches
- Updated tracking sheet for referencing by the therapists

BIR Miscellaneous:

- Taught Alex how to send out birthday cards and how to use the postage machine in the mail room.
- Printed W-2 forms for subjects in order to distribute gift cards for participation

September 10, 2019

EksoGT Intensity Study:

- Completed CRF for patient case study and updated data in RedCap
- Met with therapist to resolve issues in CRF and verify correct activity type

BIR Miscellaneous:

- Helped clinical research coordinator resolve issues with Actigraphs in her study.

TBIMS:

- Filed TBIMS patient information
- Labeled new folders for parkland hospital system TBIMS subjects but had to order more folders

September 11, 2019

BIR Miscellaneous:

- Scored several SCI knowledge surveys from patients at BIR
- Input data from SCI knowledge surveys into survey program online
- Recorded possible discrepancies and errors in the CRF for SCI knowledge surveys

EksoGT Intensity Study:

- Started a new SCI subject on a HR recording watch before leaving

September 12, 2019

EksoGT Intensity Study:

- Worked on thesis
- Met with Dr. Bennett about analysis of HRR data, FIM, and RPE
- Also tried to figure out timeline for thesis completion and presentation completion

GLBCVA:

- Initialized Actigraphs for next week's assessments and put more Actigraphs on charging station for tomorrow.

September 13, 2019

EksoGT Intensity Study:

- Synchronized watches

- Updated CRFs and RedCap with new activity information

GLBCVA:

- Taught other intern how to package Actigraphs so that patients can return them to BIR after data collection
- Initialized several Actigraphs
- Packaged several Actigraphs
- Updated tracking log

September 16, 2019

EksoGT Intensity Study:

- Continued updating study documents and RedCap
- Worked on thesis
- Intensity Matters weekly meeting, checked and rechecked patient CRFs, retrieved resting HR, retrieved eRehab data for discharged patients, and discussed potential new patients for the study.

GLBCVA:

- Initialized Actigraph for a Friday assessment this week
- Updated tracking sheet

FES Dose-Response Study:

- Met with therapists, Dr. Swank, and Libby to discuss upcoming FES study.

September 17, 2019

EksoGT Intensity Study:

- Worked on thesis
- Added two additional patients to watches

GLBTBIMS:

- Finished filing TBIMS subject face sheets and created folders for Parkland-specific folders

September 18, 2019

GLBCVA:

- Initialized Actigraphs for the next week's 3-month assessments

EksoGT Intensity Study:

- Worked on thesis
- Met with Dr. Swank over deadlines and analyses of current patient sample

BIR Miscellaneous:

- Weekly Research Department meeting
- Listened to ordering software training
- Listened to RedCap database training and overview

September 19, 2019

EksoGT Intensity Study:

- Continued analysis of percentage of heart rate reserve for each study subject

- Worked on thesis

September 20, 2019

EksoGT Intensity Study:

- Had issues synchronizing the watches today since Polar pushed a firmware update that kept some of the watches from syncing therapy data for the week.
- Eventually synchronized watches and updated the firmware for each
- Updated CRFs and RedCap

GLBCVA:

- Initialized and packaged Actigraphs for next week's assessments.

Clinician Experiences with EksoGT:

- Worked with Coulter on drafting a first version of a poster for ACRM in November.

September 23, 2019

EksoGT Intensity Study:

- Pulled the raw bpm s^{-1} interval data from the watches for each patient and verified against RedCap entries to make sure only valid sessions were included
- Processed data in excel for each of the stroke patients
- Met with Dr. Swank about what we needed to have done in order to do the initial analysis of the data for my thesis
- Updated tracking sheet for watches and spoke with the SCI team about recruiting additional patients to fill the vacancies
- Worked on thesis in the morning, finished some concluding statements and limitations section

Clinician Experiences with EksoGT:

- Worked on some minor edits to the poster for ACRM, tried to include some additional data from the final manuscript

UNTHSC:

- Contacted my graduate committee and had them sign my Intent to Defend form for my thesis defense on Halloween.

September 24, 2019

Clinician Experiences with EksoGT:

- Worked on poster content

EksoGT Intensity Study:

- Processed data using excel for the stroke patients

GLBCVA:

- Initialized and packaged Actigraph for a patient this Friday
- Worked with Dr. Swank to process actigraphy data using the Actilife software.
- Helped write SOP for Actigraph initialization

September 25, 2019

GLBCVA:

- Downloaded recovered Actigraph files to SELECT computer and converted files to the correct format
- Validated wear time and scored the data.
- Processed baseline assessment data and created report for baseline data to send to Dr. Swank

EksoGT Intensity Study:

- Finalized raw data report of the Stroke participants in the Intensity study to send to Dr. Bennett
- Cross checked excel data against redcap database data to verify accuracy
- Began working on the SCI report

September 26, 2019

EksoGT Intensity Study:

- Processed the rest of the SCI data through Excel, getting HRR for the analysis.

Clinician Experiences with EksoGT:

- Helped Coulter revise his edits of the poster presentation

GLBCVA:

- Met with Stephanie about Actigraphs and the needed updates to the SOP for managing Actigraphs at BIR.
- Wrote the SOP for repairing and troubleshooting simple problems with the Actigraph devices

BIR miscellaneous:

- Attended research department auditing meeting

September 27, 2019

GLBCVA:

- Created repair request for two broken Actigraphs and sent them back to Actigraph.
- Initialized Actigraphs for next week's study participants
- Re-initialized cancelled patient's actigraph for their new appointment
- Updated tracking logs

Clinician Experiences with EksoGT:

- Addressed Dr. Swank's critiques of the ACRM poster, adding in adverse events and diagnoses of patients. Also added summary of table in results

EksoGT Intensity Study:

- Synchronized watches and added additional SCI patient to the study.
- Updated tracking logs
- Finished study SCI data in Excel, besides inputting resting HR

BIR miscellaneous:

- Sent out birthday cards with address information update cards

September 30, 2019

EksoGT Intensity Study:

- Worked on thesis
- Met with Molly and discussed open watches
- Retrieved resting HR and beta blocker information from Molly regarding SCI and stroke patients

October 1, 2019

EksoGT Intensity Study:

- Met with Dr. Bennett over the analysis of the stroke and SCI data
- Spoke with Dr. Swank for some time about my discussion and direction of the paper.

FES Intensity Study:

- Met with neuro resident therapists and Dr. Swank to begin planning for FES study.
- Set meetings for teaching about the methods used in collecting, recording, and downloading HRR data to CRF and database web software.

Clinician Experiences with EksoGT:

- Helped Coulter finalize the poster for ACRM and adjusted some of the formatting to make the poster more readable.

TBIMS:

- Spoke with Stephanie about troubleshooting Garmin watch hardware for next TBIMS meeting.

BIR Miscellaneous:

- Attended walk with a doc and pet Roman the golden retriever.
- Got vaccinated against the flu.

October 2, 2019

GLBCVA:

- Downloaded data from 5 patient-returned Actigraphs, updated the tracking sheets, and updated Actigraph patient data with 3-month assessment weights.

FES Intensity Study:

- Updated the CRF with FES RT300-specific variables, pulse width, frequency, stimulation mA.
- Added functional, activities of daily living, and mobility aspects of the CARE Tool rehabilitation assessment to the CRF.

EksoGT Intensity Study:

- Worked on thesis and spoke to Dr. Swank about my discussion draft

BIR Miscellaneous:

- Attended the BIR Research Department meeting

October 3, 2019

GLBCVA:

- Downloaded data from several patient-returned Actigraphs, updated the tracking sheets, and cross-checked Actigraph data with that on RedCap.
- Initiated 6 Actigraphs for next week's 3-month assessments
- Cleaned several patient-returned Actigraphs.

EksoGT Intensity Study:

- Worked on thesis.

WOWii:

- Entered exit survey data for the fifth cohort of the study into RedCap.

October 4, 2019

GLBCVA:

- Packaged Actigraphs for next week's 3-month assessments.
- Met with Stephanie and Evan about issues with coding document and the recruitment log

EksoGT Intensity Study:

- Worked on thesis
- Met with Dr. Swank over results of the study and the correlation analysis

WOWii:

- Continued entering exit survey data for the fifth cohort of the study into RedCap

October 7, 2019

WOWii:

- Finished entering WOWii cohort 5 exit surveys into the RedCap database

EksoGT Intensity Study:

- Met with Molly and discussed open watches and some of the results in my study.
- Sent an email to Dr. Bennett and got an updated table for the collapsed activity categories versus intensity and RPE
- Continued to work on my thesis and finalized a first draft.
- Addressed Libby's edits to my Introduction, Methods, Abstract, and Problem & Hypothesis sections
- Sent a draft of my thesis to Dr. Millar for revisions

October 8, 2019

GLBCVA:

- Created CRF for actigraphy data for GLBCVA
- Found workaround to merging and calculating total minutes for actigraphy data from Actigraph software's Excel output table.
- Washed several devices and wrist bands.
- Downloaded several Actigraphs' data and pulled 3-month assessment data to correct biometrics
- Finished up missing sections of the SOP for Actigraph data processing steps

Clinician Experiences with EksoGT Study:

- Finalized the poster today after sending to Dr. Swank and addressing Molly's corrections

October 9, 2019

GLBCVA:

- Met with Dr. Swank and Libby over the actigraphy data and my proposed CRF
- Discussed what the chosen variables mean in context

EksoGT Intensity Study:

- Worked on thesis

WOWii Study:

- Entered more WOWii Exit Surveys into RedCap

October 10, 2019

FES Intensity Study:

- Met with the therapist neuro-residents and Dr. Swank to discuss HR monitor procedures and logistics.
- Set up time tomorrow to show them how to enter the data in the CRF and RedCap.

EksoGT Intensity Study:

- Worked on thesis presentation
- Met with Dr. Swank and discussed some of the general outline details
- Met with Dr. Bennett and sorted through some of the analysis of RPE vs HRR.

BIR Miscellaneous:

- Helped set up for Dr. Driver's birthday party
- Attended Dr. Driver's birthday party

GLBCVA:

- Downloaded Actigraph data, updated the tracking sheet, and cleaned the wristband.

October 11, 2019

Ekso Intensity Study:

- Synchronized HR smart watches.
- Worked on thesis and presentation power point
- Entered data from the watches into patient CRFs

October 14, 2019

BIR Miscellaneous:

- Prepared Birthday card mailers and sent them out for the last half of October

GLBCVA:

- Sent Libby the updated and edited CRF from last week

Ekso Intensity Study:

- Worked on thesis
- Set up meeting with PT residents to work through the data entry process

October 15, 2019

Ekso Outpatient Clinic Outcomes Study:

- Built database with Coulter for the Outcome measures being looked at in the outpatient clinic with usage of Ekso.
- Met with Libby about the database structure and data entry flow

GLBCVA:

- Downloaded the data off of four Actigraphs to the SELECT office computer
- Cleaned Actigraph watchbands
- Updated the tracking sheet
- Added my tracking sheet to the research drive for Evan and Stephanie to access.

FES/Ekso Intensity Study:

- Met with Dr. Swank about starting FES patient today
- Received the necessary data for the first FES patient and set up in Polar watch
- Taught resident how to operate watches and how to set customized HRR zones in the watch software while I started the first patient on the FES study.
- Then started a second patient on FES study

APPENDIX C

APPROVAL FORMS

IRB Approval – Expedited Review of Continuing Review

To: Simon Driver, PhD

Copy to: Libby Callender, Simon Driver, PhD

Date: October 17, 2018

Re: 015-287
Baylor Institute for Rehabilitation Registry Protocol
Reference Number: 319108

Your request for continuing review was reviewed by a designated member of Baylor Scott & White Research IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category(ies) from the 1998 approved list:

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

This review included the following components:

Submission Components

Form Name	Version	Outcome
Continuing Review Submission Form	Version 3.0	Approved as Presented
Study Application - Review by BSWRI IRB	Version 1.1	Approved as Presented

Study Document

Title	Version #	Version Date	Outcome
BIR Umbrella Protocol v2 1-17-18	Version 1.5	01/17/2018	Approved
SCI Superutilizer 30 day ASCIP	Version 1.0	08/31/2018	Approved
SCI Readmission Race Insurance ASCIP	Version 1.0	10/05/2017	Approved
SCI Readmissions Superutilizer ACRM	Version 1.0	10/05/2017	Approved
SCI Readmissions Superutilizer BUMC Scholarly Day	Version 1.0	10/05/2017	Approved
SCI Healthcare Utilization Manuscript FINAL	Version 1.0	10/05/2017	Approved
TBI Healthcare Utilization Race & Insurance_ACRM Poster	Version 1.0	10/05/2017	Approved
2017 UTH Research Day Poster_Callender	Version 1.0	10/05/2017	Approved

BAYLOR Research Institute
Affiliated with Baylor Health Care System

IRB Approval – Expedited Review of New Study

To: Simon Driver

Copy to: Libby Callender, Simon Driver

Date: December 10, 2015

Re: 015-287
Baylor Institute for Rehabilitation Registry Protocol
Reference Number: 094850

Your new proposal was reviewed by a designated member of Baylor IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category(ies) from the 1998 approved list:
Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

This review included the following components:

Study Application	
Form Name	Outcome
Study Application - Review by BRI IRB	Approved as Presented

Study Document			
Title	Version Number	Version Date	Outcome
Umbrella registry Form 15	Version 1.1	11/12/2015	Approved
BIR Umbrella Protocol v1 9.22.2015	Version 1.1	11/12/2015	Approved
Umbrella registry Form 34	Version 1.0	11/12/2015	Approved
Umbrella registry Form 18	Version 1.0	11/12/2015	Approved

North Texas Regional Institutional Review Board
UNT Health Science Center
BOARD ACTION

IRB Project #: 2019-097 Date Submitted: New CRM Project

Principal Investigator: Stephen Mathew, PhD with CRM student Jake Dipasquale

Project Title: Baylor Institute for Rehabilitation Registry Protocol (BIR Umbrella)

Sponsor Protocol #: Institution: UNT Health Science Center

Department: Clinical Research Management Contact Info: x5407

In accordance with North Texas Regional IRB policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given,is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval. Only use the IRB approved (stamped) study material.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

- [x] Project has received approval through: **July 9, 2020**
- [ ] Informed consent(s*) approved as submitted on :

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official North Texas Regional IRB approval stamp can be used with subjects.

*Including:

- [ ] Study Protocol dated _____ approved as submitted.
- [ ] Investigator's Brochure _____ approved as submitted.
- [ ] Protocol Synopsis approved as submitted on: _____
- [ ] Amendment _____ to the protocol approved as submitted.
- [ ] Progress Report/Continuing Review completed, project has received approval through: _____
- [ ] Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. ***YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.***
- [ ] Project is disapproved for the reason(s) outlined (see attached).
- [ ] Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).
- [ ] Completion of project is acknowledged and all required paperwork has been received.
- [x] Special Findings/Other

The North Texas Regional IRB acknowledges the research activity is conducted under the oversight of the Baylor Scott and White IRB (BSWR 015-287). Dr. Mathew serves as the faculty advisor/contact for this CRM internship project.

Leigh Jordan

Chair/Vice Chair/Designated Reviewer, Institutional Review Board

July 9, 2019

Date

Board Action (revised January 2019)

APPENDIX D

CASE REPORT FORM

Intensity Matters Pilot	
Subject ID: ___ - _____	FES ID:_____
Patient Acct #:_____	EksoGT ID: _____
Polar Watch #:_____	

Demographic and Injury Information	
1. Sex *sex* 1 – Male; 2 – Female	☐
2. Ethnicity *ethnicity* 1 – Hispanic; 2 – Non-Hispanic; 9 – Unknown/Missing	☐
3. Race *race* 1 – American Indian/Alaska Native; 2 – Asian; 3 – Native Hawaiian/Pacific Islander; 4 – Black or African American; 5 – White or Caucasian; 6 – More than one race; 9 – Unknown/Missing	☐
4. Date of Birth *dob* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
5. Injury Date/Onset Date *doi* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
6. Rehab Admission Date *doa* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
7. Rehab Discharge Date *dod* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
8. Insurance type *Ins* 1 – Private Insurance; 2 – Self-pay or uninsured; 3 – Medicaid; 4 – Medicare; 5 – Tricare; 6 – Other; 9 – Unknown/Missing	☐
9. Diagnosis *diagnosis* 1 – SCI; 2 – Stroke; 3 – MS; 4 – TBI; 5 – Amputee; 8 – Other; 9 – Unknown	☐
10. What was the mechanism of injury if traumatic? *mechInj* 1 – Motor Vehicle; 2 – Motorcycle; 3 – Bicycle; 4 – ATV/ATC/Go-Cart; 5 – Other Vehicular; 10 – Gunshot Wound; 11 – Assaults with Blunt Instrument; 12 – Other Violence; 13 – Water Sports; 14 – Field/Track Sports; 15 – Gymnastic Activities; 16 – Winter Sports; 17 – Air Sports; 18 – Other Sports; 19 – Fall; 20 – Hit by Falling/Flying Object; 21 – Pedestrian; 77 –Other Unclassified; 88 – N/A, non-traumatic; 99 - Unknown	☐☐
11. Is the subject a paraplegic or tetraplegic (for SCI only)? *paratet* 1 – Paraplegic; 2 – Tetraplegic; 8 – N/A, non-SCI; 9 – Unknown	☐
12. What is the level of spinal cord injury (for SCI only)? *scilevel* 1 – Cervical; 2 – Thoracic; 3 – Lumbar; 8 – N/A, non-SCI; 9 – Unknown	☐
13. What is the subject's ASIA Impairment Scale (for SCI only)? *ais* 1 – A (Complete); 2 – B (Sensory Incomplete); 3 – C (Motor Incomplete); 4 – D (Motor Incomplete); 5 – E (Normal); 8 – N/A, non-SCI; 9 – Unknown	☐
14. Type of stroke (for stroke only) *stroketype* 1 – Left; 2 – Right; 3 – Bilateral; 8 – N/A, non-stroke; 9 – Unknown	☐
15. Presence of hemianopsia (for stroke only) *hemianopia* 1 – Yes; 2 – No; 8 – N/A, non-stroke; 9 – Unknown	☐
16. GCS at onset of injury (for TBI only) 3-15; 77 – Sedated/Intubated; 88 – N/A, non-TBI; 99 - Unkown	☐☐
17. Resting Heart Rate (HR) *resthr*	☐☐☐

Intensity Matters Pilot	
Subject ID: ___ - _____	FES ID:_____
Patient Acct #:_____	EksoGT ID: _____
Polar Watch #:_____	

FIM Instrument								
		Admission				Discharge			
Self-Care	**A. Eating** *eating*							
	B. Grooming *grooming*							
	C. Bathing *bathing*							
	D. Dressing – Upper Body *dressingub*							
	E. Dressing – Lower Body *dressinglb*							
	F. Toileting *toileting*							
Sphincter Control	**G. Bladder Management** **H.** *bldrmgmt*							
	I. Bowel Management *bwlmgmt*							
Transfers	**J. Bed, Chair, Wheelchair** *txbedchwc*							
	K. Toilet *txtoilet*							
	L. Tub, Shower *txtubshow*							
Locomotion	**M. Walk (W)/Wheelchair (C)** *locomowlk/ locomowc*	**W**		**C**		**W**		**C**	
	N. Stairs *locomostar*							
Motor Subtotal Score *sumfimmoto*								
Communication **A – Auditory** **V – Visual** **B – Both**	**O. Comprehension** *comprehens*							
	P. Expression *expression*							
Social Cognition	**Q. Social Interaction** *socinterac*							
	R. Problem Solving *prblmsolv*							
	S. Memory *memory*							
Cognitive Subtotal Score *sumfimcog*								
Levels	**7** – Complete Independence (Timely, Safely) **6** – Modified Independence (Device)					**No Helper**			
	5 – Supervision (Subject ≈ 100%+) **4** – Minimal Assist (Subject ≈ 75%+ **3** – Moderate Assist (Subject ≈ 50%+)					**Helper**			
	2 – Maximal Assist (Subject ≈ 25%+) **1** – Total Assist (Subject < 25%)								

Intensity Matters Pilot

Subject ID: ___ - _______________ FES ID:___________________

Patient Acct #:_______________ EksoGT ID: ______________

Polar Watch #:_______________

Date	Activity Duration	Therapy Activity	Min HR	Max HR	Avg HR	HRZ 1 (%)	HRZ 2 (%)	HRZ 3 (%)	HRZ 4 (%)	HRZ 5 (%)	RPE
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	_______	______	______	______	______	______	______	______	______	______
__/__/______	_____:_____	______	______	______	______	______	______	______	______	______	______

Therapy Activities

WALKING: 1a – Overground; 1b – EKSOGT; 1c – Treadmill; 1d – Lite Gait; 1e – Gait Trainer

FUNCTIONAL TRAINING: 2a – Transfer practice (basic, toilet, car, etc); 2b – Mat skills

STRENGTH TRAINING: 3a – Supine exercises; ; 3b – Sitting exercises; 3c – Standing exercises; 3d – Stretching – any position

AEROBICS: 4a – MotoMed: 4b – NuStep; 4c – RT300; 4d – EasyStand Glider; 4e – Hand Cycle; 4f – UBE

MOBILITY (STATIC): 5a – Single limb stance / pre-gait; 5b – Static standing balance / tolerance; 5c – Dynamic standing balance activities; 5d – Standing frame

WHEELCHAIR RACING: 6a – Wheelchair Propulsion Manual; 6b – Wheelchair Propulsion Power