INPATIENT REHABILITATION SERVICES AND PHYSICAL ACTIVITY LEVEL

By

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Rationale: Patients in inpatient rehabilitation facilities are required to attend three hours of therapy on five of seven consecutive days. The members of the rehabilitation team including occupational and physical therapists, and speech-language pathologists use different approaches in therapy, yet have a similar aim in the wellbeing of the patient. The common ground between different types of therapy is that the therapy interventions may increase the patient's activity level through occupational participation and physical activity. However, despite the opportunity that therapy provides for physical activity, many patients are spending too much time sedentary during their inpatient stay. Research suggests that sedentary time is associated with chronic diseases and has been linked to poorer functional outcomes. The purpose of this research was to determine the physical activity levels during occupational therapy, physical therapy, and speech-language pathology services and during the time and day of receiving rehabilitation services and not receiving rehabilitation services in patients in inpatient rehabilitation.

Method: Thirty-eight participants were recruited from Vidant Medical Center's inpatient rehabilitation facility for this prospective, repeated measures study. Participants were screened for moderate-to-severe cognitive impairments and wore an activity tracker to monitor physical activity for a duration of up to two weeks.

Results: Significant differences were found in total activity counts between occupational therapy, physical therapy, and speech-language pathology services and in pairwise comparisons. Occupational therapy had the highest total activity counts among all therapies. A significant difference was found between times that participants were in therapy versus times that participants were not in therapy. A significant difference was found between days that participants received therapy versus days that participants did not receive therapy.

Discussion: Significant physical activity differences among types of therapy could be attributed to the variations in therapy activities across therapy types, timing of therapy sessions, and/or level of patient impairment. Movement that is required to participate in inpatient rehabilitation such as bed and functional mobility and therapy activities contribute to the increased physical activity during the times that participants are participating in therapy. Non-therapy days most often occur on a weekend day, which is less structured than weekdays that require three hours of therapy. The increase in physical activity seen with therapy highlights a necessity of providing the patients with generalizability of therapy interventions, adaptations of therapy interventions, or individualized programs that can be implemented during non-rehabilitation times and post-discharge without a therapist present.

INPATIENT REHABILITATION SERVICES AND PHYSICAL ACTIVITY LEVEL

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CHAPTER 1: PROBLEM FORMULATION

Individuals admitted to an inpatient rehabilitation facility are in the process of recovery from one or more conditions such as neurological, orthopedic, and cardiopulmonary conditions. The Center for Medicare and Medicaid services is one of the payors of the rehabilitation services that are provided in inpatient rehabilitation including occupational therapy (OT), physical therapy (PT), and speech-language pathology (SLP) (Forrest et al., 2019).

Occupational and physical therapists, and speech-language pathologists of the rehabilitation team use different approaches to therapy, yet have a similar aim in the wellbeing of the patient. OT seeks to use everyday life activities to enhance or enable participation throughout a patient's daily life (American Occupational Therapy Association [AOTA], 2020). Common goals of PT include promoting reconditioning of the cardiovascular and musculoskeletal systems and maintaining or improving muscle strength and endurance (Atwood & Nielson, 1985). SLP aims to treat speech, language, social communication, cognitive-communication, and swallowing disorders (American Speech-Language-Hearing Association [ASHA], 2020). The common ground between OT and PT is increasing total daily energy expenditure and exercise capacity through participation in occupations and physical activity (Dibben et al., 2018). SLP may also increase the patient's energy expenditure if they require patients to perform bed mobility or transfers in order to sit or stand during therapy sessions.

All of these rehabilitation services have the ability to help individuals achieve their physical activity recommendations through movement and occupational participation. The standard physical activity recommendation for adults is to achieve at least 150 minutes per week of moderate-intensity aerobic activity or 75 minutes per week of vigorous-intensity aerobic activity, or a combination of both. In addition, moderate to high intensity muscle-strengthening

activity at least two days per week is highly recommended (American Heart Association [AHA], 2018). Although some individuals may have precautions that limit their movement, many others are failing to meet the recommended daily physical activity levels despite a lack of movement restrictions. Meeting the physical activity recommendations is especially important for individuals with cardiac disease and stroke who are at higher risk for adverse cardiac events and recurrent stroke (Dibben et al., 2018; Wondergem et al., 2019).

To our knowledge, there is currently little literature discussing the amount of physical activity that individuals achieve during OT, PT, and SLP services in inpatient rehabilitation facilities. More research is needed to determine if there is a difference between physical activity level during the times that individuals are receiving inpatient rehabilitation services and the times that they are not receiving inpatient rehabilitation services.

CHAPTER 2: LITERATURE REVIEW

Therapy services for inpatient rehabilitation

Physical activity is typically not assessed in healthcare settings (Barnes & Schoenborn, 2012), despite that cardiorespiratory fitness is considered a "vital sign" in clinical practice (Ross et al., 2016). Regardless, individuals admitted to an inpatient rehabilitation facility receive an intense, multidisciplinary rehabilitation program. Individuals are required to attend three hours of therapy on five of seven consecutive days. The three-hour rule applies to all individuals in inpatient rehabilitation facilities regardless of age or condition (Forrest et al., 2019).

Rehabilitation services can provide and promote physical activity as a by-product of therapy. PT provides opportunity for physical activity in and of itself through movement and exercise, while OT provides opportunities for physical activity in conjunction with the performance of occupations such as activities of daily living (ADLs) or instrumental activities of daily living (IADLs) (La Rovere & Traversie, 2019). SLP can increase physical activity by encouraging bed mobility and transfers for effective and safe therapy participation.

Physical activity provided through therapy services during a rehabilitation period can be incredibly beneficial for many different populations. A systematic review found that the amount of physical activity performed during the inpatient stay following surgery was negatively correlated with length of hospital stay (Abeles et al., 2017). While the support provided to patients during their inpatient stay is available throughout the day, at post-discharge, patients' access to support and services that help maintain health and function is greatly diminished (Ezeugwu & Manns, 2017). Physical activity is an important factor to consider post-discharge because it may help reduce post-operative complications and improve functional recovery (Kehlet, 1997; Lawrence et al., 2004). The physical activity that occurs during rehabilitation can

be a learning opportunity for patients to be motivated to perform physical activity outside of therapy sessions.

Effects of sedentary time

Sedentary time consists of any behavior that incurs 1.5 Metabolic Equivalent of Tasks[1] (METs) or less, such as sitting, watching television, and lying down (Pate et al., 2008). Termed an "underrecognized epidemic," the older adult population recovering from an acute illness in the hospital spend approximately 83% of their day sedentary, specifically, lying in bed (Brown et al., 2009). Research suggests that sedentary time is associated with chronic diseases including cardiovascular disease (Ford & Caspersen, 2012; Owen et al., 2010). Also, greater duration of sedentary time has been linked to poorer functional outcomes (Askim et al., 2014; Mattlage et al., 2015). Mattlage et al. (2015) placed an ActiGraph™ on the stroke-affected ankle of participants to quantify sedentary time per day. The primary finding of this study was that stroke patients spent 94% of their day sedentarily. Additionally, while controlling for baseline performance, the researchers also found that the more sedentary time spent during acute care was associated with poorer performance on the *Physical Performance Test* which assessed the performance of ADLs. This measure was taken after ActiGraph™ data collection, just before discharge (Mattlage et al., 2015). Similarly, Askim et al. (2014) studied a sample of 106 stroke patients in a stroke unit. The researchers found that the more time spent in bed in the early phase of stroke recovery was strongly associated with poorer outcome three months post-discharge in the *modified Rankin Scale* which is a measure of the degree of disability and dependence (Askim et al., 2014). This shows that sedentary time may be a risk factor for, and have a negative impact

[1] METs are a concept which represents the energy cost of physical activities as a multiple of the resting metabolic rate. The energy cost of any activity can be calculated by dividing the relative oxygen cost of the activity (ml O2/kg/min) and multiplying it by 3.5. One metabolic equivalent is the amount of oxygen consumed while sitting at rest (3.5 ml O2 per kg body weight x min) (Jetté et al., 1990).

on, functional recovery. Thus, reducing sedentary time and increasing physical activity throughout the day during this critical time of rehabilitation can be of high priority. It is imperative that sedentary time is monitored during the hospital stay, and a physical activity consultation is held before discharge.

Effects of physical activity

Physical activity can be sought out for its own sake in leisure activities or purely for its health enhancing benefits. Regardless, the benefits of physical activity can be reaped, no matter the motive. Cacciatore et al. (2019) found that the higher the involvement in physical activity for any purpose including leisure, ADLs, or IADLs, the lower the risk of mortality in heart failure patients despite comorbidities, disability, and physical function. Physical activity has many benefits for overall mental and physiological functioning as well. One study found a negative correlation between physical activity and inpatient mental health admission. Specifically, higher self-report and objective recording of physical activity were associated with less use of inpatient mental health services (Korge & Nunan, 2018). A meta-analysis reported that physical activity can provide significant benefits of increased gait speed, improved scores on the *Berg Balance Scale*, improved performance in ADLs, and improved scores in the mental health component of quality of life in frail older adults (Chou et al., 2012). Overall, the literature is consistent with the idea that physical activity is crucial in improving strength, endurance, coordination, and functional task performance (Centers for Disease Control and Prevention, 2020).

Despite the many benefits, physical activity may have a negative connotation to some individuals who associate it with exercise or physical stress. However, physical activity can be done for leisure or have a specific, meaningful purpose to each individual, such as ADLs or IADLs that are commonly the primary focuses of OT. One study found that OT treatment time

during an inpatient spinal cord injury (SCI) rehabilitation was spent performing physical activity comprised of a variety of activities that incorporated strength, endurance, range of motion, and stretching. Strengthening and endurance components of OT sessions serve as precursors for functional status improvement. As strength and endurance increase, ADL training is more feasible and may begin. Working towards functional independence in ADLs can provide a sense of independence for patients with self-care needs (Foy et al., 2011). This is significant because meaningful occupations are likely to spark interest in individuals who may otherwise choose not to participate in physical activity.

PT and SLP are often offered in conjunction with OT. Research has shown that the exercises that are provided in PT, such as strengthening exercises, improve the overall performance of functionality (ADLs and IADLs), gait speed, balance, and quality of movement (Holviala et al., 2006; Kloosterman et al., 2009; Turbanski & Schmidtbleicher, 2010). For example, Holviala et al. (2006) found that, in middle-aged and older women, strengthening exercises led to significant improvements in walking speed and dynamic balance. A systematic review noted that improvement of the upper extremity function in patients with tetraplegia is one of the greatest needs for functional recovery. For this reason, in this population, an intensive rehabilitation program is essential in order to optimize function and functional ability of the upper extremity (Kloosterman et al., 2009). Turbanski & Schmidtbleicher (2010) showed how quality of movement is improved through strengthening exercises. In male wheelchair athletes with SCI, improved performance in strength exercises occurred with training, which implicates a potential of enhanced intermuscular and intramuscular coordination (Turbanski & Schmidtbleicher, 2010). Physical activity can also be as simple as functional mobility, such as sitting up in bed, transferring to a chair, or indoor ambulation. The physical exertion required to

move from a lying position to a sitting position is sometimes enough movement to cause a patient's heart rate to increase. If a speech-language pathologist helps a patient to sit up in order to work on feeding or speaking, the by-product of movement can be a secondary physical benefit of the therapy session. The combination of these three rehabilitation services provides opportunities for individuals to increase physical activity while reaching their rehabilitation goals.

Increasing physical activity through rehabilitation services

The presence of a healthcare professional may help to reduce how much of the day that an individual spends in sedentary time. This is especially important for those individuals who are not able to stand or walk without supervision. Bernhardt et al. (2007) found that when therapists or nurses were present, stroke patients were less frequently engaged in sedentary time and more frequently engaged in standing and walking activities. Use of the affected arm increased from 1% to 6% in the presence of a therapist or nurse as well. When alone, patients spent less than 10% of the day standing or walking (Bernhardt et al., 2007). A systematic review of randomized controlled trials showed that participation in cardiac rehabilitation increased physical activity by 26% in adults with heart failure or cardiac disease (Dibben et al., 2018).

Earlier, more intensive, and longer rehabilitation sessions have been associated with better outcomes. Dejong et al. (2009) showed that earlier and more intensive physical activity during therapy sessions was associated with better outcomes at discharge in patients in inpatient rehabilitation recovering from a joint replacement. In skilled nursing facilities and inpatient rehabilitation facilities, similar amounts of therapies were provided. However, the intensity of therapy in inpatient rehabilitation was greater than that provided in skilled nursing facilities. The greater intensity provided at the inpatient rehabilitation was associated with better outcomes at

discharge. Additionally, the number of days from surgery to rehabilitation admission was negatively associated with motor *Functional Independence Measure* gain at discharge (UB Foundation Activities, Inc., 2002). That is, the earlier that rehabilitation started after surgery, the better the Functional Independence Measure score (DeJong et al., 2009). Another study found that, in 116 patients admitted to an inpatient rehabilitation facility, increased therapy time was related to higher overall level of function at discharge (Kirk-Sanchez & Roach, 2011). These findings provide insight that timing, intensity, and duration of therapy have an effect on the outcome of rehabilitation services and should be considered when planning interventions.

Some studies suggest that little physical activity is occurring during therapy sessions. A systematic review including various rehabilitation settings showed that older adults in inpatient rehabilitation had a low level of activity during the daytime. Older adults recovering from orthopedic problems of the lower extremities walked for an average of only eight minutes per day, regardless of their ability to walk independently (Tijsen et al., 2019). Another study showed that the amount of cardiovascular stress experienced during OT and PT is negligible. The measurement of heart rate indicated that patients with SCI spent very little time during OT and PT sessions in moderate to vigorous intensity physical activities. This amount is one quarter of the recommended SCI specific aerobic guidelines. These results indicate that patients may not perform sufficient cardiovascular activity that could optimize their neurologic, cardiovascular, and/or musculoskeletal health (Zbogar, Eng, Noble et al., 2017). In addition, Zbogar, Eng, Noble et al. (2017) reported that the amount of movement repetitions was notably low during OT and PT sessions of patients recovering from SCI with paraplegia and tetraplegia. Repetitions were measured by attempt or full movement of the entire upper extremity, the hand only, the entire lower extremity, and gait. Overall, the movement repetitions were markedly too low to reap

musculoskeletal and endurance benefits or optimize neuroplastic changes (Zbogar, Eng, Miller et al., 2017). A takeaway from these findings is that increasing intensity and repetitions of exercises could increase skill learning, strength, and/or endurance during inpatient rehabilitation. These implications are pivotal for all patients because the physical activity recommendations for Americans are equivalent across the span of adulthood (AHA, 2018).

Not only is it important to increase physical activity during the inpatient stay, but it is also important to promote the importance of physical activity in daily life after discharge. Inpatient rehabilitation offers a chance for individuals to slowly increase their physical activity levels in a supervised and safe setting. Rehabilitation services are effective in accelerating and promoting functionality in ADLs and IADLs (Zbogar et al., 2016). However, research shows that there is a significant decrease in physical activity that follows discharge in patients with SCI (van den Berg-Emons et al., 2008). Van den Berg-Emons et al. (2008) completed a prospective study on patients with SCI who received therapy services during inpatient rehabilitation. Physical activity level was measured at the start of inpatient rehabilitation, three months later during inpatient rehabilitation, at discharge, two months after discharge, and one year after discharge. Findings indicated that physical activity level increased average body motility by 19% during inpatient rehabilitation. However, after discharge, the physical activity level showed a considerable decline. Two months post discharge, the duration of dynamic activities decreased by 33% (van den Berg-Emons et al., 2008). This information suggests that physical activity is increased only temporarily with rehabilitation services, and that preparation for discharge in terms of physical activity level may need to be reevaluated.

With the time and capacity to increase physical activity levels, it may be beneficial to recommend, teach, and encourage physical activity outside of therapy before discharge. This

could be done through group therapy sessions, patient-regulated exercise, and caregiver education. Another factor to consider is that patients may be spending too much time alone. Many patients have mobility limitations that restrict them from engaging in physical activity unless they are accompanied by staff or guests (Bernhardt et al., 2007). An enriched environment providing more opportunity for engagement in self-regulated physical activity is likely to be beneficial in addressing this. Research has shown that an enriched environment – music, audio books, regular books and other reading materials, puzzles, games, hobby supplies, tablets, computers, recreation opportunities, communal areas for eating and socializing – may help facilitate activity in cognitive, physical, and social domains in these environments (Tijsen et al., 2019). This reinforces the notion that building a support system throughout the rehabilitation facility and providing opportunities for patient engagement in activities outside of therapy can encourage more physical activity.

There is literature that provides information about the mechanisms of therapy that can help to increase physical activity. However, further research is needed to seek if and how much OT, PT, and SLP increase physical activity in inpatient rehabilitation patients during therapy and during times when they are not receiving therapy. For all populations, research is needed to find the best way to encourage physical activity during rehabilitation that creates habits which follow patients into their home. Thus, the purpose of this research was to determine the physical activity levels during OT, PT, and SLP services and during the time and day of receiving rehabilitation services and not receiving rehabilitation services in patients in inpatient rehabilitation. Specifically, the research questions are:

(1) Are there significant differences in the physical activity levels between OT, PT, and SLP services?

(2) Is there a significant difference in the physical activity levels between the time of receiving rehabilitation services and the time of not receiving rehabilitation services?

(3) Is there a significant difference in the physical activity levels between the day of receiving rehabilitation services and the day of not receiving rehabilitation services?

CHAPTER 3: METHODOLOGY

Design

This study used a prospective, repeated-measures design to address the research questions. This design was chosen to assess the effect that rehabilitation services have on physical activity level. It addressed if there is a difference in physical activity level between OT, PT, and SLP services, between the time of receiving rehabilitation services and the time not receiving services, and between the days receiving rehabilitation services and the days not receiving services in inpatient rehabilitation units. The participants acted as their own controls.

The duration of the data collection was up to two weeks. This was dependent upon how long the participant was admitted to inpatient care, what day of the week they were admitted, and how soon we received a referral for the patient. The independent variables were rehabilitation services including different therapy services including OT, PT, and SLP for research question 1, therapy times during which participants received OT, PT, and/or SLP for research question 2, and therapy days during which participants received OT, PT, and/or SLP for research question 3. The dependent variable was physical activity level. Physical activity level was measured in total activity counts (TAC) using a physical activity monitor.

Participants

The target population was patients in the inpatient rehabilitation units at Vidant Medical Center in Greenville, NC who received OT, PT, and/or SLP services. Inclusion criteria were (1) being 18 years or older, (2) recovering from one or more of the following conditions, but not limited to: stroke, brain injury, specified neurologic conditions, major multiple trauma, congenital deformity, burns, amputation, systemic vasculitis with joint involvements, fracture of the hip, knee or hip replacement, active polyarthritis, and/or severe or advanced osteoarthritis

(Forrest et al., 2019). Exclusion criteria were (1) admitting diagnosis and/or past medical history of spinal cord injuries, (2) the presence of moderate-to-severe cognitive impairment according to the *Six-Item Screener* score of 3 or below (3 or more errors), (3) inability to wear ActiGraph™ on their wrist 24-hours per day for 9-11 days, (4) less than three full rehabilitation days and/or one full non-rehabilitation days during data collection, and (5) currently having isolation precautions according to the facility.

These exclusion criteria were decided due to the precautions and excessive limitations of physical activity in patients who have experienced an SCI and/or have isolation precautions. Additionally, moderate-to-severe cognitive impairment may pose potential difficulty in rehabilitation generalizability. Finally, wearing ActiGraph™ for data collection and analysis is required for the purpose of the study.

Convenience sampling was used to recruit participants. The occupational therapists in inpatient rehabilitation units at Vidant Medical Center in Greenville, NC referred individuals who fit the inclusion criteria. Due to limitations of time and size of the patient pool for recruitment, it was difficult to ensure a large number of participants. For this reason, we had a goal of recruiting 50 participants. However, due to limited patient referrals, we successfully recruited and collected data from 38 participants.

Instrumentation

Six-Item Screener (SIS). (Callahan et al., 2002). The SIS is a very quick screening that takes approximately one to two minutes to administer. The first three questions assess orientation to the current date. The last three questions ask the patient to recall words in order to assesses memory. There are six total points possible for this screening (Callahan et al., 2002). The SIS is considered a quicker, yet reliable alternative to the *Mini Mental Status Exam* (MMSE) which

was the most commonly used cognitive assessment in the U.S., U.K., and Canada (Woodford & George, 2007). When compared to other commonly used screens for cognitive impairment, such as the MMSE, *Word List Recall*, and the *Blessed Dementia Rating Scale*, the SIS showed a high level of validity (Callahan et al., 2002). Thus, this screening is a valid and reliable fit for the purpose of our study.

The SIS was used to screen for the presence of moderate-to-severe cognitive impairment in potential participants. If a patient scored a 3 or below (three or more errors) on this screening, they were not eligible for the study due to the goals of this study. Some patients with cognitive impairments may have physical activity restrictions due to safety concerns which would have limited our ability to collect enough data from that individual. Additionally, we needed the participants to be able to accurately respond to questionnaires. With a moderate or severe cognitive impairment, this may not have been possible.

ActiGraph™ GT9X Link. ActiGraph™ is a research-grade activity tracker that provides an objective assessment of physical activity level such as TAC, step counts, and activity time measured in METs (Wood et al., 2008). This wearable technology provides an opportunity to better understand and investigate sustainable physical activity in inpatient population (Straiton et al., 2018). Data stored on the ActiGraph™ GT9X Link is downloaded and analyzed with the ActiLife Data Analysis Software. TAC per day is a metric that incorporates data on physical activity across all intensities (light, moderate, and vigorous), frequencies, and durations (Boyer et al., 2016).

A systematic review concluded that ActiGraph™ has good reliability and validity with favorable overall accuracy (Heesch et al., 2018). Test-retest reliability was assessed in three studies, but there was still uncertainty within the findings about the number of days required for

reliable estimates of sedentary behavior. All validation studies of the ActiGraph™ used the ActivPal as the concurrent measure and showed moderate to good concurrent validity for classifying sedentary behavior in free-living conditions (Heesch et al., 2018). Hansen et al. (2014) examined the validity of the ActiGraph™ during walking and found that the ActiGraph™ can be useful to distinguish between different walking speeds on level groups. The data output from the ActiGraph™ in the study rose linearly with walking speed over the level walking range and explained 82% of the variance in energy expenditure (Hansen et al., 2014).

An ActiGraph™ GT9X Link can be worn on the waist using an elastic belt or on the wrist using a watch band. Both wearing positions record accelerations in vertical, antero-posterior, and medio-lateral axes. Tudor-Locke et al. (2015) found that the ActiGraph™ worn on the wrist detected consistently fewer visually counted steps than the ActiGraph™ attached to the waist at most speeds on a treadmill during laboratory testing. Contrastingly, the same study found that the ActiGraph™ on the wrist produced a higher average step count than the ActiGraph™ on the waist under free-living conditions. This difference may be due to the difference in behaviors of the two settings. The rhythmic ambulation that is produced on a treadmill is rare during common daily activities that consist of sedentary and light-intensity activities. The difference between the waist and wrist sites is likely due to the common disjointed wrist and waist movement patterns that occur in free-living conditions (Tudor-Locke et al., 2015).

The accuracy of ActiGraph™ monitors has also been tested in populations with slow or altered gait patterns, although the literature regarding this concern is limited. Campos et al. (2018) found that step counts from the ActiGraph™ were similar to that of another reference accelerometer worn at the ankle in a sample of post-stroke patients. Additionally, Webber et al.

(2016) compared the StepWatch with the ActiGraph™ GT3X+ in older adult rehabilitation patients. This study found that the ActiGraph™ detects steps during walking in older adults with slow or altered gait as well as the StepWatch does (Webber et al., 2016). Albaum et al. (2019) examined the accuracy of the ActiGraph™ in patients in inpatient spinal cord rehabilitation. The ActiGraph™ was found to have excellent agreement with manually counted steps during PT sessions as well as during walking tasks during PT and self-directed activities (Albaum et al., 2019). For the purpose of this study, a wrist-worn ActiGraph™ GT9X Link watch was used to measure physical activity levels in TAC.

Procedure

Upon the approval of the University and Medical Center Institutional Review Board, the researchers gave a brief in-service to therapists at Vidant Medical Center in inpatient rehabilitation units on the study to solicit referrals. After therapists introduced the study to the patients and the patients agreed to learn more about the study, the patients were referred to the study to take further action. A researcher scheduled the individual introduction session with the potential participant at Vidant Medical Center. If they were still interested in the study, then the researcher administered an initial screening to determine the eligibility of the potential participants using the inclusion and exclusion criteria. If they qualified, potential participants reviewed and signed consent forms with a clear explanation of the study and an opportunity to have any questions answered by the researcher. The consent form also asked the participant to grant the permission to have access to the participant's medical records to collect medical information according to the medical information form (Appendix A). Upon completion of the consent form, the participants were given a study code for labeling results of all assessments and data.

During the same initial visit, the researcher collected demographic information from the participants using the study demographic form (Appendix B). The researcher then gave instructions regarding the ActiGraph™. The participants were asked to wear the ActiGraph™ on their non-dominant wrist or less affected wrist for at least 10 waking hours per day for nine to eleven full days. The researcher provided instructions that the watch could be removed only when showering or bathing and at nighttime during sleeping hours. Approximately two months into data collection, due to wear compliance issues, researchers changed wear instructions and began asking participants to wear the ActiGraph™ for 24 hours per day for 9 to 11 full days; only removing the watch during showering or bathing so that data collected had a greater chance of being complete.

Two days after the initial visit, the researcher called or visited the participants to check in on them. The researcher ensured that the participant did not have any trouble with the ActiGraph™ and was abiding by the wear schedule to the best of their ability. A subsequent date was set between the researcher and the participant, prior to the participant's discharge date, for the researcher's return. The researcher left contact information for the participants to use if they had any further questions.

Approximately one day prior to the participant's discharge from the inpatient rehabilitation facility, a researcher returned to the participants. At this return meeting, the ActiGraph™ was collected and a $20 Walmart gift card was given to the participants for their participation. At least one day post-discharge, a researcher accessed the participant's medical records to collect the therapy schedule, therapy notes, and medical information according to the medical information form. Protocol at Vidant Medical Center requires that therapists record the start and end time in their therapy notes. The researcher reviewed the therapy notes from the medical

records to collect information on the types of therapy received, dates of the therapy session, times of day of the therapy session, durations of the therapy session, and assistance levels at admission and discharge according to the Medicare CARE Tool (Appendix C). The score of the *Brief Interview of Mental Status* (BIMS) at admission determined by an occupational therapist was recorded from the patients' medical records. A score of 0-7 indicates severe cognitive impairment, a score of 8-12 indicates moderate cognitive impairment, and a score of 13-15 indicates intact cognitive response (Thomas et al., 2018). The score of the *Johns Hopkins Fall Risk Assessment Tool* determined by nursing staff was also recorded from the medical records. A score of 6-13 indicates moderate fall risk and a score of greater than 13 indicates a high fall risk (Institute for Johns Hopkins Nursing, 2007). If there was any missing information that could not be identified in the medical records, the researcher sought the information from participants and/or therapists.

Data Analysis

ActiLife Analysis. Data downloaded from the ActiGraph™ was analyzed using the ActiLife Data Analysis Software. For wear time validation, Choi (2011) algorithm was used, and "Use Vector Magnitude" was selected. The "exclude non-wear time analysis" option was also chosen to ensure that correct wear time duration was calculated for therapy day and non-therapy day duration. This gave us the most accurate wear time validation. A minimum of three days of wear time were required for days when the participant received OT, PT, and/or SLP services. A minimum of one full day of wear time was required for days when the participant did not to receive rehabilitation services.

For research question 1, TAC was collected for each window of time per therapy session. Researchers reviewed patients' medical records and recorded the times during which each patient

was receiving OT, PT, and SLP. Filters were manually entered into the ActiLife software to distinguish TAC per therapy type, and a spreadsheet of data was created for each discipline for each participant.

For research questions 2 and 3, filters were manually entered into the ActiLife software to distinguish TAC between therapy and non-therapy time and day. Filters were created for 6am-6pm on all days that data was collected (prior to the last day of data collection) and 6am-4pm on the last day of data collection. The data on the last day of data collection was stopped at 4pm due to researchers collecting the watch from the participant at that time. For each participant's data, the wear time validation results on ActiLife, which show when the ActiGraph was worn, were compared to therapy times. When, according to the wear time validation, the data were not available for any of the therapy time, the time was excluded and the data for that time was not downloaded or included in the data analyses. If a participant wore the watch for part of a therapy session, filters for those therapy sessions were altered to include only the therapy time when the watch was worn. Non-wear time during therapy or non-therapy time were excluded from the data analyses. Some participants did not wear the watch for the entire day on non-therapy days. Data for the non-therapy days during which participants did not wear the ActiGraph for a duration of at least six hours were also excluded from data analyses.

Statistical Analyses. Statistical analyses were conducted using IBM SPSS Statistics, Version 27.0. The TAC per minute of wear time was calculated for rehabilitation times and non-rehabilitation times. Hourly average TAC was calculated by multiplying TAC per minute of wear time by 60 for uniform use in data analysis. For assumption checking, all datasets for each research question's variables were tested using the Kolmogorov-Smirnov test for normality and histograms and box plots were visually inspected.

The first question of this study was to determine the difference in physical activity level between OT, PT, and SLP services in patients in inpatient rehabilitation. This research question was analyzed using the linear mixed model due to the missing data of some patients who did not receive speech-language pathology services. This test controls for confounding variables and follows the assumptions that data is approximately normally distributed and that the data does not contain outliers. According to the Kolmogorov-Smirnov test for normality and visual inspection, TAC for OT, PT, and SLP were approximately normal and no outliers skewed the data.

The second research question of this study was to determine the difference in physical activity level between the time of receiving rehabilitation services and the time not receiving rehabilitation services in patients in inpatient rehabilitation. The third research question was to determine the difference in physical activity level between the days receiving rehabilitation services and the days not receiving rehabilitation services in patients in inpatient rehabilitation. When assumptions were checked for research questions 2 and 3, the data was not approximately normally distributed. Therefore, the non-parametric Wilcoxon Signed Ranks Test was used to analyze the data.

CHAPTER 4: RESULTS

Participant Recruitment

Participant recruitment began in September of 2020 and ended in March of 2021. We received 55 referrals from therapists at inpatient rehabilitation units of Vidant Medical Center. Those referrals that were agreeable to the study were screened for meeting inclusion and exclusion criteria (N=47). Two referrals were excluded from the study for not meeting criteria. At the time of data analysis for this study, there were 45 participants who had completed the data collection process and 38 out of 45 participants had usable data. Data from seven participants were excluded from analysis due to high non-wear time of ActiGraph (N=4), fewer than three days of therapy days (N=1), withdrawal from study (N=1), and a lost activity tracker (N=1). Four participant's data was only used for research questions 1 and 2 due to no data collected on a non-therapy day.

Demographic and Medical Information and Descriptive Measures

Demographic and medical information is reported as means (SD) for continuous variables and N (%) for categorical variables. The mean age of the study's participants was 63.50 (12.50) years, and the majority of participants were white (55.3%), female (57.9%), married (42.1%), and lived with someone else (76.3%) in a house (68.4%). Table 1 provides the demographic information for the participants and the results of the descriptive measures. Medical history was also collected for participants. It is notable that the majority of participants were admitted to the inpatient rehabilitation facility for orthopedic conditions (39.5%) and experienced weakness (81.6%) during their stay. Table 2 provides the relevant medical history for the participants.

Table 1. *Demographic information and descriptive measures results.*

	N = 38
Age (year), *M (SD)*	63.50 (12.50)
Race, *N (%)*	
White	21 (55.3)
African American	15 (39.5)
Other	2 (5.3)
Sex, *N (%)*	
Female	22 (57.9)
Male	16 (42.1)
Marital status, *N (%)*	
Married	16 (42.1)
Single, never married	6 (15.8)
Divorced	8 (21.1)
Widowed	6 (15.8)
Separated	2 (5.3)
Level of education, *N (%)*	
Master's degree	2 (5.3)
Bachelor's degree	4 (10.5)

	N = 38
Associate degree	2 (5.3)
Some college (1-4 years, no degree)	10 (26.3)
High school graduate (or equivalent)	10 (26.3)
High school (grades 9-12, no degree)	8 (21.1)
Nursery/kinder/elementary (grades 1-8)	2 (5.3)
Living status, *N (%)*	
Lives with someone else	29 (76.3)
Lives alone	9 (23.7)
Living environment, *N (%)*	
House	26 (68.4)
Apartment	6 (15.8)
Other	6 (15.8)
Previous occupation before hospitalization, *N (%)*	
Management	1 (2.6)
Business and financial operations	2 (5.3)
Education, training, and library occupations	1 (2.6)
Healthcare practitioners and technical occupations	2 (5.3)
Healthcare support occupations	3 (7.9)

	N = 38
Personal care and service occupations	1 (2.6)
Food preparation and serving related occupations	2 (5.3)
Installation, maintenance, and repair occupations	1 (2.6)
Transportation and material moving occupations	1 (2.6)
Not employed	3 (7.9)
Disabled	5 (13.2)
Retired	16 (42.1)
Total household annual income (N=37), *N (%)*	
Over $100,000	3 (7.9)
$90,000 - $99,999	0 (0)
$80,000 - $89,999	2 (5.3)
$70,000 - $79,999	1 (2.6)
$60,000 - $69,999	5 (13.2)
$50,000 - $59,999	0 (0)
$40,000 - $49,999	4 (10.5)
$30,000 - $39,999	5 (13.2)
$20,000 - $29,999	3 (7.9)
$10,000 - $19,999	10 (26.3)

	N = 38
Less than $10,000	4 (10.5)

Table 2. *Medical information of participants.*

	N = 38
Hospitalization information	
Acute care length of stay in days, *M (SD)*	15.74 (27.49)
Inpatient rehab length of stay in days, *M (SD)*	13.66 (3.71)
Inpatient rehabilitation admitting diagnosis	
Orthopedic, *N (%)*	15 (39.5)
Cardiopulmonary, *N (%)*	9 (23.7)
Neurological & Other, *N (%)*	14 (36.8)
BIMS score, *M (SD)*	13.71 (1.59)
Johns Hopkins Fall Risk Assessment at admission, *M (SD)*	12 (3.06)
Medical history	
Total number of all existing medical diagnoses, *M (SD)*	10.08 (4.65)
History of major diagnoses, *N (%)*	
Hypothyroidism, controlled or uncontrolled	2 (5.3)
CVA	4 (10.5)

	N = 38
Depression	6 (15.8)
PVD	4 (10.5)
COPD	6 (84.2)
Dementia	0 (0)
Cancer	6 (15.8)
TBI	0 (0)
MS	0 (0)
Anxiety	1 (2.6)
Limitations to physical activity, *N (%)*	
Hemiplegia	0 (0)
Tetraplegia	0 (0)
Paralysis	0 (0)
Safety precautions	29 (76.3)
Weakness	31 (81.6)
Nausea	15 (39.5)
Medicare CARE Tool	
Self-care items, *M (SD)*	
Admission score (N = 38)	3.60 (0.65)

	N = 38
Discharge score (N = 37)	5.09 (0.62)
Mobility items, *M (SD)*	
Admission score (N = 38)	3.26 (0.57)
Discharge score (N = 37)	4.93 (0.74)

Note. BIMS = Brief Interview for Mental Status; CVA = cerebrovascular accident; PVD = peripheral vascular disease; COPD = chronic obstructive pulmonary disease; TBI = traumatic brain injury; MS = multiple sclerosis. Medicare CARE Tool can be found in Appendix C.

ActiGraph Wear Time Descriptive Measures

Among the 38 participants, the mean (SD) total number of therapy sessions during the inpatient stay included in the data analyses was 9.92 (3.81) for OT, 10.13 (3.72) for PT, and 5.90 (3.41) for SLP. The median of total wear time for therapy days ranged from 486 minutes to 720 minutes. The median of total wear time for non-therapy days ranged from 551 minutes to 720 minutes.

Research Question 1

Research question 1 was to determine the difference in physical activity level between OT, PT, and SLP in adults receiving inpatient rehabilitation. TACs were significantly different between OT, PT, and SLP ($F = 52.61$, $P < 0.001$) according to the linear mixed-model. Bonferroni-corrected, pairwise comparisons showed a significant difference between OT and PT ($P < 0.001$; 95% CI 815.67 -1387.38), a significant difference between OT and SLP ($P < 0.001$; 95% CI 1188.26 - 2450.52), and a significant difference between PT and SLP ($P = 0.018$; 95% CI 119.94 - 1315.80). OT showed the highest level of TAC out of all therapies followed by PT and lastly SLP. Linear mixed-model analysis results are shown in Table 3.

Table 3. *Research question 1: Difference in physical activity level between occupational therapy, physical therapy, and speech-language pathology.*

	Total activity count, *M (SD)*	Between groups
OT (N = 38)	3641.24 (238.84)	
PT (N = 38)	2539.72 (187.95)	52.61, <0.001[a]
SLP (N =10)	1821.85 (299.45)	
OT - PT		815.67 - 1387.38, <0.001[b]
OT - SLP		1188.26 - 2450.52, <0.001 [b]
PT - SLP		119.94 - 1315.80, 0.018[b]

Note. OT, occupational therapy; PT, physical therapy; SLP, speech-language pathology.
[a]*F, P*-value for linear mixed-model
[b]*95% CI, P*-value for Bonferroni-corrected, pairwise comparisons

Research Question 2

Research question 2 was to determine the difference in physical activity level between the time of receiving rehabilitation services and the time of not receiving rehabilitation services in adults receiving inpatient rehabilitation. Participants showed a significant difference (Z = 5.373, $P < 0.001$) in TAC between therapy times and non-therapy times. The results of the non-parametric Wilcoxon Signed Ranks Test are shown in Table 4.

Table 4. *Research question 2: Difference in physical activity level between the time of receiving rehabilitation services and the time not receiving rehabilitation services* (N = 38).

	Mdn (IQR)	*Z, P*-value
Therapy times total activity count	3083.20 (2134.67, 3783.61)	5.373, < 0.001
Non-therapy times total activity count	1357.38 (856.66, 2238.45)	

Research Question 3

Research question 3 was to determine the difference in physical activity level between the days receiving rehabilitation services and the days not receiving rehabilitation services in adults receiving inpatient rehabilitation. Participants showed a significant difference ($Z = 4.488$, $P < 0.001$) in TAC between therapy days and non-therapy days. The results of the non-parametric Wilcoxon Signed Ranks Test are shown in Table 5.

Table 5. *Research question 3: Difference in physical activity level between the days of receiving rehabilitation services and the days not receiving rehabilitation services* (N = 34).

	Mdn (IQR)	*Z, P*-value
Therapy days total activity count	1652.04 (1315.25, 2708.55)	4.488, < 0.001
Non-therapy days total activity count	1350.14 (845.59, 2058.62)	

CHAPTER 5: DISCUSSION

This study was conducted (1) to determine the difference in physical activity level between OT, PT, and SLP services; (2) to determine the difference in physical activity level between the time of receiving rehabilitation services and the time of not receiving rehabilitation services; and (3) to determine the difference in physical activity level between the days receiving rehabilitation services and the days not receiving rehabilitation services in patients in inpatient rehabilitation. In this study, data were collected from 38 participants receiving therapy in an inpatient rehabilitation facility for up to two weeks each to investigate the differences in TAC between types of therapy, therapy times versus non-therapy times, and therapy days versus non-therapy days. We found significant differences in all three research questions.

Differences in Physical Activity Level Among Therapy Services

The primary finding for research question 1 was significant differences in physical activity levels between all three types of therapy sessions. Surprisingly, OT showed the highest level of physical activity over PT, although, as expected, both OT and PT both showed more physical activity over SLP. Since PT tends to consist of more gross motor activity, one might expect PT sessions to promote greater physical activity. However, these significant differences may be due to the variations in therapy activities across therapy types, timing of therapy sessions, and/or level of patient impairment.

These differences in physical activity level may have been due to the different focuses and goals of therapy services. According to professional definitions, OT practitioners are trained to recognize the patient as a whole with considerations of mind, body, and spirit which have a transactional relationship (AOTA, 2020). Moreover, due to its focus on the human body's functioning in its entirety, instead of isolated parts focused on impairment, the OT profession is

set apart from other rehabilitation professions (AOTA, 2020). OT treatment sessions are comprised of the therapeutic use of everyday life occupations such as eating, dressing, toileting, grooming, bathing, and functional transfers. These interventions utilizing occupations may be more motivating for patient engagement in therapy sessions because the elements of occupations elicit feelings of self-determination and autonomy responsibility (Kennedy & Davis, 2017). PT treatment sessions focus on mobility and movement through exercise and hands on care to improve strength, range of motion, gait, and balance training. Beaulieu et al. (2015) found that most of PT time (25%-38%) was spent on gait activities regardless of mobility limitations. While these focuses are important to clients, the focuses of the treatment may be more limited and less motivating than that of OT. Speech-language pathology treatments encompasses all aspects of communication and eating including expression, comprehension, and chewing and swallowing (Bode et al., 2004). Beaulieu et al. (2015) showed that most of SLP was spent on swallowing activities (20%), followed by problem-solving/reasoning activities (18%), and verbal expression activities (10%) for patients with traumatic brain injury (TBI) in multiple inpatient rehabilitation facilities.

Therapy sessions incorporating a wide variety of activities such as ADLs and IADLs (involving upper or lower extremities) may offer more therapy options for individuals with differing abilities compared to mobility activities incorporating the use of lower extremities and head and neck activities. Upper extremity activity has shown to require greater cardiovascular output compared to lower extremity activity (Pendleton & Schultz-Krohn, 2018a). Machado-Vidotti (2014) investigated the autonomic cardiac response during upper versus lower extremity resistance exercise (one repetition max of incline bench press and leg press) in 10 healthy older men. This study found a more pronounced sympathetic increase for upper limb exercise than for

lower limb exercise. Sympathetic response was measured by heart rate and blood pressure. These findings support our results to explain the difference in physical activity level between OT and PT.

Differences in physical activity between types of therapies may also be attributed to timing of therapy sessions. According to the medical records that were collected, more therapy times were spent on PT sessions in the afternoon, whereas more therapy times were spent on OT sessions in the morning. This timing may be due to ADL components of OT sessions that are involved in morning self-care routines. Patients may be more motivated, engaged, or active in the morning versus the afternoon since they have not expended as much energy at that point during the day.

Lastly, participant's level of impairment may be a contributing factor to the differences in physical activity among OT, PT, and SLP. The majority of our participants had admitting diagnoses that are orthopedic problems in lower extremities as well as cardiopulmonary problems. Patients with limitations in the lower extremities are likely to have balance and mobility restrictions, requiring them to use a walker. This nuance can cause the upper extremities to move less during ambulation. This may be a confounding factor that caused results to show that PT caused seemingly less physical activity than OT. In addition, although it was a small difference, our participants required more assistance in mobility items of Medicare CARETool than in self-care items. The average score on the Johns Hopkins Fall Risk Assessment Tool was moderate/borderline high fall risk. Therefore, our participants were very likely restricted in their mobility and may have been considered unsafe and less capable in activities involving standing, ambulation, or stair-climbing. Compared to PT and SLP services, OT may have more options of

activities that are physically more active in nature and can be performed by mobility-restricted adults.

Common activities performed in OT sessions include ADLs (bathing, toileting/toileting hygiene, dressing, eating/swallowing, feeding, functional mobility, and personal hygiene/grooming) or IADLs (communication management, financial management, home establishment/management, meal preparation/cleanup, and shopping) (AOTA, 2020). Patients recovering from a hip fracture are a population who often have mobility precautions during recovery. In OT sessions, safe mobility begins early by educating on use of adaptive equipment for independence in ADLs, while abiding by hip and weightbearing precautions (Pendleton & Schultz-Krohn, 2018b). Similarly, patients with cardiovascular or pulmonary conditions often have mobility restrictions due to energy conservation needs. Metabolic equivalents, as they relate to the patient's response to occupational participation (oxygen consumption), are monitored throughout treatment by the occupational therapist. As a patient appropriately tolerates one activity (i.e. seated sponge bathing), they can progress to the next highest metabolic equivalent level activity (i.e. standing sponge bathing). As occupational therapists teach energy conservation techniques and lifestyle modifications, patient mobility progression increases safely (Pendleton & Schultz-Krohn, 2018a). Overall mobility restrictions, such as the ones described, are likely to be more hindering in mobility-focused activities of PT than function-focused occupations of OT.

Comparison of Therapy and Non-Therapy

As expected, there was a significantly higher physical activity level during therapy times than those during non-therapy times and significantly higher physical activity level on therapy days than those on non-therapy days. We expected the findings on the physical activity level

during therapy and non-therapy times (research question 2), due to the nature of individual inpatient rehabilitation sessions. It is required for patients at inpatient rehabilitation to receive three hours of therapy five out of seven days a week (Forrest et al., 2019). The 3-hour rule applies to all patients in an inpatient rehabilitation facility regardless of age, admitting diagnosis, functional level, or comorbidities. This requirement is based on the expectation that the patient admitted to the inpatient rehabilitation facility can benefit from this intensive, multidisciplinary rehabilitation program (OT, PT, and SLP) and daily notes from the rehabilitation team must provide evidence that the patient's level of function is improving. It does not take into account the patient's need for other hospital services (Forrest et al., 2019).

In addition, most of these therapy hours are provided individually, rather than in a group format (Hammond et al., 2015). Hammond et al. (2015) conducted a study on individuals with TBI to explore the amount and content of group therapies provided at inpatient rehabilitation. Of the 2,130 patient admissions among nine inpatient rehabilitation facilities, 79.9% received at least one group therapy session, but group therapy only accounted for an average of 13.7% of a patient's total therapy sessions and 15.8% of all therapy hours. Our participants were instructed, guided, and assisted to perform therapeutic activities and tasks mostly one-to-one, if not all, by the licensed and skilled therapists; therefore, it is not surprising that our participants had higher physical activities levels during the therapy times than non-therapy times.

Non-therapy times typically consist of patient care and leisure activities that are not as physically involved or intensive as that time spent during the three hours of inpatient therapies. The SCIRehab project was a multicenter collaborative study conducted to describe and quantify the interventions provided during rehabilitation (Whiteneck et al., 2011). The study collected data from 600 patients with traumatic SCI admitted to six inpatient rehabilitation facilities.

Results concluded that, of the total treatment hours provided throughout the inpatient rehabilitation stay, OT and PT accounted for approximately 60% of the entire treatment time, nursing accounted for 17%, therapeutic recreation accounted for 9%, psychology and social work/case management accounted for 6% each, and SLP accounted for 2%. Seventeen percent of nursing only included documented nursing interventions provided by registered nurses and did not include direct nursing care such as providing personal and wound care and administering medications (Whiteneck et al., 2011). Doctor visits, diagnostic tests and scans, and medical treatments (i.e. dialysis) are also included in hospital care time. This finding indicates that individuals in inpatient rehabilitation may spend as high as 40% of their time on less active tasks.

Time not spent in hospital care often includes leisure activities such as resting, visiting with family and/or friends, watching television, and reading most of which are considered sedentary. When there are additional restrictions from the facility, such as those related to COVID-19 precautions, there could be even fewer opportunities for activities outside of therapy times. At Vidant Medical Center's inpatient rehabilitation facility, due to the COVID-19 pandemic, visitors were significantly restricted and were required to remain in the patient's room or the café (WITN, 2020a; WITN, 2020b; WAVY Web Staff, 2021; Vidant Health, 2021). These visitor restrictions may have had an impact on the patients' ability to move throughout the hospital, thus affecting physical activity level during non-therapy times as well.

The findings of Smith et al. (2008) and Bear-Lehman et al. (2001) are consistent with our findings on significantly higher physical activity level on therapy days than those on non-therapy days. These studies found that patients with differing diagnoses receiving inpatient rehabilitation were less active on non-therapy days than on therapy days. Smith et al. (2008) compared physical activity of older adults receiving inpatient rehabilitation with that of community-

dwelling older adults. The study compared median uptime (time spent in an upright position) on weekdays versus weekend days in both groups. They found no significant difference for community dwelling adults, but found significantly reduced uptime in adults in inpatient rehabilitation on weekend days, marked by no therapy sessions. Bear-Lehman et al. (2001) observed the time use of 12 participants in an inpatient rehabilitation unit. These researchers used behavioral mapping to directly log participants' daily activities. They found that inactivity and alone time consistently increased on weekend days versus weekdays. Additionally, Peiris et al. (2012) found that orthopedic patients receiving inpatient rehabilitation were least active on Sundays when no therapy was provided, evidenced by 141 fewer steps and 0.2 less hours in upright activities, compared to weekdays when therapy was provided. Non-therapy days most often occur on a weekend day, which is less structured than weekdays in terms of care and may account for this reduction in physical activity.

Being physically active may be associated with higher levels of energy and lower levels of fatigue. When individuals are required to participate in therapy for three hours on therapy days, they may have higher energy and less fatigue during other hours of the day, resulting in a higher physical activity level for the entire day. Ellingson et al. (2014) found this association to be true in their study of 73 female participants. These participants completed several questionnaires regarding feelings of energy and fatigue in relation to general mood, health, and wellbeing. Participants then wore an ActiGraph™ for seven days during waking hours in addition to completing a daily activity log. Researchers found that participants who met physical activity recommendations had significantly higher levels of vigor and vitality. Additionally, those participants who were physically active and still did not meet physical activity recommendations but had lower amounts of prolonged sedentary time had significantly lower

levels of fatigue. The positive effects of physical activity were present regardless of prolonged sedentary behaviors (Ellingson et al., 2014). This is comparable to patients in inpatient rehabilitation facilities because no matter the amount of bed rest or sedentary time that they accumulate, any additional physical activity may have positive effects on their overall health and levels of fatigue. This emphasizes the importance and need of early, more intensive, and possibly longer rehabilitation sessions in order to encourage better outcomes for individuals in inpatient rehabilitation units.

Based on our findings, rehabilitation services may hold a critical role to reduce the overall sedentary and "bed rest" time among individuals receiving inpatient rehabilitation. While rest is necessary for healthy recovery in all adults, prescribed bed rest may not contribute to recovery as much as it has previously been thought. Allen et al. (1999) performed a study with 39 trials of bed rest for 15 different conditions. Of the 24 trials that investigated bed rest as a general treatment following a medical procedure, no patient outcomes improved significantly and eight worsened significantly. Of the 15 trials that investigated bed rest as a primary treatment, no patient outcomes improved and nine worsened significantly (Allen et al., 1999). The secondary complications associated with bed rest suggest that additional rest may not be a requirement for a full and healthy recovery. Additionally, several studies have suggested that increased therapy time for individuals in inpatient rehabilitation facilities is related to higher overall level of function at discharge (Kirk-Sanchez & Roach, 2011). Another study that collected data on 3500 patients in an inpatient rehabilitation facility increased therapy from five to seven days per week. They reported a decrease in average length of stay from 20.3 days to 19.3 days (DiSotto-Monastero et al., 2012). These findings indicate that, while rest is necessary

for overall healthy functioning, additional rest may not be a necessary treatment requirement for individuals in inpatient rehabilitation facilities.

These findings on the benefits of increased therapy time and decreased sedentary time imply that rehabilitation services are crucial in the process of recovery by accelerating functional recovery and decreasing risk of complications. One study randomly assigned stroke patients in an inpatient rehabilitation facility to an experimental group who received the usual care (three hours of therapy) plus a patient-directed activity program or a control group who received only usual care. The patient-directed activity program focused on functional activity and included two 30-minute activity bouts, leading to increase in physical activity time by 50%. The patient-directed activity program was created by the patient's clinical team and was individualized to the patient's needs, including upper and lower extremity activities that were based on principles of neuroplasticity and self-management. The activities included a manual with written and visual instructions, and grading options. Outcome measures included range of motion and coordination, functional mobility, balance, and physical activity (ActiGraph^{TM}) at admission and discharge from inpatient rehabilitation, and three months post rehabilitation discharge. Researchers found that patients in the experimental group took more steps and reported higher quality of life at discharge and after three months (Swank et al., 2020).

Enhancing generalizability of therapy interventions through adaptations and/or individualized programs that can be implemented during non-rehabilitation times may help to increase physical activity over the course of the entire day and inpatient rehabilitation stay. The ultimate goal of OT is the generalization of learned skills in unfamiliar contexts (Boyt Schell et al., 2019). Training rehabilitation recipients in safely performing occupations, activities, and/or tasks on their own outside of therapy times is a simple and easy way to encourage physical

activity outside of therapy time, especially on non-therapy days. This can be done for individuals who are independently and safely mobile as well as those who require assistance to transfer out of bed, although the latter individuals would require more adaptations and safety measures. Items for self-care such as brushing teeth, combing hair, and washing face can be placed in the bathroom to encourage mobility or at bedside to simply encourage occupational participation. Physical therapy and SLP exercises and treatments may be adapted to allow individuals to perform simple movements safely and independently while abiding to hospital precautions and patient restrictions. Providing a rehabilitation recipient with an individualized program with grading options may help to motivate him/her to be more active throughout the day. When educating individuals on the importance of these self-initiated occupations, activities, and tasks, it would be beneficial for individuals to be aware that additional physical activity can be a vehicle to possibly returning home more quickly. This addition to inpatient care may help to accelerate recovery, thus decreasing length of stay.

CHAPTER 6: LIMITATIONS

Despite the important findings related to physical activity level among individuals receiving inpatient rehabilitation, our study has several limitations. Although our participants all received OT and PT, and some also received SLP at an inpatient rehabilitation facility, their admitting diagnoses varied. Therefore, our results are applicable to the general inpatient rehabilitation population, not a single population with a specific diagnosis. We provided the information on the diagnosis groups based on their admitting diagnoses; however, we were not able to include this variable as a covariant in our analyses due to the limited number of participants in certain groups, including neurological and other groups. Future studies should include higher number of participants using a proper statistical method to avoid type I and type II errors. More buy-ins by the inpatient rehabilitation facilities and inclusion of multiple inpatient rehabilitation facilities for recruitment can ensure the faster recruitment of the higher number of participants. In addition, stratified sampling by diagnosis groups can be used to ensure a participant pool that represents overall individuals receiving inpatient rehabilitation. With a larger sample size, participants can be grouped by admitting diagnosis and analyzed for within-group differences, and generalizability can be improved.

The amount of time that each participant wore the ActiGraph™ varied based on the amount of time that they were admitted to the inpatient rehabilitation unit and how much they abided by our request to wear it during waking hours or for 24-hours per day. This inconsistency may have been caused by the participant's health status and diagnosis at the admission, willingness and desire to comply with our instructions, and understanding of our instructions. Due to this inconsistency, ActiGraph™ data during all waking hours for every participant were not available. Therefore, our data may not be representative of each participant's overall waking

hours. While this is not ideal, we only included the data of those participants who complied to the wear schedule for a significant amount of time (at least six hours). This standard may have limited too much inconsistency that might have skewed the data.

The participants in this study wore the ActiGraph™ on the wrist and not the waist. The accuracy of the ActiGraph™ worn on the wrist may not be as good as the accuracy when worn on the waist. However, the waist-worn ActiGraph™ was not feasible at inpatient rehabilitation because some of the participants were in a wheelchair or immobile for extended periods of time. Also, wearing the ActiGraph™ on the wrist may improve the adherence to the wearing schedule and data collection. Additionally, improving patient wear-time compliance and finding a measure of physical activity that is more precise yet still feasible for wear on individuals with limited mobility could improve the accuracy of the data collected. Individuals receiving inpatient rehabilitation may wear two physical activity monitors, one on wrist and another on waist, and the compliance in wearing these physical activity monitors can be improved through higher support from nursing staff.

Our findings showed that TAC was highest in OT versus PT or SLP. However, it is possible that the TAC in PT was underrepresented. Many individuals in inpatient rehabilitation use a wheelchair or walker for assistance during functional mobility. Holding onto a walker during PT sessions may have reduced the amount of TAC counted because the upper extremities are not moving as they typically would during ambulation. This is another limitation to using the wrist-worn ActiGraph™ instead of waist-worn.

CHAPTER 7: CLINICAL RELEVANCE TO OCCUPATIONAL THERAPY

This study has the potential to expand the OT literature regarding the impact that OT has on physical activity level during inpatient rehabilitation. This research highlights the impact that motivation may have on patient involvement in therapy services and the physical activity benefits of occupation-as-means and occupation-as-end. Occupational therapy is rooted in the use of occupations that are motivating to the client for optimal engagement in treatment. This foundational philosophy of OT is sometimes overlooked because preparatory activities are used as the primary means of intervention sessions. Our findings emphasize the implication that using valued occupations may be the encouragement that a patient needs for maximal occupational engagement and participation. In addition, occupations used as means and aimed as end can offer a variety intervention options that have the high potential to increase physical activity level. While preparatory activities are useful to some degree, occupational therapists should never forego the therapeutic use of occupation and holistic, client-centered approaches to maximize functional independence and physical activity level for health benefits.

While the 3-hour Medicare rule for therapy in inpatient rehabilitation facilities must be abided by and time allotted for therapy sessions is limited, this study begins to uncover the need for additional physical activity outside of therapy hours. Occupational therapists should consider the feasibility and implementation of individualized therapy plans for patients to perform independently and safely without a therapist present. These plans should be generalizable to different contexts with appropriate adaptations for patient's safe participation. Occupational therapists already have a thorough foundational knowledge in grading and adaptation; therefore, providing these modifications to individualized programs is well rooted in their scope of practice. These individualized programs for non-therapy times align with the OT goal that is to

promote the highest level of functional independence possible, with additional benefits of an increase in physical activity.

CHAPTER 8: CONCLUSION

Existing literature supports the notion that physical activity for individuals receiving inpatient rehabilitation services can be beneficial, as it is associated with numerous positive health outcomes. Although inpatient rehabilitation services have shown to improve independence and wellbeing during daily activities, the literature on whether those services influence physical activity levels during therapy times is scarce.

The findings of this study provide knowledge on the impact that rehabilitation services, OT, PT, and SLP, have on increasing physical activity levels and, hence, decreasing sedentary time. This research gives insight into the differences in physical activity levels between types of therapy services as well as the differences between rehabilitation times and non-rehabilitation times. Results concluded that individuals receiving inpatient rehabilitation are most physically active during OT, during therapy times, and on therapy days.

Internal motivation may be a contributing factor that explains why individuals were more active in OT sessions when compared to PT or SLP. In addition, the nature of the activities performed in the OT treatment sessions which primarily involve the upper extremities and require more energy may be attributable. A need for motivating, attainable physical activity opportunities outside of therapy sessions is something that should be considered by all therapy professions. The findings of this research can be applied to mixed populations in inpatient rehabilitation facilities in order to provide a generalizable and individualized therapy program to possibly increase physical activity, decrease hospitalization length of stay, and/or increase functional outcomes post-discharge.

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APPENDIX A

Medical Information:

Acute care admission date: _____ Acute care discharge date: _____

Inpatient rehabilitation admitting diagnosis: _____

Total inpatient rehabilitation length of stay: __ / __ / _____ to __ / __ / _____ = _____ Days

Self-Care Items and Mobility Items (American Occupational Therapy Association, 2018):

Previous level of function in Self-Care Items and Mobility Items of Medicare CARETool (American Occupational Therapy Association, 2018):

Total number of falls experienced during Acute Care stay and Inpatient Rehabilitation stay and the dates for each fall incident:

Total number of falls during Acute Care stay and the date for each: _____

_____

Total number of falls during Inpatient Rehabilitation stay and the date for each: _____

_____

All existing medical diagnoses: Total number of diagnoses: _____

O	O	O
O	O	O
O	O	O
O	O	O
O	O	O

History of major diagnoses:

O CVA	O TBI	O Others: _____
O Peripheral vascular disease	O MS	
O COPD	O Hypothyroidism (controlled/uncontrolled)	
O Dementia	O Depression	
O Cancer (type/status?)	O Anxiety	

Limitations to physical activity:

O Hemiplegia	O Nausea
O Tetraplegia	O Others: _____
O Paralysis	
O Safety precautions	
O Weakness	

APPENDIX B

Demographics:

Date of Birth: __ __ / __ __ / __ __ __ __ Age: _____ yrs

Race:
O White
O African-American
O American Indian
O Pacific Islander
O Other_____

Gender:
O Male
O Female
O Other

Highest education completed:
- O No schooling/less than 1 yr
- O Nursery/kinder/elementary (grade1 1-8)
- O High school (grades 9-12, no degree)
- O High school graduate (or equivalent)
- O Some college (1-4 yrs, no degree)
- O Associate's degree
- O Bachelor's degree
- O Master's degree
- O Professional degree (MD, JD, etc)
- O Doctorate degree (PhD, EdD, etc)

Marital status:
- O Single, never married
- O Married
- O Widowed
- O Separated
- O Divorced
- O Not recorded

Living status:
- O Lives alone
- O Lives with spouse
- O Lives with son or daughter
- O Lives with sister or brother
- O Lives with other relative
- O Lives with non-relative
- O Other _____
- O Not recorded

Living environment:
- O House
- O Apartment
- O Other _____

Previous occupation before hospitalization:
- O Management
- O Business and financial operations
- O Computer and mathematical occupations
- O Architecture and engineering
- O Life, physical, and social science
- O Community and social service
- O Legal occupations
- O Education, training, and library occupations
- O Arts, design, entertainment, sports, and media
- O Healthcare practitioners and technical occupations
- O Healthcare support occupations
- O Protective service occupations
- O Food preparation and serving related occupations
- O Building and grounds cleaning and maintenance
- O Personal care and service occupations
- O Sales and related occupations
- O Office and Administrative support occupations
- O Farming, fishing, and forestry occupations
- O Construction and extraction occupations
- O Installation, maintenance, and repair occupations
- O Production occupations
- O Transportation and material moving occupations
- O Military specific occupations
- O Not employed
- O Disabled

Total Household Annual Income:
- O Less than $10,000
- O $60,000-$69,999

- O $10,000-$19,999
- O $20,000-$29,999
- O $30,000-$39,999
- O $40,000-$49,999
- O $50,000-$59,999
- O $70,000-$79,999
- O $80,000-$89,999
- O $90,000-$99,999
- O Over $100,000

APPENDIX C

Client:_____ MRN: _____ Eval Date: _____ DC Date:_____

Self-Care and Mobility Section GG Items

Self-Care CARE Items (Activities of Daily Living)

The Self-Care CARE Items do not replace standardized assessments that occupational therapy may use for evaluation. These items are being implemented across all post-acute care (PAC) settings by Medicare (CMS). For more information and scoring information, see the Medicare Assessments linked on the last page. Many assessments that provide information about ADL performance also provide information about cognition, vision, and other concerns. After completing the Occupational Profile, complete and document various assessments to gather essential data for your initial evaluation.

Use the form below to score and document self-care items. This tool can be implemented in any adult care setting.
See page 2 for scoring information. See page 3 for transfer and mobility items.

6 = *Independent;* **5** = *Setup or Cleanup Assistance;* **4** = *Supervision or Touching Assistance;* **3** = *Partial/Moderate Assistance;* **2** = *Substantial/Maximal Assistance;* **1** = *Dependent;* **07** = *Refused;* **09** = *Not Applicable;* **10** = *Not attempted due to environment limitation;* **88** = *Not attempted due to medical condition/safety.*

Self-Care Items (Assessment Item GG 0130***)

	Admission	Goal	Discharge	Item	Definition
A				**Eating**	The ability to use suitable utensils to bring food and/or liquid to the mouth and swallow food and/or liquid once the meal is placed before the person.
B				**Oral Hygiene**	The ability to use suitable items to clean teeth. Dentures (if applicable): The ability to insert and remove dentures into and from the mouth, and manage denture soaking and rinsing with use of equipment.
C				**Toilet Hygiene**	The ability to maintain perineal hygiene, adjust clothes before and after voiding or having a bowel movement. If managing an ostomy, include wiping the opening but not managing equipment.
D				**Wash Upper Body****	**Wash Upper Body is only reported in LTCH.** The ability to wash, rinse, and dry the face, hands, chest, and arms while sitting in a chair or bed.
E				**Shower/ Bathe Self***	**Shower/Bathe Self is only reported in IRF, SNF, and HH.** The ability to bathe self, including washing, rinsing, and drying self (excludes washing of back and hair). Does not include transferring in/out of tub/shower.
F				**Upper Body Dressing***	The ability to dress and undress above the waist; including fasteners, if applicable.
G				**Lower Body Dressing***	The ability to dress and undress below the waist, including fasteners; does not include footwear.
H				**Putting on/Taking off Footwear***	The ability to put on and take off socks and shoes or other footwear that is appropriate for safe mobility; including fasteners, if applicable.
					Add "1" for each response of **07, 09, or 88.**
				IRF, SNF, or HH Total	For IRF, SNF, or HH, add lines A, B, C, E, F, G, H (A score of 7–42 is possible.)
				LTCH Total	For LTCH, add lines A, B, C, D (A score of 4–28 is possible.)

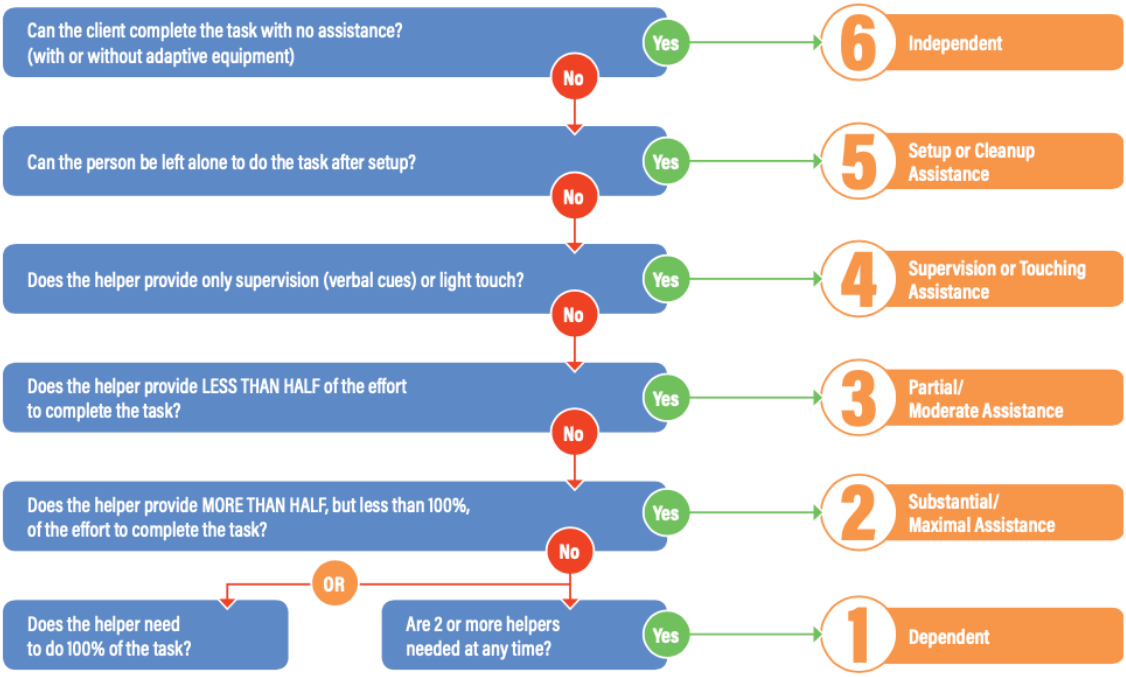
*Indicates the item is not yet reported to CMS in Long Term Care Hospitals (LTCH).
**Indicates the item is *only* reported to CMS in LTCH.
***These items correspond with item GG 0130 in the 4 Medicare assessments, including the Skilled Nursing Facility Minimum Data Set (MDS), Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF–PAI), Long Term Care Hospital Continuity Assessment Record Evaluation Tool (LTCH CARE), and the Home Health Outcome and Assessment Information Set (OASIS).

HH = home health; IRF = inpatient rehabilitation facility; SNF = skilled nursing facility; LTCH = Long Term Care Hospital.

Note the facility will report the client's "usual performance over the first 3 days of admission" for each item to CMS.

Scoring Algorithm

See the chart below to help score each item. Adaptive equipment and assistive devices may be used for any score. For more information, see www.aota.org/CARE.



6: Independent—Person completes the activity by himself/herself with no assistance from a helper.
5: Setup or cleanup assistance—Helper SETS UP or CLEANS UP; person completes activity. Helper assists only prior to or following the activity. (The helper can walk away and leave the person to complete the task.)
4: Supervision or touching assistance—Helper provides VERBAL CUES or TOUCHING/STEADYING and/or CONTACT GUARD ASSISTANCE as person completes activity. Assistance may be provided throughout the activity or intermittently.
3: Partial/moderate assistance—Helper does LESS THAN HALF the effort. Helper lifts, holds, or supports trunk or limbs but provides less than half of the effort.
2: Substantial/maximal assistance—Helper does MORE THAN HALF the effort. Helper lifts or holds trunk or limbs and provides more than half the effort.
1: Dependent—Helper does ALL of the effort. Person does none of the effort to complete the activity. Or, the assistance of 2 or more helpers is required for the person to complete the activity.

07: Refused.
09: Not applicable.
10: Not attempted due to environmental limitations.
88: Not attempted due to medical condition or safety concern.

Mobility CARE Items (Assessment*** Item GG 0170)

6 = *Independent;* **5** = *Setup or Cleanup Assistance;* **4** = *Supervision or Touching Assistance;* **3** = *Partial/Moderate Assistance;* **2** = *Substantial/Maximal Assistance;* **1** = *Dependent;* **07** = *Refused;* **09** = *Not Applicable;* **10** = *Not attempted due to environment limitation;* **88** = *Not attempted due to medical condition/safety.*

	Admission	Goal	Discharge	Item	Definition
A				**Roll left and right**	The ability to roll from lying on back to left and right side, and return to lying on back on the bed.
B				**Sit to lying**	The ability to move from sitting on side of bed to lying flat on the bed.
C				**Lying to sitting on side of bed**	The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support.
D				**Sit to stand**	The ability to come to a standing position from sitting in a chair, wheelchair, or on the side of the bed.
E				**Chair/bed-to-chair transfer**	The ability to transfer to and from a bed to a chair (or wheelchair).
F				**Toilet transfer**	The ability to get on and off a toilet or commode.
G				**Car transfer**	The ability to transfer in and out of a car or van on the passenger side. Does not include the ability to open/close door or fasten seat belt.
I				**Walk 10 feet**	Once standing, the ability to walk at least 10 feet in a room, corridor, or similar space. If admission performance is 07, 09, 10, or 88, Skip to "M, 1 Step (curb)."
J				**Walk 50 feet with 2 turns**	Once standing, the ability to walk at least 50 feet and make 2 turns.
K				**Walk 150 feet**	Once standing, the ability to walk at least 150 feet in a corridor or similar space.
L				**Walking 10 feet on uneven surfaces**	The ability to walk 10 feet on uneven or sloping surfaces (indoor or outdoor), such as turf or gravel.
M				**1 Step (curb)**	The ability to go up and down a curb and/or up and down 1 step. If admission performance is coded 07, 09, 10, or 88, skip to "P, Picking up object."
N				**4 Steps**	The ability to go up and down 4 steps with or without a rail. If admission performance is 07, 09, 10, or 88, Skip to "P, Picking up object."
O				**12 Steps**	The ability to go up and down 12 steps with or without rail.
P				**Picking up object**	The ability to bend/stoop from standing position to pick up small object, such as spoon, from floor.
	Score "R" and "S" only if the client uses a wheelchair. Check: ☐ manual wheelchair ☐ motorized wheelchair				
R				**Wheel 50 feet with 2 turns**	Once seated in wheelchair/scooter, can wheel at least 50 feet and make 2 turns.
S				**Wheel 150 feet**	Once seated in wheelchair/scooter, can wheel at least 150 feet in corridor or similar space.

***These items correspond with item GG 0170 in the 4 Medicare assessments, including the Skilled Nursing Facility Minimum Data Set (MDS), Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF–PAI), Long Term Care Hospital Continuity Assessment Record Evaluation Tool (LTCH CARE), and the Home Health Outcome and Assessment Information Set (OASIS).

References

Centers for Medicare and Medicaid Services. (2017). *Proposed measure specifications and standardized data elements for CY 2018 HH QRP notice of proposed rule making.* Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Proposed-Measure-Specifications-and-Standardized-Data-Elements-for-CY-2018-HH-QRP-Notice-of-Proposed-Rule-Making.pdf

Gage, B., Smith, L., Ross, J., Coots, L., Kline, T., Shamsuddin, K., . . . Mallinson, T. (2012a). *The development and testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final report on the development of the CARE Item Set* (Vol. 2). Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-Reliability-Testing-Volume-2-of-3.pdf

Gage, B., Deutsch, A., Smith, L., Schwartz, C., Ross, J., Coots, L., . . . Mallinson, T. (2012b). *The development and testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final report on Care Item Set and current assessment comparisons* (Vol. 3). Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-and-Current-Assessment-Comparisons-Volume-3-of-3.pdf

Full Medicare Assessments

Review the most recent full Medicare assessments for each post-acute care setting:

Inpatient Rehabilitation Facility Resident Assessment Instrument (IRF-PAI):
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html

Minimum Data Set (MDS) used in Skilled Nursing Facilities:
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html

Outcome and Assessment Instrument Set (OASIS) used in Home Health Agencies:
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html

Long Term Care Hospital Continuity Assessment Record (LTCH CARE):
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html

For More Information

Review AOTA information on the implementation of the self-care and mobility measures using items from the Continuity Assessment Record Evaluation (CARE) at **www.aota.org/CARE**

AOTA Practice Resources

Productive Aging Evidence-Based Practice Resources
http://www.aota.org/Practice/Productive-Aging/Evidence-based.aspx

Health & Wellness Evidence-Based Practice Resources
http://www.aota.org/Practice/Health-Wellness/Evidence-Based.aspx

Rehabilitation & Disability Evidence-Based Practice Resources
http://www.aota.org/Practice/Rehabilitation-Disability/Evidence-Based.aspx

AOTA Occupational Profile Template
http://www.aota.org/profile

APPENDIX D

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** ·
rede.ecu.edu/umcirb/

Notification of Amendment Approval

From: Biomedical IRB
To: Young Joo Kim
CC:
Young Joo Kim
Date: 10/28/2020
Re: Ame3_UMCIRB 20-001463
UMCIRB 20-001463
Inpatient rehabilitation services and physical activity level

Your Amendment has been reviewed and approved using expedited review on 10/27/2020. It was the determination of the UMCIRB Chairperson (or designee) that this revision does not impact the overall risk/benefit ratio of the study and is appropriate for the population and procedures proposed.

Please note that any further changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a Final Report application to the UMCIRB prior to the Expected End Date provided in the IRB application. If the study is not completed by this date, an Amendment will need to be submitted to extend the Expected End Date. The investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Document	Description
Changing the storage of electronic research data to ECU OneDrive from the Departmental Piratedrive due to the diminishing space in the Departmental Piratedrive.	

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418