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Implementing the Hodgson Red Yellow Green Mobilization Consensus Recommendation in a Medical and Surgical ICU: A Retrospective Study Exploring the Effectiveness of an Early Mobilization Decision Protocol in ICU

Swati Patel
patelswc@shu.edu

Implementing the Hodgson Red Yellow Green Mobilization Consensus Recommendations in a Medical and Surgical ICU: A Retrospective Study Exploring the Effectiveness of an Early Mobilization Decision Protocol in ICU

By

Swati Patel

Dissertation Committee:

Chair: Dr. Genevieve Pinto Zipp

Dr. Ning J. Zhang

Dr. Fortunato Battaglia

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APPROVAL FOR SUCCESSFUL DEFENSE

And

COMPLETION OF DISSERTATION MANUSCRIPT

Swati Patel has successfully defended and completed the text of the doctoral dissertation for the **PhD in Health Sciences** degree, during this **Spring Semester, 2020**.

DISSERTATION COMMITTEE

(Please sign and date beside your name)

Chair:

Dr. Genevieve Pinto Zipp _____ Date: 3/22/202

Committee Member:

Dr. Ning J. Zhang _____ Date: 3/22/2020

Committee Member:

Dr. Fortunato Battaglia _____ Date: 3/22/2020

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ABSTRACT

Background: More than 4 million people are admitted annually to intensive care units (ICUs). Due to immobility, many ICU survivors experience significant cognitive, psychological, and physically disabling side effects regardless of admitting diagnosis. Multiple studies and quality improvement projects have shown the safety, feasibility, and benefits of early mobilization in the ICU setting. Hodgson et al (2014) published consensus recommendations for safe active mobilization of mechanically ventilated critically ill adults. To date, there is no standardized and simple triage protocol for identifying patients for early mobilization. No study so far has described operationalizing and implementing the Red-Yellow-Green system described by Hodgson et al. NYU Langone- Brooklyn initiated a Quality improvement project from January 2018 to June 2018 to overcome this barrier in clinical practice. The project implemented early mobilization in the Medical and Surgical ICUs at NYU Langone-Brooklyn hospital by operationalizing the Red-Yellow-Green system described in Hodgson et al. This evidenced based project was guided by the Translating Research Into Practice (TRIP) model and the multidisciplinary team approach. **Methods:** A retrospective chart review of all ICU patients during the early mobilization period from January to June 2019 was used to conduct a within group pre-test posttest analyses for the primary functional and behavioral outcomes (IMS, FSS, AMPAC, RASS and CAM-ICU). A between groups design was used to assess the secondary outcomes of all ICU patients from a historical comparison period of January to June 2017 and all ICU patients during the early mobilization period of January to June 2018, regarding ICU and hospital lengths of stay and discharge recommendation. The sample was obtained from patients admitted to MICU and SICU at an urban community teaching hospital with 28 beds. Chart review was performed for 388 patients in MICU and 293 patients in SICU to include the data of

all patients who participated in the early mobilization protocol. **Results:** During the early mobilization period, MICU functional scales improved significantly as measured by functional scales: IMS from 5.9 to 6.2 ($p < .001$); FSS-ICU from 14.5 to 15.5 ($p < .001$); and AMPAC from 12.6 to 13.1 ($p < .001$). Behavioral scales improved significantly in the MICU: There was a significant difference in MICU RASS score ($Z = -2.27$, $p = .023$) and upon discharge majority of the patients were alert and calm with RASS score clustered towards middle at score 0; There was a significant difference between MICU initial and final CAM-ICU scores ($\chi 2$ (1, N=388) = 54.14, $p < .001$). 49.3% of the patients that had pretest confusion did not have posttest confusion. SICU functional scales improved significantly as measured by functional scales: IMS from 6.2 to 7.1 ($p < .001$); FSS-ICU from 16.5 to 19.0 ($p < .001$); and AMPAC from 13.8 to 15.2 ($p < .001$). Behavioral scales: There was a non-significant difference in SICU RASS score ($Z = -1.83$, $p = .067$) however upon discharge majority of the patients were alert and calm with RASS score clustered towards middle at score 0; There was a non-significant difference between SICU initial and final CAM-ICU scores ($\chi 2$ (1, N=293) = 0.16, $p = .690$). 22 % of the patients that had pretest confusion, did not have posttest confusion, however upon discharge majority of the patients scored negative in CAM-ICU indicating less confusion/delirium upon ICU discharge. Both overall hospital LOS and ICU length of stay decreased compared to the historical comparison period: MICU patients' hospital LOS decreased from 10.6 to 8.4 days ($p < 0.001$); MICU LOS decreased from 2.9 to 2.5 ($p = .002$); SICU patients' hospital LOS decreased from 12.0 to 9.3 days ($p < .001$); SICU LOS decreased from 5.7 to 3.7 days ($p < .001$). Discharge to community increased compared to the historical control from 48% to 52% in MICU and from 39.9% to 60.1% in SICU. No adverse events occurred during the pilot period. **Conclusion:** Based upon this retrospective review the Interdisciplinary Early Mobilization team

demonstrated consistent and reliable implementation of the Hodgson Red Yellow Green Mobilization system. Accurately identifying candidates for Early Mobilization yielded statically significant and robust outcomes for several Functional and Behavioral outcome measures. Early mobilization should be part of routine care during patient's ICU stay. The results from the QI project showed that, in addition to reducing ICU and hospital LOS, early ICU intervention enabled more patients to be discharged to community instead of post-acute care facilities. A hospital wide cultural change is essential to unleash the full potential of early mobilization in the ICUs. Having a protocol that is simple and feasible enables hospitals to achieve such goals safely without clinical complications.

Keywords: early mobility; early mobilization; ICU-acquired weakness; multidisciplinary; outcomes; physical rehabilitation; quality improvement, barriers; critical care;

CHAPTER- I
INTRODUCTION

INTRODUCTION

Each year in United States, more than 4 million people are admitted to Intensive care units (ICUs). More than 750,000 ICU admits in United States receive mechanical ventilation, with almost 300,000 requiring prolonged support. Approximately 13 to 20 million people annually require life support in intensive care units worldwide. Eighty to ninety percent of these patients are surviving ICU stay due to advancement in the medical technology. Sedation is a common practice in the ICU setting, to prevent patients from removing lines and tubes, but is often a barrier to getting a patient out of bed (Joint commission, 2004; Engel et al., 2013).

Due to immobility, a high proportion of ICU survivors experience significant cognitive, psychological, and physically disabling side effects because of secondary impairments resulting from their ICU stay. Regardless of their admitting diagnosis nearly half of ICU survivors are unable to return to their previous work more than 1 year after hospital discharge (Timmers et al., 2011; Engel et al., 2013). Even though patients are surviving acute illnesses, long-term complications from physical immobility and sedation practices result in increased delirium, longer lengths of stay in ICU and in the hospital overall, and increased duration of ventilation (Schweickert et al., 2009).

In the last decade, rehabilitation of mechanically ventilated patients in ICUs has been a topic of growing interest. Multiple studies and quality improvement projects have been conducted across the world to gather evidence on safety, feasibility, and benefits of early mobilization practices in the ICU setting.

In 2014, Hodgson et al published recommendations developed through expert consensus on safety criteria for active mobilization of mechanically ventilated critically ill adults. While a variety of studies has been published on implementing early mobilization in ICUs, none we could locate so far had described operationalizing and implementing the Red-Yellow-Green system described in Hodgson et al. In addition, we used the Translating Research Into Practice (TRIP) model and a multidisciplinary team approach to guide an evidence-based strategy in operationalizing the Hodgson guidelines for our setting.

The goal of this study was to report the Quality improvement program development and the outcomes monitored for quality purposes along with an assessment of cost, safety, and feasibility. In addition, we compare the early mobilization period in the ICUs with a season-matched historical control as a way of putting the benefit of these guidelines in perspective.

BACKGROUND OF THE PROBLEM

Effects of bedrest

Bedrest is an important risk factor for developing ICU acquired weakness with its detrimental effects beginning within 24-48 hours (Jones et al., 2004). These primarily included rapid deconditioning, decrease in muscle strength and muscle atrophy. Prior studies of young healthy adults have demonstrated a 5-9% loss of quadriceps muscle mass and 20-27% decrease in muscle strength after 2 weeks of immobilization (Jones et al., 2004; Suetta et al., 2009). This muscular declined in further pronounced in older adults and in mechanically ventilated patients (Kortebein et al., 2007; English and Paddon-Jones, 2010). Studies have reported a 12.5% decrease in the cross-sectional area of skeletal muscles during the first week of admission to the ICU (Puthucheary et al., 2013). Some study participant's demonstrated signs of inflammation, necrosis and replacement of muscle fibers with adipose and connective tissue on muscle biopsies of mechanically ventilated patients (Derde et al., 2012; Puthucheary, 2013). A prospective longitudinal study of 222 patients diagnosed with acute respiratory distress syndrome (ARDS) followed up at 3, 6, 12, and 24 months reported a 3-11% decrease in muscle strength for every additional day of bedrest in the ICU after adjusting for other potential risk factors leading to long-term weakness. The study also reported that this population had significantly lower six-minute walk distance and quality of life scores compared to the population norms at 2-year follow-up. (Fan et al., 2014)

ICU acquired conditions- Potential negative effects of immobility

Prolonged immobility results in a plethora of conditions like ICU acquired weakness (ICU-AW), post-intensive care syndrome (PICS), iatrogenic immobilization injuries, ICU-induced myopathy and ICU-induced polyneuropathy (Corcoran et al.,2017). These conditions are often as disabling as the medical conditions that brought the patient to ICU initially (requires

proof). The resulting long-term physical complications include impairment in muscle strength, physical function and quality of life (Herridge et al., 2011).

ICU-AW is defined as the presence of clinically detectable weakness in ICU patients with no possible etiology other than critical illness (Stevens et al., 2009). Subtle signs including weakness in withdrawal to noxious stimuli, decreased spontaneous movements and diffuse muscle wasting characterize ICU-AW. Patients reported signs and symptoms are difficulty with activities of daily living, diffuse muscle weakness, diffuse wasting and decrease in deep tendon reflex, after discharge from the ICU (Hough & Needham, 2007). Studies report ICU-AW in more than one third of patients who required requiring mechanical ventilation during their ICU admission (Denehy, 2013). Extremity weakness has also been shown to be associated with respiratory muscle weakness requiring prolonged weaning from mechanical ventilation (De Jonghe et al., 2007; Hermans et al., 2014), which concurrently increases the risk for ventilator associated pneumonia and recurrent respiratory failure (Fan et al., 2014). Observational studies have reported an incidence ranging from 25% to 57% of ICU-AW with a positive association between ICU-AW and increased duration of mechanical ventilation (11 days vs. 8 days, p = .009), increased length of stay in the ICU and hospital (36 days vs. 23 days, p = .007), greater costs per patient (23,277 vs. $17,834, p = .040) and increased 1–year mortality (30.6 % vs. 17.2 %, p = .02) (Hermans et al., 2014). Patients with ICU-AW also experience significant long-term impairment in respiratory muscle strength, poor functional recovery, and reduced return to work as the neuromuscular recovery lags behind that of other organ systems. Consequently, the quality of life is affected significantly for months and years after hospital discharge (Herridge et al., 2011; Wieske et al., 2015). Further studies have shown that More than 50% of patients discharged from the ICU had developed ICU-AW, which was positively associated with death between ICU discharge and day-90 (De Jonghe et al., 2002; Bednarik et al., 2005).

Along with ICU-AW, Hough et al reported that 34% of patients with severe and persistent ARDS developed neuromyopathy during hospitalization. Critical illness, polyneuropathy, and myopathy are hypothesized to occur due to exposure to corticosteroids and neuromuscular blocking agents administered during ICU stays. However, a multicenter randomized controlled trial failed to report any differences in the average muscle strength between the intervention and control group (36 % in treatment group vs. 31% in intervention group). The authors concluded that the incidence of muscle weakness was not significantly

increased by the use of the neuromuscular blocking agent in the study population (Hough et al., 2009). Hence, neuromyopathy observed in the ICU can potentially be the result of immobility and not due to the administration of neuromuscular blocking agents (Hough et al., 2012).

ICU associated delirium is commonly reported in mechanically ventilated patients; 20-80% of ICU patients experience temporary alterations in cognition, which is characterized by inattention and disorganized thinking at any point (Morandi, Jackson & Ely, 2009). ICU associated delirium is associated with increased mortality, longer ICU and hospital stay and increased duration of ventilation (Schweickert et al., 2009) along with costs of approximately $4 to $16 billion (Ely et al., 2001). The length of Days of delirium is also closely associated with the degree of cognitive impairment one year after ICU discharge. A study of 821 ICU patients with respiratory failure or shock, 74% were delirious during their hospital stay with a and a quarter to a third of these patients had a decline in their cognitive score at 1 year follow-up (Pandharipande, 2013). Seventy-eight percent of ICU discharged patients continued to experience cognitive dysfunction with gross impairment in memory, attention and concentration. Another follow-up cohort confirmed these findings and noted further dysfunction in mental processing speed and executive function (Hopkins et al., 2005)

Psychological and Emotional dysfunction- Hopkins et al. have reported that not all brain dysfunctions after critical illnesses are cognitive and that 20-40% of discharged patients have prominent psychological sequelae of critical illness, including anxiety, depression and post-traumatic stress disorder (PTSD) (Hopkins et al., 2001). Hopkins et al. reported that 16-24% of patients showed moderate-to-severe depression and anxiety on screening examinations had at 1-2 year follow-up, with their anxiety at 1 year was associated with the duration of mechanical ventilation (Hopkins et al., 2010). A study completed in Toronto amongst ARDS cohort suggests that there may be some improvement in depressive symptoms over time, but moderate-to-severe symptoms persisted in 19% of the patients, 5 years later (Hough and Herridge, 2012). Another common and debilitating problem after critical illness is PTSD with psychiatrist-diagnosed PTSD being reported among 44% of ARDS patients at hospital discharge, 25% at 5 years post-discharge, and 24% at 8 years post-discharge from the ICU (Davydov, Desai and Needham, 2008).

It is clear that survivors of critical illnesses are at risk for substantial and persistent impairments in physical, cognitive and mental health. The adverse effects from ICU admission and prolonged immobility affect multiple organ systems and are often as disabling as the medical problem for which the patient was admitted to the ICU initially with complete resolution often taking years (Sukantarat et al., 2007; Oeyan et al., 2010; Herridge et al., 2011). Additionally, other retrospective studies from medical and surgical ICUs reveal that at least half of discharged patients regardless of age were unable to return to their premorbid levels of activity (Thomson et al., 2008; Morris et al., 2008). It has been theorized that the weakness experienced by critical illness patients arises in part from an interaction of inflammatory and metabolic changes and is exacerbated by the detrimental effects of prolonged bedrest commonly imposed on ICU patients. Evidence suggests that early intervention in the initiation of ICU admission is required to prevent these undesired effects and providers should not wait until discharge to try to improve long-term outcomes (Derde et al., 2012; Fan et al., 2014. Corcoran et al., 2017).

ICU-AW prevention/treatment

Recognizing the need to address the diminished quality of life experienced by patients discharged from the ICU due to functional, cognitive and psychological impairment, the Society of Critical Care Medicine (SCCM) organized a conference in 2010 to create the acronym PICS (*post-intensive care syndrome)* ((Needham et al., 2012; Bermis- Dougherty and Smith, 2013). The outcome was the development of a protocol that included collaborative inter-professional improvements in care to reduce PICS through increasing education, identification of research areas and barriers to quality improvement (QI) initiatives (Needham et al., 2012; Engel et al., 2013).

Similarly, to prevent and reduce ICU survivor impairments, several expert panels recommended the wide spread implementation of the (1) Awakening and Breathing Coordination, Delirium and Early Mobility Bundle (ABCDE) bundle (Morandi, Brummel & Ely, 2011) (2) ICU Pain, Agitation and Delirium (PAD) care bundle (Barr et al., 2013) (3) World Health Organization's international Classification of functioning, disability and heath model of assessment and care (Iwashyna and Netzer, 2012) and recommendations of the European Respiratory Society and European Society of Intensive Care Medicine Task Force on Physiotherapy for critically ill patients (Gosselink et al., 2008). The aim of these

recommendations is the prevention of ICU acquired conditions by the early implementation of treatment programs designed to improve ICU patients' physical, cognitive, and mental health impairments, with structured rehabilitative patient physical activity (Bailey et al., 2007, Morris et al., 2008).

The Awakening and Breathing Coordination, Delirium and Early Mobility Bundle (ABCDE) has been developed and used widely to address immobility-related problems in the ICU (Morandi, Brunnel & Ely, 2011). It is a complex evidence-based multicomponent practice bundle that focuses on the early intervention in the ICU and is positively associated with shorter duration of mechanical ventilation, improved physical function, reduction in delirium incidence, and decrease in ICU length of stay for mechanically ventilated patients (Costa et al., 2017). Implementing the bundle in a pre-post 296 subject study, 187 mechanically ventilated showed that those in the post- group had more ventilator- free days (median of 24 days vs. 21 days, p =.04), were more likely to mobilize out of bed at least once during the ICU stay (odds ratio 2.11, p = .003), and were less likely to experience delirium during the ICU stay (odds ratio 0.55, p = .03), compared to the pre-group (Balas et al., 2014). With the growing literature on ICU acquired weakness and harms of bedrest, early mobilization and rehabilitation of critically ill patients are gaining attention.

What is Early mobilization in ICUs?

"Early" mobilization refers to initiation of the rehabilitation activities immediately upon respiratory and hemodynamic stabilization, generally within 24-48 hours after ICU admission (Bailey et al., 2007; Needham & Korupolu, 2010).

In the last decade, the rehabilitation of mechanically ventilated patients in ICUs has been a topic of growing interest. Multiple studies and quality improvement projects have been conducted across the world to gather evidence on safety, feasibility, and benefits of early mobilization practices in the ICU setting. There is a strong historical basis for early mobilization and rehabilitation of mechanically ventilated patients in the ICU since late 19th century (Ries et al., 1899). Researchers in 1899 recognized that a decrease in post-operative bedrest period from days or weeks to hours would result in reduced muscle weakness (Ries et al., 1899). In subsequent years, similar studies focusing on decreasing the bedrest period were conducted

among patients recovering from surgery and among women in the postpartum period. (Cunningham, 1907; Epstein & Fleischer, 1927; Rock, 1929). Similar concepts of early mobilization were used to help injured soldiers during the World War II to return to battlefield faster (Bergel, 1990; Keys, 1944).

An early controlled trial was published in 1944 comparing 100 subjects receiving early mobilization to 100 subjects that received usual care in ICU after receiving similar surgeries. Subjects who received early mobilization were out of bed and ambulated on the first post-operative day, whereas the group receiving usual care was confined to bedrest for 10-15 days. The total number of post-operative complications was higher among subjects receiving usual care compared to those receiving early mobilization (17 versus 46). These complications included local surgical, pulmonary, cardiac, vascular, genitourinary and gastrointestinal complications. No safety concerns related to mobilization (e.g. pulmonary embolism or coronary thrombosis) were reported in the group receiving early mobilization (Powers, 1944). Around this time a conference on bedrest was held and major journals were publishing articles on related topics such as the "evil sequel of complete bedrest" and "abuse of rest in bed" (Dock, 1944; Ghormley, 1944).

However, in the intervening years sedation practice became the standard practice post care in order to prevent the patients from removing lines and tubes. This caused an increase in bed -rest and created a barrier to patient mobilization. In 1998, Thomas Petty, a leader in pulmonary and critical care medicine highlighted the historical practices from early days of critical care, in contrast to later practice by saying, " When we first started our unit in 1964, patients who required mechanical ventilation were awake and alert and often sitting in a chair…. But what I see these days are paralyzed, sedated patients, lying without motion, appearing to be dead, except for the monitors that tell me otherwise" (Petty, 1998). ICU patients who were intubated were often managed with deep sedation and bedrest during the early stages of ICU admission (Hesham, Nelliot and Needham 2016). The critically ill patients were not considered appropriate for early physical activity because they were deemed to be too medically unstable or were too dependent on life-sustaining equipment. More recent evidence contradicts these assumptions and has demonstrated that early mobility of ICU patients is both safe and feasible (Engel et al., 2013). In the last fifteen years many controlled trials (Chiang et al., 2006; Morris et al., 2008; Burtin et al., 2009; Schweickert et al., 2009; Chang et al., 2011; Denehy et al., 2013)

and point prevalence studies (Berney et al., 2013; Nydahl et al., 2014) investigating the safety and feasibility of early progressive mobilization in the ICU have been published and have shown significant impacts on functional and behavioral outcomes (Hodgson, et al 2014).

Given the presence of increased awareness of issues surrounding prolonged bedrest, more literature has emerged discussing decreased use of sedation for ventilated patients, the detrimental effects of bedrest, ICU acquired weakness, and the benefits of early mobilization in the ICU.

Significance:

Findings of many systematic reviews are contributing to a shift in ICU practice. Patients who were previously on total bedrest and heavily sedated are receiving early progressive mobilization and less sedation, which in turn is resulting in decreased ICU and hospital length of stay, improved functional outcomes and decreased financial costs (Bassett et al., 2012). Gruenberg et al. reported that long stays in the ICU are associated with high costs and significant financial burden on patients and their families, which in turn affect society at large. The cost of patient care in ICUs in the United States has been estimated to account for 1-2% of the gross national product and 15-20% of U.S. hospital costs, which represent 38% of total U.S. healthcare costs (Gruenberg et al., 2006). Corcoran et al., reported that the a quality improvement (QI) project at NYU Langone Hospital-Tisch started from 2012 to 2014 which aimed at decreasing the length of stay and financial burden on large institutions and increasing focus on value-based medicine, resulted in a $2.2 million direct cost savings representing a 29% decrease in direct costs when compared to pre-QI project data. After taking into account expenses for the QI project and increased staffing costs by $655,336 (annualized), the net cost savings was $1.5 million. The study reported that cost saving was the product of decrease in length of stay (20% in ICU length of stay and 40% decrease in hospital length of stay) and decrease in average direct cost resulting from a decline in sedation medication use, decreased ventilator days, increased discharge to community and decrease in 90 day readmission (Corcoran et al., 2017). Robert et al., reported net cost saving of $817,836 with the actual length of stay reduction of 22% for ICU and 19 % for the hospital in 900 annual admissions. The study included sensitivity analyses of 24 scenarios out of which 20 scenarios (83%) demonstrated net savings. Sensitivity analyses used

conservative and best-case scenarios for length of stay reduction and varied the per-day ICU and hospital costs across ICUs with 200-2,000 annual admission and yielded financial projections ranging from $87,611 (net cost) to $3,763,149 (net savings). The study concluded that, based on the financial model based on actual experience and published data projects, that investment in an ICU early rehabilitation program can generate net financial savings for U.S. hospitals. Even under the most conservative assumptions, the projected net cost of implementing such a program is modest relative to the substantial improvements in patient outcomes demonstrated by ICU early rehabilitation programs (Robert et al., 2013).

Purpose of the study:

Multiple studies and quality improvement projects have shown the safety, feasibility, and benefits of early mobilization in the ICU setting. Historically, early mobilization in the ICU has not always been a common practice at NYU Langone Health- Brooklyn Hospital. To address the immobility related problems, our hospital system initiated a quality improvement project to enhance patient experiences and overall outcomes throughout the medical center.

Hodgson et al (2014) published consensus recommendations for safe active mobilization of mechanically ventilated critically ill adults. No study so far had described operationalizing and implementing their Red-Yellow-Green system. This project implemented early mobilization in the Medical and Surgical ICUs by operationalizing the Red-Yellow-Green system described in Hodgson et al. It used the Translating Research Into Practice (TRIP) model and a multidisciplinary team approach to guide an evidence-based strategy for this process.

The purpose of the study was to assess the safety and feasibility of the use of the NYU Langone hospital-Brooklyn Early mobilization protocol (Red-Yellow-Green system) to enhance overall patient experience by improving various functional and behavioral outcomes without having adverse events or increase in the cost of treatment by initiating “early mobilization” in ICU.

Research Questions and Hypothesis:

The study aimed to answer the following research questions:

- Research Question- 1: Is the early mobilization protocol administered from ICU admission to discharge effective in improving functional status of the patient as measured by ICU mobility scale?
    - Hypothesis- 1: Early mobilization protocol administered from ICU admission to discharge will improve functional status of the patient as measured by ICU mobility.

- Research Question- 2: Is the early mobilization protocol administered from ICU admission to discharge effective in improving functional independence of the patient as measured by FSS- ICU scale?
    - Hypothesis- 2: Early mobilization protocol administered from ICU admission to discharge will improve functional independence of the patient as measured by FSS-ICU scale.

- Research Question- 3: Is the early mobilization protocol administered from ICU admission to discharge effective in improving functional independence of the patient as measured by AMPAC basic mobility scale?
    - Hypothesis- 3: Early mobilization protocol administered from ICU admission to discharge will improve functional independence of the patient as measured by AMPAC basic mobility scale.

- Research Question- 4 Is the early mobilization protocol administered from ICU admission to discharge effective in decreasing agitation and sedation in ICU patients as measured by Richmond Agitation and Sedation Scale- RASS?
    - Hypothesis- 4: Early mobilization protocol administered from ICU admission to discharge will decrease agitation and sedation in ICU patients as measured by Richmond agitation and sedation scale- RASS

- Research Question- 5: Is early mobilization protocol administered from ICU admission to discharge effective in decreasing ICU acquired delirium as measured by CAM- ICU?

- Hypothesis- 5: Early mobilization protocol administered from ICU admission to discharge will decrease ICU acquired delirium as measured by CAM- ICU.

- Research Question- 6: Is the early mobilization protocol administered in the ICU effective in decreasing ICU length of stay compared to the usual care control from the prior year?
    - Hypothesis- 6: Early mobilization protocol administered in the ICU is effective in decreasing ICU length of stay compared to the usual care control from the prior year.

- Research Question- 7: Is the early mobilization protocol administered from ICU admission to discharge effective in increasing discharge to community after discharge from hospital
    - Hypothesis- 7: Early mobilization protocol administered from ICU admission to discharge is effective in increasing discharge to community after discharge from hospital

Theoretical/Conceptual Framework:

The study was guided by the knowledge translation research framework, to assess the safety and feasibility of the protocol based on the Hodgson et al. expert consensus "Red-Yellow-Green" recommendations.

A. Knowledge translation research:

Knowledge translation is a relatively new term that has rapidly gained prominence in multiple health care disciplines, most notably in medicine, public health, and health care policy development and administration. The Canadian Institutes of Health Research coined and defined it in 2000 as "the exchange, synthesis and ethically sound application of knowledge within a complex system of interactions among researchers and users to accelerate the capture of the benefits of research for patients through improved health, more effective services and products, and a strengthened health care system". The premise of knowledge translation is not novel as it is

synonymous with " the translation of research to practice", "getting research into practice," "knowledge use", "knowledge dissemination", "knowledge transfer and evidence translation", "research uptake", and "evidence uptake and others". (Canadian Institute of health research 2004-2009)

The purpose of knowledge translation is to "address the gap between research knowledge and its application in clinical practice" and to advocate easy research adaptability in real world settings such as in quality improvement, clinical trials and guideline creations and implementation. Knowledge translation also aims to combine research, education, quality improvement, and electronic systems development in order to improve patient care by the real life implementation of evidence-based research (Khoddam et al, 2014). It is postulated that the failure to translate new knowledge into clinical practice is harmful to patients as they lack exposure to new medical advances with patients failing to receive recommended standards of care or receiving unproven treatments.

Certain experimental study design that are known to be very efficient in the research setting may not be replicated in the clinical environment due to applicability barriers and can limit the knowledge translation. **Randomized controlled trials** are the criterion standard for studying the efficacy of interventions designed to increase evidence uptake. However, there are challenges associated with the study of complex interventions and system changes designed to influence practice. Some common problems encountered in randomized controlled trials that take place in ICUs include problems with timing, end point selection, and heterogeneous populations in terms demographics and clinical conditions. **Cluster randomized trials** are based on the concept of randomizing groups of patients who usually have a major shared trait such as their diagnoses, underlying conditions or treatment department. However, it has multiple pitfalls, most notably due to inherent biases (Wears, 2002). Donner et al note that issues regarding informed consent, subsampling and implicated biases, the involvement of matching and stratification, failure to identify the unit of inference and the assessment of intracluster correlation in small studies. Further issues arise due to the possibility that outcomes can be influenced by cluster-specific patient or health care provider characteristics that are unrelated to the intervention under investigation (Donner et al, 2004). **Pre-/post designs** can also be used in studying the effectiveness of knowledge translation interventions. The major issue with their routine application is due to their inferiority when compared to randomized controlled and cluster

randomized trials in terms of their strength of inference and susceptibility to bias. The major erroneous interferences are in terms of secular trends and observer bias.

Knowledge translation may best be viewed as the bridge between continuing medical education, continuing professional development, and quality improvement in the hope of closing the research-to-practice gap (Davis et al., 2003). It is imperative that clinical researchers remember that recommended interventions that improve patient care and outcome are only beneficial when implemented into clinical practice. In this regard, they should anticipate the design necessary for demonstrating an effective strategy for ongoing evidence uptake and implementation (Donaldson, 2004.)

Research in knowledge translation include studies to examine and elucidate the discrepancies between research and clinical application, the militating factors, barriers, implications of this failure and mechanisms to overcome this. Knowledge translation is comprised of resource development and access, bedside evidence-based medicine, clinical quality improvement, and the use of decision aids to improve research knowledge to guideline adherence.

Much of knowledge translation research is presented as quality improvement research initiatives. **Continuos quality improvement** is any initiative that includes the designing, implementing, and monitoring adherence to system-wide changes that facilitate the incorporation of best evidence into patient care **(**Lang, Wyer and Haynes, 2007). In the ICU setting, early mobilization would be an example of the gap that exists between research and clinical application. Although the evidence supports early mobilization in ICU patients to reduce long term complications, the implementation in clinical settings have been limited due to potential barriers. Dubb et al (2016) isolated and identified 28 barriers to the safe implementation of early mobilization in the ICU of which half was patient associated, 18% was due to structural concerns, the same due to ICU culture and 14% was process related. They also noted that the uniqueness of each ICU in terms of patient population, expertise, available technologies and hospital culture in terms of implementing early mobilization protocols. Patient associated barriers include reduced consciousness due to inherent illness, or medication, hemodynamic instabilities or the presence of lines. Structural barriers included staff limitations due to population, level of education and expertise. Individual ICU culture can pose barriers to implementation mainly in the form of obstruction or ignorance of benefits. Process related

barriers can encompass lack of multidisciplinary coordination as well as unclear roles of expectations.

Evidence uptake must surmount many challenges including the identification of potential barriers. The most comprehensive scheme for considering the barriers to evidence uptake classifies barriers into the three domains of knowledge, attitude, and behavior. The main barriers within the realm of knowledge include the volume of new literature relevant to clinical practice, the amount of time required to master this information, and barriers to online access. The category of attitude include skepticism and mistrust of clinical research, and uncertainty or ambiguity towards research applicability to practice. In terms of barriers due to behavior, they may encompass internal and external impediments that favor the current ineffective or unsafe protocol. These include environmental factors such as the cost of the initiation of a new protocol, medico legal concerns and patient expectations that obstruct change, institutional and regulatory issues regarding research implementation.

This can be accomplished by the incorporation of quality improvement methodology into evidence-based initiatives with the implementation of specific components. This implementation should include an adherence improvement strategy of evidence-based management and monitoring adherence through an "evidence uptake" indicator (Bizovi, Wears and Lowe 2002). Evidence uptake indicators refer to any mode by which the impact of evidence-based practice can be assessed using process measures that integrate clinician knowledge, actual performance of the practice, and patient/clinician outcomes. This can include the use of questionnaires, case studies and evaluations (Donaldson et al).

Compliance aids and clinical decision support systems offer crucial opportunities in knowledge translation, especially with the context of early mobilization in ICU. Many therapeutic interventions that have been proven beneficial in the context of early mobilization, involves and integrative and collaborative approach with other specialties. One such approach is the development of clinical checklist and multidisciplinary team discussion among physicians and partnering acute care disciplines (Trzeciak et al., 2006.) Such an intervention provide standardized protocols for patient care including implementation anticipation and planning by involving key stakeholders in the guideline selection and creation process.

The creation of clinically applicable protocols requires the acknowledgement of inherent biases and barriers to implementation and evaluation. Clinically applicable protocols must also

factor in and make attempts to rectify cost-effectiveness, protocol adaptability and evolution, educational opportunities for clinicians and patients in order to provide the greatest benefit.

B. SAFETY AND FEASIBILITY: EXPERT CONCENSUS RECOMMENDATION- Hodgson et al. 2014

In order for early progressive mobilization to be undertaken safely in an ICU setting, with a minimal risk of adverse sequelae, it is essential that patients be carefully assessed prior to any mobilization intervention. This is necessary to mitigate undue concerns about adverse events which may result in mobilization being withheld where it might otherwise be beneficial. Patient assessment is facilitated by the availability of objective criteria to determine the safety and reasonableness in initiating patient mobilization (Devlin and Pohlman, 2014). The development of such a criteria requires the utilization of expert opinion to achieve consensus and the determination of the validity of these criteria by empiric research.

One such example lies in the consensus meeting conducted by a group of 23 multidisciplinary experts including 17 physiotherapists, 5 intensivists and 1 nurse, from Australia, United States , New Zealand and Finland currently involved in early mobilization research. They performed a systematic literature review and the identification of early mobilization in ICU protocols and publicans that outlined safety criteria. The panel members discussed recommendations from the smaller working parties in order to determine where consensus had been reached and where further discussion was required. This was followed by the drafting of a summary of the safety criteria for mobilization and circulated to panel members until the group had reached consensus or agreed that they could not reach consensus with consensus being 100% agreement amongst the group. A critical element that was adopted was that these criteria should be regarded as a guide and should always be used in conjunction with clinical reasoning. It was agreed that the input into the decision to mobilize should lie with all members of the multidisciplinary team (i.e. physiotherapy, medical, nursing staff) with the treating clinician having ultimate responsibility for decision making. The consensus group agreed that a standard traffic-light system of recommendations would be used to assist clinicians in evaluating safety criteria, where red would indicate the need for caution as the risk of an adverse event, or consequences of an adverse event was high, yellow would indicate that

mobilization was possible, but only after further consideration and/or further discussion among the ICU multidisciplinary team, and green would indicate that the patient was safe to be mobilized (see Figure 1). It was agreed that the most conservatively scored parameter must take precedence over all other scores (for example, a single red would be sufficient to caution about the potential for high risk of an adverse event during mobilization, even if all other parameters were green). In considering the decision to mobilize a patient, the criteria should be assessed on the status of the patient at the time of planned mobilization, but changes in condition, and direction of trends, in the preceding hours should also be taken into account. The potential consequences of an adverse event in an individual patient should also be considered as part of the overall clinical reasoning process. The group decided that recommendations would be developed only for active mobilization and that no guidance would be provided with respect to safety criteria for passive mobilization. Active mobilization was defined as any activity where the patient assisted with the activity using their own muscle strength and control: the patient may have required assistance from staff or equipment, but they were actively participating in the exercise. Activities that comprise active mobilization are out-of-bed mobilization (i.e., any activity where the patient sat over the edge of the bed (dangling), stood, walked, marched on the spot or sat out of bed) and in-bed mobilization (i.e., any activity undertaken whilst the patient sat or laid in bed such as rolling, bridging, upper-limb weight training). The level of mobilization should be determined by the patient's strength and endurance, as well as an assessment of the safety criteria. The safety criteria covered by the consensus group were divided into four categories: respiratory considerations, including intubation status, ventilator parameters and the need for adjunctive therapies; cardiovascular considerations, including the presence of devices, cardiac arrhythmias and blood pressure; neurological considerations, including level of consciousness, delirium and intracranial pressure, and other considerations, including lines and surgical or medical conditions. The results of the consensus were presented at the Seventh International Meeting of Physical Medicine and Rehabilitation in Critically Ill held in San Diego on 17 May 2014. At this meeting, there were 94 multidisciplinary clinicians, from both academic and non-academic hospitals, interested in early mobilization in ICU. Each of the criteria was discussed individually as documented and consensus was sought from attendees. Consensus was reached when 100% of attendees agreed to the proposed wording of the document.

The aim of the quality improvement project was to develop consensus recommendations on safety criteria to determine readiness for actively mobilizing adult, mechanically ventilated, ICU patients. Utilizing previous evidence and expert opinion, the consensus group achieved consensus for most of the respiratory, cardiovascular, neurological and other safety considerations. The criteria that have been used to determine when critically ill patients can be mobilized have varied between studies. Criteria for the early mobilization of adult ICU patients were published by Stiller and Phillips in 2004 (Stiller and Philliphs, 2003), primarily based on physiological principles and their clinical experience, and were later endorsed by Gosselink et al. for the European Society of Intensive Care Medicine (Gosselink et al., 2008). However, the level of evidence supporting these recommendations is limited. Compared to previous studies that have outlined safety parameters for the early mobilization of ICU patients, the recommendations outlined in this paper appear to be less conservative and more comprehensive by covering a wider array of clinical scenarios. The recommendations and clinical scenarios were identified by the group in an attempt to maximize mobilization of ICU patients.

The strength of the safety recommendations outlined in this paper is that they are based on evidence from relevant clinical studies and required consensus of panel members, all of whom have clinical expertise and were currently involved in research regarding the early mobilization of ICU patients. Further research is required to validate each of the safety considerations discussed in these recommendations and the recommendations as a whole, both in centers with expertise in ICU mobilization and in centers without. The implementation of these recommendations has the potential to maximize early mobilization while minimizing the risk of adverse safety events, which in turn might improve functional outcomes and translate into reduced ICU and hospital length of stay. Future research required includes systematic evaluation of these recommendations.

As per our knowledge so far, no study has been published that has validated the safety criteria in the clinical setting. The criteria based on the traffic light pattern are clinically more feasible to use and able to capture the majority of ICU patients. The QI project at NYU Langone Heath created a checklist based on the safety criteria and mobility codes based on the traffic light pattern were assigned to each patient. This increased the interdisciplinary communication throughout the day and facilitated common knowledge among the care team in order to allow patient mobilization without any safety concerns.

Summary:

Early mobilization in the ICU is a multidisciplinary team-based intervention that aims to promote early arousal and mobility in the critically ill patients. Prior research pertaining to early mobilization in ICU demonstrated that inter-professional rehabilitation services provided to critically ill patients is cost efficient and safe, reduces ICU acquired weakness, improves functional and behavioral outcomes and enhances quality of life post- hospital discharge (Corcoran et al., 2017).

Researchers have concluded that the standardization of an early mobilization protocol that is applicable and feasible in clinical setting with the incorporation of multidisciplinary teams, creating standardized protocol that are safe and feasible to use and increasing the duration and frequency of rehabilitation therapy services during ICU stays and post discharge may result in positive outcomes in different hospitals (Hesham, Nelliot & Needham 2016).

CHAPTER-2
REVIEW OF LITERATURE

The early mobilization of patients in the ICU has received considerable attention in clinical and scientific literature over the past several years with multiple RCTS, systematic reviews, case series and quality improvement projects studying the effects of mobilization and physical therapy. These studies have identified the factors affected by and involved in mobilization and physical therapy and include patient safety, ambulation capacity, muscle strength, functional outcomes behavioral outcomes, duration of mechanical ventilation, ICU length of stay, hospital length of stay, and mortality.

Admission to the ICU is usually reserved for the most critically ill patients in a hospital and is carried out in order to optimize their care by continuous monitoring and stabilization while allowing for potential for emergency mechanical ventilation. These patients usually have limited mobility due to their inherent condition or because of the use of necessary medical equipment. Other barriers to mobility includes and are not limited to hemodynamic instability, altered sleep patterns, the presence of vascular attachments and sedation (Adler 2012). This lack of mobility can cause impaired exercise capacity and persistent weakness, suboptimal quality of life, enduring neuropsychological impairments and high costs of health care utilization even after discharge (Doiron, Hoffman and Beller, 2018).

ICU acquired weakness (ICUAW) occurs in patients admitted to the ICU and it may not be related to the acute illness that the patient had been admitted with. It is has been associated with the extended mechanical ventilation, sepsis, systematic inflammatory responses multi-organ failure and hyperglycemia (Desai 2011). ICUAW has also been associated with a higher incidence of hospital mortality (Ali 2008), higher healthcare-related costs, with the persistence of weakness being associated with higher mortality one year after ICU admission (Hermans 2014a) .It is postulated that ICUAW is due to a heterogeneous muscle pathophysiology comprised of muscle atrophy and decreased contractile capacity (Dos Santos 2016). Parry 2015, Puthuchery, 2013 and Stevens, 2007 found that ICU patients can sustain loss of muscle mass within the first week of admission to the ICU with the incidence of ICUAW as much as 46%. In a two-year follow-up, the presence of ICUAW was associated with impairments in physical function and

six-minute walk distance (Crapo 2002), as well as lower physical function subscale scores of the Short Form-36 survey (Ware 1992),) at 6, 12 and 24 months follow-up (Fan 2014).

Post-intensive care syndrome describes any new or residual problems seen in survivors of critical illness after discharge from ICU. These problems include cognitive impairments that include altered memory, attention and executive functioning; psychological difficulties like depression, anxiety and post-traumatic stress disorder as well as physical impairments in pulmonary, neuromuscular and physical function. These problems can affect the performance of activities of daily living (ADLs) and decreased quality of life in these patients (Needham 2012). Some researchers have hypothesized that ICU-based interventions may reduce short and long term physical and neuropsychological impairments in ICU patients. They further stress the importance for studying this vulnerable and potentially problematic patient population (Doiron, Hoffman and Beller, 2018).

Early mobilization of mechanically ventilated patients is listed in ICU literature as one of the interventions to have both short- and long-term benefits. A controlled trial involving 280 mechanically ventilated patients incorporated a structured protocol including a dedicated mobility team (critical care nurse, nursing assistant and physical therapist) involving four levels of activities ranging from passive range of motion in the bed to active transfer to chair. This regimen was implemented 7 days a week, starting within 48 hours of mechanical ventilation. After adjusting for BMI, Acute Physiology and Chronic Health Evaluation II, and vasopressors, subjects in the intervention group who received at least 1 physical therapy session more than did subjects receiving usual care (80% vs. 47%, $p < .001$), were out of bed much earlier (5.0 vs. 11.3 days, $p < .001$) and had a shorter ICU length of stay (5.5 days vs. 6.9 days, p= 002) and hospital stay (11.2 days vs. 14.5 days, p= .006).-No harmful events were documented during mobility session and there was no cost difference between the two arms including the mobility team cost (Morris et al., 2008.) A follow-up study by the same authors reported that a lack of early mobility was associated with higher odds of death or readmission within 1 year of hospitalization (odds ratio = 1.77, 95% CI = [1.04, 3.01], p= .36) (Morris et al., 2011). Similar studies are listed in the table below.

Table -1

Literature review summary

Title	**Authors**	**Study Population**	**Study Design**	**Interventions**	**Outcomes**
Early Mobilization Reduces Duration of Mechanical Ventilation and Intensive Care Unit Stay in Patients With Acute Respiratory Failure	Lai et al.,2017	Medical ICU with 19 beds in Taiwan	Retrospective observational study.	PT twice daily for 30 minutes each, 5 days/week 4 levels in the protocol 1 – PROM in bed 2 – AROM in bed (PT following simple commands) 3 – AROM and light resistance sitting edge of bed 4 – Transferring to and performing exercises while sitting in bedside chair	•Reduction in ventilation from 7.5 days to 4.7 days •Reduction in ICU stays from 9.9 days to 6.9 days •Reduction in hospital stays from 24 days to 19.2 days •No adverse effects from the mobilization

ICU Early Mobilization: From Recommendation to Implementation at Three Medical Centers.	Engel et al.,2013	Three early mobilization ICU programs were studied – Wake Forest University Medical Center, Johns Hopkins Hospital, and UCSF Medical Center	Three ICU early mobilization quality improvement projects are summarized utilizing the Institute for Healthcare Improvement framework of Plan-Do-Study-Act.	A 4 stage program was followed: 1 – PROM in bed (If RASS < -2) 2 – Bed-level PT treatment 3 – Edge of bed activities, including full chair position for orthostatic training (once patient is engaged and participating and vital signs are stable) 4 – Standing, bedside chair, and gait training (once patient demonstrates trunk control, vital signs stay stable, and patient remains alert	•Reduction in ICU stays from 6.9 to 5.5 days •Reduction in hospital stays from 14.5 to 11.2 days •Hospital savings of over half a million dollars in direct patient care costs (at Wake Forest Medical Center) •No adverse effects from the mobilization!

				and oriented during treatment)	
Early Rehabilitation in the Medical and Surgical Intensive Care Units for Patients With and Without Mechanical Ventilation: An Interprofessional Performance Improvement Project	Cochran et al.,2017	MICU and SICU at a Level 2 Trauma Hospital (NYU Langone Medical Center)	Performance improvement project (PIP). Historical control group from pre PIP	Patients were seen within 3 days of admission. Patients received PT 1-2 times per day, OT 1 time per day and SLP 1 time per day	•Reduction in ICU stays from 4.6 days to 3.7 days •Reduction in hospital stays from 6 days to 3.4 days • More patients discharged home with services (40.5% rather than 18.2%) •Projected savings of $2.2 million per year. •No adverse effects from the mobilization
Early intensive care unit mobility therapy in the	Morris et al., 2008	MICU patients with acute	-Prospective study.	4 levels in the protocol	•Protocol patient received at

treatment of acute respiratory failure		respiratory failure requiring mechanical ventilation Protocol n = 165; Usual Care n= 165.	- Randomization using block allocation	1 – PROM in bed by nurse assistant 2 – AAROM-AROM in bed by PT (PT following simple commands) 3 – AROM and light resistance sitting edge of bed 4 – Transferring out of bed to chair Usual care- received PROM by bedside nurse and unconscious patients were turned every 2 hours.	least 1 physical therapy session more than did Usual Care (80% vs. 47%, $p <$ .001) •Protocol patients were out of bed earlier (5 vs. 1.3 days, $p <$ .001) , had therapy initiated more frequently in the intensive care unit (91% vs. 13%, $p <$ .001), and had similar low complication rates compared with Usual Care

					•Protocol patients, ICU length of stay was 5.5 vs. 6.9 days for Usual Care (p = .025); hospital length of stay for Protocol patients was 11.2 vs. 14.5 days for Usual Care (p = .006 •No harmful events during mobility session • No cost difference (survivors vs. non-survivors) between the two arms, including Mobility Team costs.

The Cochrane Review summarized the effects of early intervention defined as mobilization or active exercise, for the critically ill patients in the intensive care unit versus the usual care group. Four RCTs (Kayambu 2015; Morris 2016; Schweickert 2009, Patman 2001) involving total of 454 patients were included in the review showing mixed results for the effect of early mobilization or active exercise on the primary outcome of physical function or performance. Schweickert 2009 concluded the 59% of intervention group returned to independent functional status at hospital discharge compared to 35% of patients in the control group. Patients in the intervention group also had a greater walking distance at hospital discharge with a median of 33.4 meters and were faster in achieving functional milestones from time of intubation, marching in place, transferring to a chair and walking. They also noted the there was no effect on physical function outcome including the number of independent ADLs achieved at ICU discharge, hospital discharge or the Barthel Index Score for independence at hospital discharge. Kayambu 2015, reported no difference between the control and intervention group in terms of the Acute Care Index of Function [ACIF] or the Physical Function ICU Test [PFIT] at discharge. Morris 2016 demonstrated no difference between groups during evaluation of the Short Physical Performance Battery [SPPB] score as a measure of physical performance at ICU and later hospital discharge. All four studies measured adverse events with three studies reporting a low incidence of adverse events not due to mobilization in the intervention groups (Morris 2016; Patman 2001; Schweickert 2009), and one study (Kayambu 2015), reporting no adverse events. This finding supports the safety and feasibility of early mobilization for mechanically ventilated, critically ill patients in the ICU. This conclusion is not conclusive as the sample size was small in each study with less than 200 patients in each study and hence, requires study in larger samples to increase the study's power.

The length of stay was also postulated to be affected by early mobilization with Schweickert 2009 demonstrating shorter length of ICU stay in the intervention group with a median of 5.9 days compared with 7.9 days in the control group. Morris 2016, also did not show any statistical difference in the length of ICU stay between the intervention and control groups similar times in ICU for the two groups. In contrast, Patman, 2001 and Kayambu 2015 reported that there was an increased length of ICU stay in the intervention group with a median of 42.7 versus 36.7 days and 12 versus 8.5 days, respectively.

Schweickert 2009 and Morris 2016 investigated the incidence of delirium in the ICU with Schweickert 2009 examining its incidence during the length of hospital stay as well. Schweickert 2009 found that those in the intervention group spent a lower number of days with delirium while in ICU as well as the entire hospital stay with a median of 2 compared to 4 days. However, Morris 2016 found no difference between groups in the incidence of delirium.

Experts currently recommend more research with larger sample sizes to evaluate the optimal timing and dosage of rehabilitation in the ICU. Based on the above literature review following gap has been identified in the early mobility research.

GAP IN THE LITERATURE:

A. CLINICAL APPLICABILIY: Despite evidence supporting feasibility, safety, and effectiveness of early mobilization to improve physical function, early mobilization is not widely utilized worldwide (Hesham, Nelliot & Needham 2016). In a study conducted in the United States among 770 subjects from 33 ICUs within the U.S. ARDS network, it was reported that sitting at the edge of the bed or greater physical activity occurred in only 16% of mechanically ventilated patients. Only 23 sessions (4%) involved patients walking while being on mechanical ventilation (Jolley et al., 2015). Similarly, a study conducted in Germany reported that among 775 mechanically ventilated subjects in 116 ICUs, 24% were sitting at the edge of the bed, out of which only 8 % of patients had endotracheal tube, and 1 out of 401 intubated patients (.2 %) stood, marched or walked (Nydhal et al., 2014). A point prevalence study from Australia and New Zealand reported that out of 224 mechanically ventilated patients in 38 ICUs, none of the subjects sat out of the bed or ambulated (Berney et al., 2013).

Many ICUs struggle to change the culture and develop protocols that are needed to provide ICU patients with early physical activity (Engel et al., 2013). One of the common barrier that has been discussed in the literature is limited resources and inadequate staffing for nursing and rehabilitation professionals. The ideal patient-to-staff ratio to allow for early mobilization remains unclear. In United States, 34% of ICUs report having a dedicated physical/occupational therapists for ICU patients. (Bakhru et al., 2015). Therapists are infrequently available with a median staffing of 6.3 and interquartile range of 4-10 physical therapist per 101 ICU beds (Malone et al., 2015). Bailey et al. recommended that mobilizing patients in the ICU should be a

team approach, and team members need to learn to work interdependently to distribute the workload. The use of technicians or assistants, when available, is recommended, and cross-training in job-roles, as allowed by practice acts, should be implemented (Bailey et al., 2007).

However, even with adequate staffing, the literature reports that mechanically ventilated patients are not as frequently mobilized. In a prospective study of 192 mechanically ventilated subjects in Australia and New Zealand where physical therapists also deliver respiratory therapy and there is median of 1 physical therapist for every 9 ICU beds, 45 % of the rehabilitation sessions were conducted in bed and 64% of the subjects did not receive early mobilization (Hodgson et al., 2015). Another Australian study reported that out of 106 ICU subjects, 47% of the patients were not mobilized because of perceived barriers like femoral lines, lack or timing of procedures and sedation practices (Leditschke et al., 2012). There are inherent complications to mobilizing critically ill patients that appear straightforward but are not well established. These apparent complications include, but are not limited to: tenuous hemodynamic status, severe weakness, multiple central catheters and life supporting monitors, artificial airways, and operational factors, such as variable rehabilitation work practices (Adler J. and Malone D., 2012).

To overcome these barriers and to successfully close this gap between research and clinical practice, evidence recommends the use of structured multistep quality improvement efforts. Various quality improvement models have been suggested. One such models that has been widely used in the literature is “Translating Research into practice model” also known as TRIP model (Pronovost, Berenholtz, & Needham, 2008). The TRIP model engages the multidisciplinary team to evaluate the research-to-practice gap within the larger health care setting. The model consists of 4 steps (Fig. 3): (1) summarizing the evidence to understand the highest-yield intervention(s) that will address the health-care problem (e.g., early mobility/rehabilitation to address physical impairments in critically ill patients); (2) identifying local barriers to the implementation of these interventions; (3) creating metrics or performance measures to evaluate progress with overcoming barriers and implementing the intervention; and (4) ensuring that all patients receive the intervention by using the “4 Es” framework (Engage, Educate, Execute & Evaluate). It involves an iterative process of engaging stakeholders and then educating them before moving onward to executing the intervention and continuously evaluating it using the progress measures from Step 1 (Needham and Korupolu, 2010).

Needham et al 2010 published a quality improvement project study done at Johns Hopkins Medical ICU that incorporated TRIP model to initiate early mobilization in the ICU for patients requiring ≥ 4 days of mechanical ventilation without any preexisting cognitive or neuromuscular problems. Four month of study data were compared with the 3-month period immediately preceding the quality improvement project. The study reported 30% decrease in the average medical ICU length of stay *(P* = .02), with a 20% increase in the number of medical ICU admissions. There was significant decrease in the use of sedative medications, with a significant increase in the proportion of days in which patients were alert (66% vs. 29%, p <.001) and not delirious (53% vs. 21%, p = .003). In addition, there was a significant decrease in the proportion of ICU days in which eligible patients failed to receive rehabilitation therapy (7% vs. 41%, p = .004). Among 294 physical therapy and occupational therapy treatments given, there were only 4 (1.4%) potential safety events that were minor in nature (Needham et al., 2010). Following the success of this quality improvement project, Johns Hopkins Hospital funded a standardized early rehabilitation program. A new sedation protocol was created with standardized delirium assessment from nurses as a routine practice and a dedicated full-time rehabilitation staff was assigned to the medical ICU (Needham and Korupolu, 2010; Hager 2013). A follow-up study to assess the sustainability of the program reported that even after 5 years of completion of the project, subjects in the post-quality improvement had a shorter time to initiation of physical therapy (adjusted hazard ratio = 8.4, 95% Cl 5.0-14.1, p < .001). There was a significant increase in the proportion of subjects ever receiving physical therapy (68% vs. 16%, p < .001) and achieving a higher daily activity level during physical therapy treatments (e.g., sitting at the edge of the bed, standing, or ambulating: 41% vs. 4%, p < .001) (Dinglas et al., 2014). Needham et al concluded that this quality improvement project serves as an important example of the steps needed to bridge the gap between research and practice, resulting in improved patient outcomes. Components needed for success of a quality improvement project included a supportive culture, the presence of a multidisciplinary team with good communication, a leader who could advocate for rehabilitation, and adequate resources (personnel, equipment, and funding) (Eakin et al., 2015).

Hence, structured quality improvement projects are crucial for closing the large gap between these research findings and routine clinical practice in order to expedite the post-ICU recovery of mechanically ventilated patients. The involvement of a multidisciplinary team with

a recognized leader, can be effective in changing ICU culture and practice to effectively deliver early mobilization and rehabilitation.

B. SAFETY AND FEASIBILITY:

Despite of all the benefits, there are inherent complications to mobilizing critically ill patients that although they appear obvious but are not well established. Some of the contributing factors that limit mobilization in ICU include, but are not limited to: tenuous hemodynamic status, severe weakness, life-sustaining catheters and monitors, sedative medication used to calm agitation or reduce energy expenditure, impaired levels of alertness from medications, sleep disturbances, electrolyte imbalances, artificial airways and operational factors such as variable rehabilitation work practices (Adler J. and Malone D., 2012). All of these act as significant barriers to early mobilization due to their adverse effects especially being potential sources of harm for already vulnerable patients. This includes catheters and supportive equipment attached to patients that can become dislodged and cause injury during exercises. Insertion and reinsertion of catheters can increase infection risk and cause unwanted stress and pain for patients and families. Critically ill patients with physiological derangements can have adverse hemodynamic responses to activity. Patients with limited aerobic capacity may respond to exertional stress with exaggerated heart rate and blood pressure responses or conversely may not have enough physiologic reserve to meet even the seemingly simple task of sitting on the edge of the bed.

The feasibility of early mobilization for mechanically ventilated patients is well recognized in the literature. A study assessed the safety and feasibility of progressive mobilization for 103 mechanically ventilated patients, and patients were progressively mobilized from supine to sitting at the edge of the bed, sitting in chair and ambulating. 1,449mobility sessions were performed with 41% sessions being performed with intubated patients, and a total of 249 sessions during which intubated patients ambulated, of which the occurrence of potential safety events were less than 1% (Bailey et al., 2007).

Despite the potential concerns about mobilizing ICU patients, especially mechanically ventilated patients, many studies-have demonstrated the safety and feasibility, with very low rates of potential safety events. A German study with 775 mechanically ventilated patients reported that frequency of the adverse events were not significantly higher between out of bed versus in bed activities (Nyadhl et al., 2014). Another follow-up study from the Johns Hopkins

Medical ICU evaluated the safety of physical therapy (PT) interventions for 1,110 consecutive medical ICU admissions (60% of which received mechanical ventilation) over a period of 53 months following completion of the quality improvement project. Of 5,267 physical therapy sessions, only 34 (0.6%) had potential safety events. Studies reported that most frequent adverse reactions were transient physiological changes (e.g., changes in mean arterial pressure and oxygen saturation) that improved with rest. Less than 8 per 10,000 physical therapy sessions had an event that required additional therapy, with no event requiring increased length of stay (Sricharoenchai et al., 2014). In an attempt to improve outcomes for the survivors of critical illness, there have been efforts to interrupt sedation (Kress 2000), to allow patients to choose their own level of sedation (Chlan 2010), and to cease sedation (Strøm 2011) for mechanically ventilated patients. As patients become increasingly responsive, they are better able to participate in active exercise and to mobilize outside of bed, even when mechanically ventilated. Bailey et al demonstrated infrequent adverse events in participants who mobilized while mechanically ventilated and concluded that early mobility of patients in the ICU is feasible and safe. To assist in the assessment of patient readiness and appropriateness to commence early mobility in the ICU, a panel of 23 multidisciplinary experts was convened in 2013 to create a criteria for the safe mobilization of mechanically ventilated patients. This study conducted by Hodgson et al., used traffic light patterns (red, yellow, green) and to provide relevant safety guidelines categorized by each body system (e.g. respiratory, cardiovascular, neurological systems and other). There was a consensus that endotracheal intubation should not be a contraindication to perform active in bed or out of bed activities (Hodgson et al., 2014). This further increases the potential sample for research and have more widespread consequences on the most severely ill ICU patients. No study so far has described operationalizing and implementing their Red-Yellow-Green system as a part of protocol formation and clinical decision making.

Literature also documents wide variety of protocol use and varied outcome measure use in different studies. If the protocol is too complicated it is harder for the clinical staff to follow through and there is increase in non-compliance leading to difficulty with the cultural change. The protocol should be feasible, streamlined, simplified and easily adaptable allowing continuous care in change of culture. A hospital wide cultural change is essential to unleash the full potential of early mobilization and having a protocol that is simple and feasible enables to achieve such goals safely without clinical complications.

C. DOSAGE OF INTERVENTION;

Experts reported that one of the key reason associated with the success of decreasing length of stay and improving patient's outcome in the ICU was the early start of rehabilitation interventions. The time to commencement of the intervention was variable across studies. In Kayambu 2015 the intervention group commenced therapy within 48 hours of admission to ICU and in Morris 2016 a median of 1 day after admission to ICU. In Patman 2001 the intervention group commenced therapy during the first 24 hours of intubation and in Schweickert 2009 at a median of 1.5 days, interquartile range (IQR) (1.0 to 2.1) after intubation had commenced. There was no agreement between the studies on what is 'early' intervention, and 'late', however the studies all began exercise in the intervention group at a median of one day after admission to ICU. The comparator of 'late' ranged from a median of two days to seven days. A controlled trial conducted in 2 university hospitals that randomized 104 mechanically ventilated patients in the usual care group or early physical therapy/occupational therapy group. Subjects who received early physical/occupational therapy after mechanical ventilation had a much greater daily median duration of interventions (19 mins. /day vs. 0 mins. /day, $p < .001$) and were more likely to return to independent physical functioning at hospital discharge (59% vs. 35%, $p = .02$), have shorter duration of mechanical ventilation (3.4 days vs. 6.1 days, $p = .02$), and have fewer days with delirium in the ICU (2 days vs. 4 days, $p = .03$), compared to the usual care group (Schweickert et al., 2009). Contrary to the above study, a single-center randomized control trial was performed with 150 subjects who were in the ICU for ≥ 5 days and randomly assigned to usual care (7 days/ week of usual physical therapy) or an intensive exercise regimen in the ICU, ward and outpatient clinic. This trial reported no significant difference in patient outcome over 12-month follow up (Denehy et al., 2013). Another post ICU follow-up multicenter randomized control trial included 120 mechanically ventilated patients who received up to 28 days of physical therapy in the ICU followed by 7 days/ week (intervention group, with average duration per session of 39 minutes) versus 3 days/ week (control group with average duration per session 22 mins) follow-up intervention in the ward after ICU discharge. The physical therapy intervention started at a median of 8 days after intubation (6-11 interquartile range). This study showed no significant difference in physical function at 1-, 3- and 6- month follow-up (Moss et al., 2015). In contrast to the positive trials, the limitation of these negative trials was that interventions started relatively late after initiation of mechanical ventilation and had control group that received much higher

intensity of the physical therapy compared to usual practice (Berney et al., 2013; Jolley et al., 2015). Based on current evidence, initiation of rehabilitation early after ICU admission and intubation is deemed safe and feasible to decrease the length of stay and improve patient outcomes compared to the usual practice in most ICUs with conservative approach leading to little or no rehabilitation, especially if patients are mechanically ventilated.

Frequency and duration of the delivery of the intervention also varied across studies. Kayambu 2015 reported that the intervention was delivered for 30 minutes, once or twice per day until the participant was discharged from the ICU and that participants remained in the study for a mean of 11.4 days. In Morris 2016, the intervention sessions were given three times per day, with a goal of achievement of repetitions, rather than a specified time for each session. The intervention was continued until discharge from hospital. In the study by Patman 2001, the intervention was delivered as required during the intubated phase, which lasted 24 hours (participants were withdrawn from the study if mechanical ventilation was required for more than 24 hours). No further details regarding the frequency and duration of the intervention were provided. Schweickert 2009 reported that the intervention was delivered every morning until participants returned to their previous level of function or were discharged. Information on the discharge location (ICU or hospital) was not stated. Study authors reported that the median duration of therapy for the intervention group during mechanical ventilation was 0.32 hours per day, IQR (0.17 to 0.48) and a median of 0.21 hours per day IQR (0.08 to 0.33) while not being ventilated.

The Cochrane review published in 2018 reported that here were differences in the content of the interventions, the providers, the timing, dosage, tailoring, and exercise progression across all studies. No two studies tested the same intervention. Additional evidence and further investigation is required to examine the type, frequency, intensity and dosage of early mobilization required in this population is needed to inform clinical decision-making about the effectiveness of early mobilization and active exercise in the critically ill population. Additional studies are needed to report costs or cost-savings of providing the intervention.

D. **IDENTIFYING PREDICTORS OF LENGTH OF STAY:**

As the number of critical care beds is dramatically increasing, the literature reports the significance of decrease in ICU length of stay to lower costs and financial burdens on patients,

families and society. Interventions involving palliative care, ethics consultations, and other methods to increase communication between healthcare personnel, patients, and patients' families were reported to be helpful in decreasing length of stay in the ICU. Factors that affect length of stay and outcomes of care in the ICU have been studied extensively; however, conclusions reached have not been reviewed to determine whether they reveal an organizational pattern (Gruenberg et al., 2006). Further studies are recommended in the literature to identify the predictors of length of stay, which in turn will be helpful to target and intervene on specific risk factors in order to decrease ICU and hospital length of stay

E. FOLLOW-UP CARE POST-ICU DISCHARGE:

Follow-up care post-ICU discharge has been documented in limited studies. Upon discharge from the ICU, patients are usually transferred to inpatient units to complete care until medically stable for hospital discharge. The frequency of structured therapy in standard medical units can differ from ICUs, with less frequent or no mobilization. Patient functional progress made in the ICU setting may diminish after patient is transferred to a standard medical unit. Little investigation has been done demonstrating the benefit of mobilization in a post ICU setting

Experts recommend more research with larger sample sizes to evaluate the optimal timing and dosage of rehabilitation in the ICU. Standardizing the early mobilization protocol, incorporating multidisciplinary teams, and increasing the duration and frequency of rehabilitation therapy services during ICU stays and post discharge may result in positive outcomes in different hospitals (Hesham, Nelliot & Needham 2016)

Chapter III
METHODS

I. Objective of QI project:

Historically, early mobilization in the ICU has not always been a common practice at NYU Langone Hospital- Brooklyn. To address the immobility related problems, our hospital system initiated a quality improvement project to enhance patient experiences and overall outcomes throughout the medical center. This project implemented early mobilization in the Medical and Surgical ICUs by operationalizing the Red-Yellow-Green system described in Hodgson et al., 2014, The Translating Research Into Practice (TRIP) model and a multidisciplinary team approach was used to guide this evidence-based approach to research. The goal of this study was to report this program's development and the outcomes monitored for quality purposes along with an assessment of cost, safety, and feasibility by retrospectively reviewing the charts of the patient admitted to medical and surgical ICU from January 2018 to June 2018. In addition, we compare the early mobilization period in the ICUs with a season-matched historical comparison period as a way of putting the benefit of these guidelines in perspective.

The objectives of the quality improvement project at NYU Langone health- Brooklyn hospital was:

- To create a protocol to initiate early mobilization and implement Hodgson red, yellow, green expert consensus recommendation in the medical and surgical ICU at NYU Langone health-Brooklyn hospital
- Assess the safety and feasibility of the use of a protocol to enhance overall patient experience without having adverse events or increase in the cost of treatment by initiating "early mobilization" in the ICU

II. Methods

Development of the program

To overcome the barriers to early mobilization in the MICU and SICU, the TRIP model similar to that used by Needham et al. at Johns Hopkins Medical Center was utilized. A multidisciplinary quality improvement project targeting early rehabilitation was planned over a 3-month period and then executed over 6 months. The planning process involved creating a quality improvement (QI) team that included stakeholders, such as key executives, front line staff and quality "champions."

This QI team critically reviewed the literature and evaluated the resources available and additional resources needed to execute the project. SMART (specific, measurable, achievable, relevant and timely) goals were identified for the project champions from each discipline, including nursing, physical therapy (PT), and respiratory therapy. These champions were funded to attend the Early Mobility Conference held at Johns Hopkins University. A work-flow analysis was conducted to assess how the initiative would overcome barriers and affect the work environment.

A ramp-up phase of 19 days (December 11 – December 31, 2017) was initiated to identify barriers not recognized during the planning phase. The project was implemented for 6 months from January 1 – June 30, 2018. Weekly meetings were conducted with QI team members to ensure that protocol or process change was effectively incorporated into practice through tools such as checklists (Appendix Figure 1), to create standard work, and to verify the validity of documentation and data collection. Physical therapists, respiratory therapists and registered nurses (RNs) documented notes after each mobility session in the Epic electronic medical record system. The protocol was re-evaluated periodically and incorporated clinicians' feedback.

Setting

This initiative was carried out in the rehabilitation department at an urban community teaching hospital with 28 beds. The Surgical ICU (SICU) had 17 beds, and the Medical ICU (MICU) had 11 beds.

Patient Eligibility Criteria

To be eligible for the early mobilization program, patients had to meet these inclusion criteria: age 18 years and older, received mobilization orders from medical doctors to initiate early mobilization, were assessed as Green or Yellow per the Hodgson Red-Yellow-Green mobilization criteria, and received at least one mobilization session during the ICU stay.

Patients were excluded if pregnant and for the following hemodynamic factors: those with grave prognosis or transferring to comfort care; requiring significant amounts of vasopressors for hemodynamic stability (MAP >60); mechanically ventilated patients who require high PEEP > 7 / FiO2 >0.6 or have acutely worsening respiratory failure; myocardial ischemia; femoral lines necessitating limited mobilization; and those on active cooling protocols. Patients were excluded for the following neurological of neurosurgical factors: unresponsive to verbal stimuli; requiring paralytic agent; with a lumbar drain or EVD that cannot be clamped; and ICP >20. Patients were excluded for the following trauma or surgical factors: unstable spinal or extremity fractures; open abdominal wound without fascia closure.

Program Description

The Intensivist ensured consistent implementation of the ICU ABCDEF standard-of-care bundle to set the stage for early mobilization and was focused on decreasing the sedative medication dosage. Every morning, the physician, RN, physical therapist, and respiratory therapist discussed mobilization planning in each ICU. Candidates for mobilization were identified using a standardized checklist. Mobilization codes (Red, Yellow, and Green) were assigned, and activity labels with the color of mobilization were placed on the bedside.

Patients coded green and yellow were assessed by the physical therapist and mobilized once per day to the highest level of mobility tolerated in coordination with the respiratory therapist and nursing staff. The intervention used during the study followed the standard of care provided in the ICU.

Nurse-led activities included daily awakening, oral care, securing lines, drains and tubes, low or high Fowlers positioning, analgesic premedication for activity, hold IV drips as possible, complete toileting, hygiene, and footwear application.

Respiratory-led activities involved pulmonary hygiene, bronchodilators, secure breathing tube, management of ventilator settings to reduce the work of breathing in preparation for mobilization, and management of transition to and from a portable ventilator.

Early mobilization with all hands on deck was led by the physical therapist with concurrent assistance from RN, respiratory therapist, and physician. Activities included safely returning patient to bed and updating activity board. During each session functional status, delirium and sedation were assessed by the mobility team and recorded in the electronic medical system.

The mobilization session was followed by an interdisciplinary debriefing analysis, sharing of lessons learned, and completion of clinical documentation.

Intervention

Therapy was delivered by a physical therapist and coordinated with a respiratory therapist and RN along with daily interruption of sedation. Once patient interaction was achieved, sessions began with active assisted (manual assistance) and active (independent) range of motion exercises in the supine position. If these exercises were tolerated, treatment was advanced to bed mobility activities, including transferring to upright sitting. Sitting balance activities were followed by participation in activities of daily living (ADL) and exercises that encouraged increased independence with functional tasks. The session progressed to transfer training (i.e., repetition of sit-to-stand transfers from bed to chair or bed to commode), and finally pre-gait exercises and walking. Progression of activities was dependent on patient tolerance and stability. Therapy intervention continued on a daily basis throughout the patient's hospital stay until he or she returned to a previous level of function or was discharged. (See Figure 1 below)

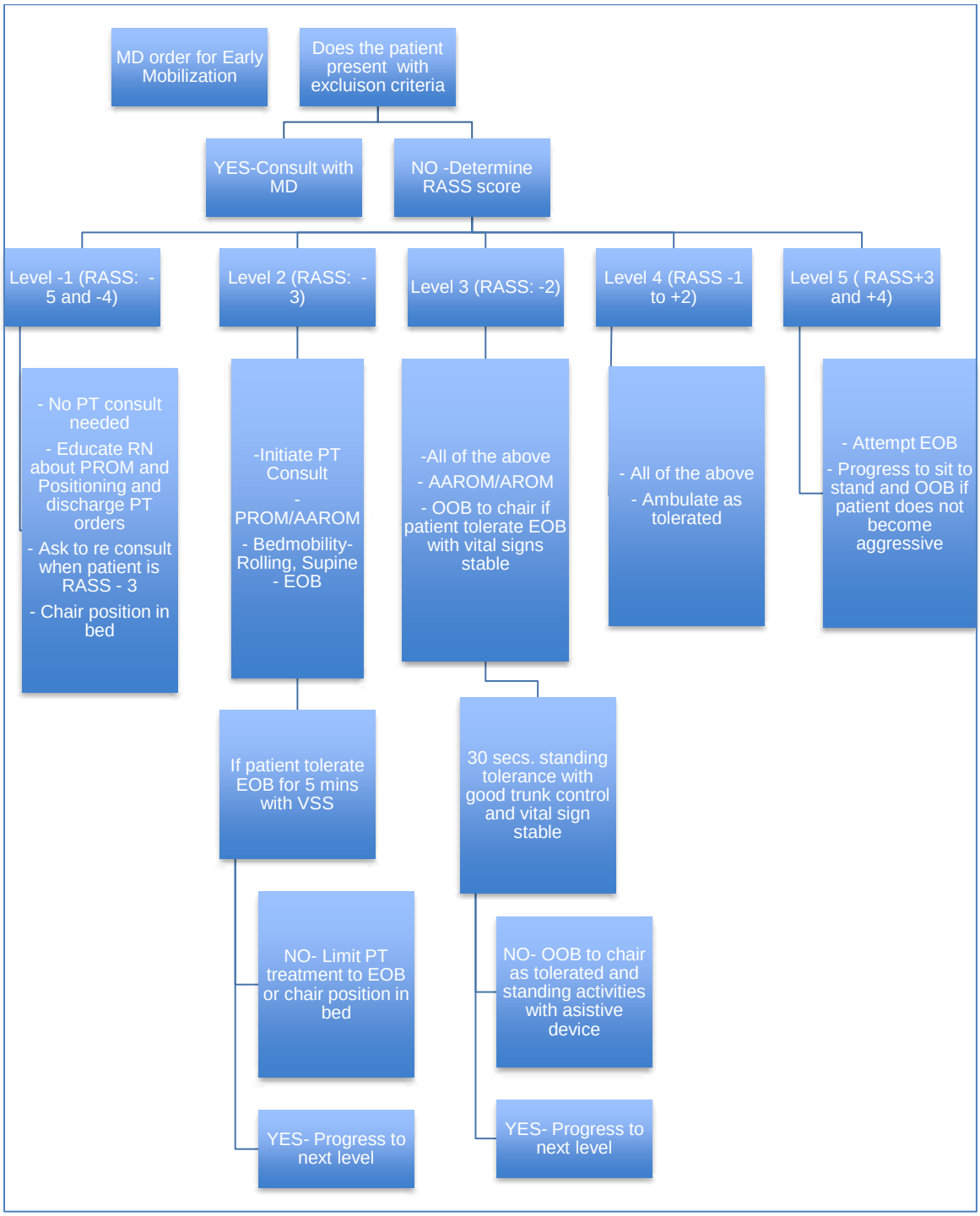

Figure 1. Physical Therapy intervention and progression of therapy. Adapted from Engel et al. 2013 Critical Care Medicine: September 2013 - Volume 41 - Issue 9 - p S69-S80.

Clinical and Quality Outcome Measures

Every time the patient was mobilized in the ICU, the following assessments were done: IMS (ICU Mobility Scale), FSS-ICU (Functional Status Score – ICU), AMPAC mobility scale, RASS (Richmond Agitation and Sedation Score), and CAM-ICU to assess delirium.

ICU length of stay, hospital length of stay, demographic variables (Age, Gender, primary diagnosis), and discharge disposition were recorded along with demographic and diagnostic characteristics.

Rehabilitation department personnel and therapists monitored patients for adverse events at each visit. Any adverse event whether thought to be related or unrelated to the protocol was reported to and compiled by the Rehabilitation department head Jeffery Fine, MD on an ongoing basis, who also verified data accuracy monthly.

Selection of the historical comparison data

Patients from a historical comparison period of January to June 2017 were compared with the early mobilization period of January to June 2018 to account for seasonal changes

III. Study Procedures

A. Research Design:

A retrospective chart review was performed for all the patients that received at least one mobilization session during the quality improvement project from January 1st 2018 to June 30th, 2018 in the medical and surgical ICU at NYU Langone hospital- Brooklyn.

The study's design was a retrospective design using a within group pre-test posttest analyses for the primary functional and behavioral outcomes (IMS, FSS, AMPAC, RASS and CAM-ICU) and between groups design for secondary outcomes where all ICU patients from a historical comparison period of January to June 2017 were compared with all ICU patients during the early mobilization period of January to June 2018 as to ICU and hospital lengths of stay and discharge recommendation to account for seasonal variations in ICU admission. The study design was exploratory as it aimed to explore the relation between initiation of the early mobilization in the ICU and its effects on post-hospital discharge destination.

B. Variables

(a) Independent Variable: Early mobilization treatment provided as per NYU Langone hospital-Brooklyn early mobilization protocol from ICU admission to ICU discharge

(b) Primary Dependent Variables:

- Parametric data collected at 2 time points (ICU admission and ICU discharge) were compared with Paired sample *t*-test)
    - ICU mobility scale
    - Functional status score
    - AMPAC

- Non – parametric data (ordinal) collected at 2 time points (ICU admission and ICU discharge) were compared using Wilcoxon signed rank test
  - Measure change in RASS (Richmond agitation and sedation score). Crosstabulation and chi squared test will be utilized to calculate proportion (%) of patients with 0 (alert and calm) RASS score upon discharge.

- Nominal/ categorical data - The McNemar test was used to determine whether the proportion of participants with negative score for initial CAM-ICU assessment is different from the proportion of participants with negative score for final CAM-ICU assessment. Crosstabulation and chi squared test was utilized to calculate proportion (%) of patients with negative CAM-ICU score upon discharge.

(c) Secondary Dependent Variables: Data assessed at 1 time point were compared with the historical data from the same time frame in the previous year for ICU LOS and post hospital discharge destination

- ICU LOS- Independent *t*- test was utilized to compare ICU LOS between early mobility period and historical comparison period
- Post-hospital discharge destination- chi squared test was utilized to calculate proportion (%) of patients discharged to community.

(d) Exploratory dependent variable:

- Participants (N)
- Demographic variables (Age, Gender)
- Primary diagnosis
- Hospital Length of stay
- Post hospital discharge destination categories

Table 2

Validity and Reliability of Outcome Measures

Outcome measure	**ICF domain**	**Description**	**Validity**	**Reliability**	**Other**
ICU Mobility Scale	Activity	Best level of function achieved in ICU using an 11- point ordinal scale		High interrater reliability between junior and senior physical therapists (kappa= 0.83, 95% CI = 0.76-0.90) (Hodgson et al, 2014)	MID for IMS: 0.89-1.40 (Tipping et al., 2018)

Functional Status score (FSS- ICU)	Activity, participation	Patient's function measured by 8 point ordinal scale	Good convergent and discriminant validity, with significant and positive correlations (r = 0.30 to 0.95) between FSS-ICU and other physical function measures (Huang et al., 2016	High interrater reliability (ICC= 0.992, 95% CI) (Ragavan et al. 2016)	MID= 2.0-5.0 (Huang et al., 2016)
AM-PAC basic mobility scale	Activity	Assess activity limitation. Basic mobility domain that assesses ambulation and transfer skills was used.	Excellent criterion validity with *r* > 0.6 (Latham et al., 2008)	Movement and physical domain (Andres et al., 2003) Excellent Test- retest reliability (ICC= 0.97, 95% CI = 0.92-0.98) Excellent Interrater/ Intrarater	Basic mobility MID = 4.28 (Latham et al., 2008)

				reliability (ICC= 0.86, 95% CI = 0.68-0.96)	
RASS	Participation	Instrument to assess sedation and agitation in adult ICU patients. It has discrete criteria and sufficient levels for sedative medication titration and agitation evaluation	In validity testing, RASS correlated highly (*r* = 0.93) with a visual analog scale anchored by "combative" and "unresponsive," including all patient subgroups (*r* = 0.84–0.98)	Excellent interrater reliability amongst 5 investigators (2 physicians, 2 nurses and 1 pharmacists (*r* = 0.956, lower 90 % confidence limit =0.948, *k* = 0.73, 95% CI = 0.71-0.75) in adult ICU patient encounters (n= 192) (Sessler et al., 2002)	

CAM-ICU	Participation	Instrument to assess incidence and recorded episodes of acute delirium	Criterion validity- Compared with reference standard 2 study nurses using the Cam-ICU has sensitivity of 100% and 93% and specificities of 98% and 100%	High inter rater reliability (*k* = 0.96; 95% CI= 0.92-0.99 (Ely et al, 2001)	

C. Sample

Charts from all patients with physical therapy orders, who met the inclusion/exclusion criteria and received at least one mobilization session during the QI period, were reviewed. The sample included in the QI project was non-randomized as the purpose of the project was intention to treat.

D. Study Population

Patients who were admitted to medical and surgical ICU at NYU Langone- Brooklyn between January 1st, 2018 and June 30th 2018 and received at least one mobilization session were included in the retrospective chart review.

(a) Number of Subjects: Estimated number of subjects that was required to have a power of at least 0.80 and large effect size as per calculations from G-power software is as follows:

- Parametric data

  Paired *t*- test (IMS, FSS, AMPAC)

A- Priori analysis for t tests-Means: Difference between two dependent means (matched pairs)

Small effect size f= 0.25,

Alpha level- 0.05,

Power- 0.80,

Tails- 2

Sample size needed for the study is 128

- Parametric data

  Independent *t*- test (Length of stay)

  A- priori analysis for t tests-Means: Difference between two independent means (two groups)

  Small effect size f= 0.25,

  Alpha level- 0.05,

  Power- 0.80,

  Allocation ratio N2/N1- 1

  Sample size needed for the study is 398 (199 in each group)

- Non parametric data

  Wilcoxon signed rank test (RASS)

  A- priori analysis for *t*- tests Means: Wilcoxon signed- rank test (matched pairs)

  Small effect size f= 0.25,

  Alpha level- 0.05,

  Power- 0.80,

  Tails- 2

  Sample size needed for the study is 134

Chart review was performed for 388 patients in MICU and 293 patients in SICU to include the data of all patients who participated in the early mobilization protocol.

(b) Gender of Subjects: QI project was implemented with intention to treat and improve quality of care, so attempts were taken to enroll all male and female patients that were admitted in the ICU. Pregnant women were excluded from participating in the quality improvement project.

(c) Age of Subjects: Adult patients admitted to ICU ages 18 or older were included in the QI project

(d) Racial and Ethnic Origin*:* There were no enrollment restrictions based on race or ethnic origin, and attempts were made to include persons of diverse racial/ethnic backgrounds to ensure that the benefits and burdens of research participation are distributed in an equitable manner.

(e) Inclusion Criteria:

- Admitted to NYU Langone health- Brooklyn hospital Medical or surgical ICU from January 1st 2018 to June 30th 2018
- Ages 18 years and older
- Received PT orders from MD to initiate early mobilization.
- Received atleast one mobilization session during ICU stay
- " Green" and " Yellow" as per mobilization criteria

(f) Exclusion Criteria:

- Patient with no PT order or no mobilization session performed in the ICU
- " Red" as per mobilization criteria
- Pregnant women

(g) Vulnerable Subjects: Vulnerable subjects including children, pregnant women, fetuses, prisoners, students, employees, and persons with decisional incapacity will not be included in the QI project.

E. Detailed study procedures

(a) Study procedures

- The source (location) of records that were reviewed were at NYU Langone hospital-Brooklyn.
- The charts that were reviewed were identified by the medical record number of the patients with physical therapy orders and admitted to medical and surgical ICU between January 1st 2018 to June 30th 2018.
- Following study team members identified charts: Co-investigator/primary contact (Assistant supervisor of physical therapy department) identified the charts that were reviewed.

(b) Confidentiality of data

The measurements were stored in the password protected and HIPAA compliant NYU shared network drive that was setup by MCIT specifically for the study data collection. The PI did not have access to the measurement data until the end of data collection. Only co-investigator/primary contact had access to the data. To protect privacy and confidentially of the subjects, subject's names or protected health information were not used. Each subject was coded numerically based on the Medical record number. Once the chart review was completed and while data analysis was being performed the data was stored for 6 months period. Data files were deleted 6 months after the data analysis was completed.

(c) Identifiable Information

- **To identify patient charts, the following identifiers will be used in this study:**
    1. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
    2. Medical record numbers

- Identifiers were recorded for research purposes. A waiver of authorization was submitted to NYU IRB to review the identifiable health information.

F. Data Analysis

(a) Data Analysis: Research Questions, Hypothesis and planned Statistical Analysis

- Research Question- 1: Is standardized early mobilization protocol administered from ICU admission to discharge effective in improving functional status of the patient as measured by ICU mobility scale?
    - Hypothesis- 1: Standardized early mobilization protocol administered from ICU admission to discharge will improve functional status of the patient as measured by ICU mobility
    - Statistical analysis: Pre-test and post-test analysis (paired *t*- test)

- Research Question- 2: Is standardized early mobilization protocol administered from ICU admission to discharge effective in improving functional independence of the patient as measured by FSS- ICU scale?
    - Hypothesis- 2: Standardized early mobilization protocol administered from ICU admission to discharge will improve functional independence of the patient as measured by FSS-ICU scale.
    - Statistical analysis: Pre- test and post-test analysis (paired *t*- test)

- Research Question- 3: Is standardized early mobilization protocol administered from ICU admission to discharge effective in improving functional independence of the patient as measured by AMPAC basic mobility scale?
    - Hypothesis- 3: Standardized early mobilization protocol administered from ICU admission to discharge will improve functional independence of the patient as measured by AMPAC basic mobility scale
    - Statistical analysis: Pre-test and post-test analysis (paired *t*- test)

- Research Question- 4 Is standardized early mobilization protocol administered from ICU admission to discharge effective in decreasing agitation and sedation in ICU patients as measured by Richmond agitation and sedation scale- RASS?
    - Hypothesis- 4: Standardized early mobilization protocol administered from ICU admission to discharge will decrease agitation and sedation in ICU patients as measured by Richmond agitation and sedation scale- RASS
    - Statistical analysis: Pre- test and post-test analysis (Wilcoxon signed rank test- non normal distribution ordinal data). Also, Crosstabulation and chi squared test will be utilized to calculate proportion (%) of patients with 0 (alert and calm) RASS score upon discharge.

- Research Question- 5: Is standardized early mobilization protocol administered from ICU admission to discharge effective in decreasing ICU acquired delirium as measured by CAM- ICU?
    - Hypothesis- 5: Standardized early mobilization protocol administered from ICU admission to discharge will decrease ICU acquired delirium as measured by CAM- ICU.
    - Statistical analysis: - The McNemar test will be used to determine whether the proportion of participants with negative score for initial CAM-ICU assessment is different from the proportion of participants with negative score for final CAM-ICU assessment. Crosstabulation and chi squared test will be utilized to calculate proportion (%) of patients with negative CAM-ICU score upon discharge.

- Research Question- 6: Is standardized early mobilization protocol administered in the ICU effective in decreasing ICU length of stay compared to the usual care comparison group from prior year?
    - Hypothesis- 6: Standardized early mobilization protocol administered in the ICU is effective in decreasing ICU length of stay compared to the usual care comparison group from prior year
    - Statistical analysis: Independent *t*-test (Early mobility vs. comparison group from prior year)

- Research Question- 7: Is standardized early mobilization protocol administered from ICU admission to discharge effective in increasing discharge to community after discharge from hospital
    - Hypothesis- 7: Standardized early mobilization protocol administered from ICU admission to discharge is effective in increasing discharge to community after discharge from hospital
    - Statistical analysis: Chi-squared test- proportion % of patients that are discharged to community (compare with comparison group from prior year)

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CHAPTER-IV
RESULTS AND DISCUSSION

As seen in figure 2, 503 patients were admitted in Medical ICU (MICU) and 327 patients were admitted in Surgical ICU (SICU) from January 1st 2018 to June 30th 2018. Retrospective chart review was conducted for the charts with the following inclusion criteria: age 18 years and older, received mobilization orders from medical doctors to initiate early mobilization, were assessed as Green or Yellow per the Hodgson Red-Yellow-Green mobilization criteria, and received at least one mobilization session during the ICU stay. 115 of 503 in MICU and 34 of 327 in SICU did not meet inclusion criteria and were not included in the retrospective chart review process. Total 388 charts in MICU and 293 charts in SICU were included in the final analysis. Within group pre-test posttest analysis was conducted for the early mobilization group patients to answer research question 1 to 5. For between group analysis and to compare data between early mobilization and historical control group, total 480 charts in MICU and 291 charts in surgical ICU were screened to obtain information for the length of stay and discharge destination data to answer research question 6 and 7. The data analysis included descriptive, inferential and correlative statistics using SPSS version 25 (IBM Corp., 2017). Significance level was set at < 0.05 and exact *p*-values are reported. Effect size was calculated for each dependent variable. Post hoc analysis was performed by using G-power software to check power.

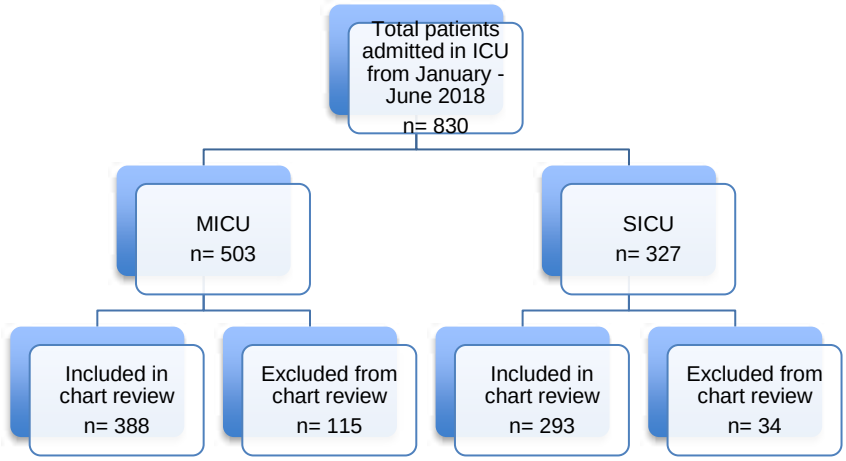


Figure 2. Consort Diagram

Primary outcomes data analysis: Within group pre-test post-test analysis was conducted for the early mobilization group patients to answer research question 1 to 5.

Patient's demographics

For MICU, the total sample size from early mobilization group was N= 388, with the average age of 71.2 years. 51.03 % (n= 198) of the sample was male and 48.96% (n= 190) was female. For SICU, the total sample size from early mobilization group was N= 293, with the average age of 65.2 years. 57.33 % (n= 168) of the sample was male and 42.66% (n= 125) was female. Proportions of the primary diagnosis for both MICU and SICU patients for early is listed in the table 3 below.

Table 3

Demographic Variables of Patients

Characteristic	**MICU**	**SICU**
N	388	293
Age (yr.)- Mean	71.2	65.2
Gender – n (%)	Male- 198 (51.03 %) Female- 190 (48.96%)	Male-168 (57.33%) Female-125 (42.66 %)
Primary diagnosis – n (%)	Pulmonary conditions- 181 (46.64 %) Cardiac conditions- 124 (31.95 %) Neurological- 18 (4.63 %) Trauma- 5 (1.28 %) Post- operative- 4 (1.03 %) Other- 56 (14.43%)	Pulmonary conditions- 10 (0.34%) Cardiac conditions- 2 (0.68 %) Neurological- 102 (34.81 %) Trauma- 82 (37.98%) Post- operative- 74 (25.25%) Other- 23 (7.84 %)

Primary Research Question- 1: Is standardized early mobilization protocol (Red-Yellow-Green system) administered from ICU admission to discharge effective in improving functional status of the patient as measured by ICU mobility scale?

To answer RQ1 a paired samples *t* test was calculated to compare the initial and final ICU mobility scale score after early mobility intervention. Analysis was performed separately for Medical (MICU) and Surgical (SICU). Following assumptions were checked before the paired *t*- test was conducted. Data were matched pairs: all participants participated in ICU mobility scale assessment upon admission and discharge. Assumed to be a random sample. ICU mobility scale is measured on the ratio scale. N = 388 for MICU and 293 for SICU, so central limit theorem applied and data were assumed to be normal. However, the normality tests for the paired differences are below:

Table 4 shows values for skewness and kurtosis for the ICU mobility score change, which can be used to describe the distribution and test for normality. For MICU, for the change in IMS score the skew is 1.99 which indicates that the sample is highly positive skewed. The kurtosis value is 8.13 which indicates a leptokurtic distribution. For SICU, for the change in IMS score the skew is 1.09 which indicates that the sample is highly positive skewed. The kurtosis value is 2.57 which indicates a leptokurtic distribution.

Table 4

Descriptive Statistics for the Differences

			Statistic	Std. Error
MICU ICU Mobility score change	Mean		.3299	.07307
	95% Confidence Interval for Mean	Lower Bound	.1862	
		Upper Bound	.4736	
	5% Trimmed Mean		.2153	
	Median		.0000	
	Variance		2.072	
	Std. Deviation		1.43936	
	Minimum		-5.00	
	Maximum		8.00	
	Range		13.00	

	Interquartile Range		.00	
	Skewness		1.990	.124
	Kurtosis		8.137	.247
SICU ICU Mobility score change	Mean		.9249	.10595
	95% Confidence Interval for Mean	Lower Bound	.7164	
		Upper Bound	1.1334	
	5% Trimmed Mean		.8182	
	Median		.0000	
	Variance		3.289	
	Std. Deviation		1.81352	
	Minimum		-5.00	
	Maximum		8.00	
	Range		13.00	
	Interquartile Range		2.00	
	Skewness		1.091	.142
	Kurtosis		2.579	.284

As shown in Table 5, the sample size is large (n=388 for MICU and n= 293 for SICU), so the Kolmogorov- Smirnov (K-S) test was used to test for normality of data. For MICU, K-S value for the differences is .42, and $p < .001$, which is significant. This means that the data are not normal. For SICU, K-S value for the differences is .31, and $p < .001$, which is significant. This means that the data are not normal. However N > 30 so central limit theorem applies and parametric test (paired sample *t*-test) is utilized for data analysis (Field, 2013).

Table 5

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	*p* value	Statistic	df	*p* value
MICU ICU Mobility score change	.428	388	.000	.595	388	.000
SICU ICU Mobility score change	.316	293	.000	.793	293	.000

a. Lilliefors Significance Correction

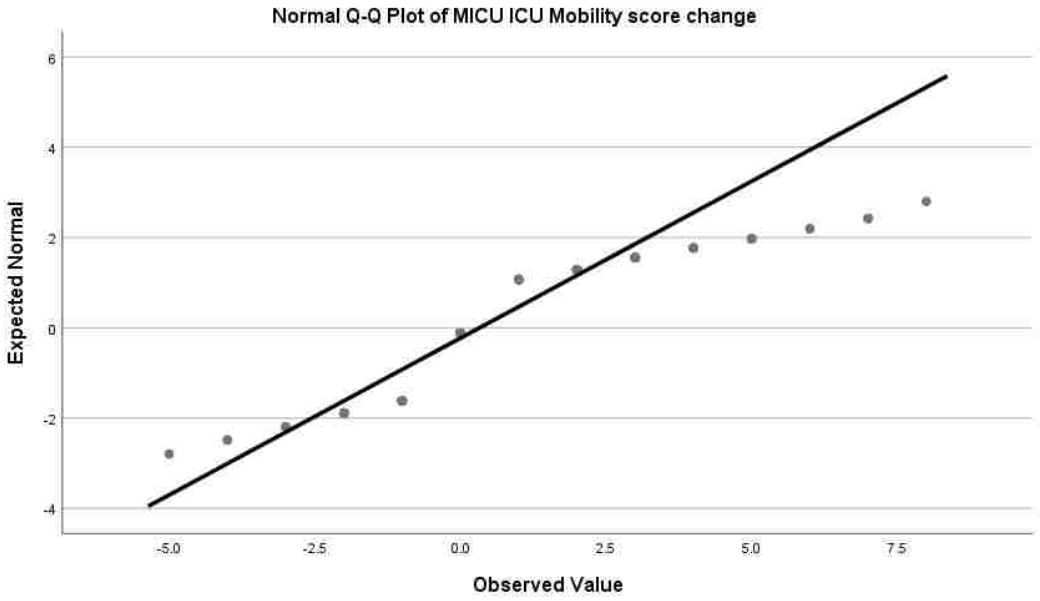


Figure 3. The Q-Q plot of the MICU differences shows that the data points are skewed and are not normally distributed.

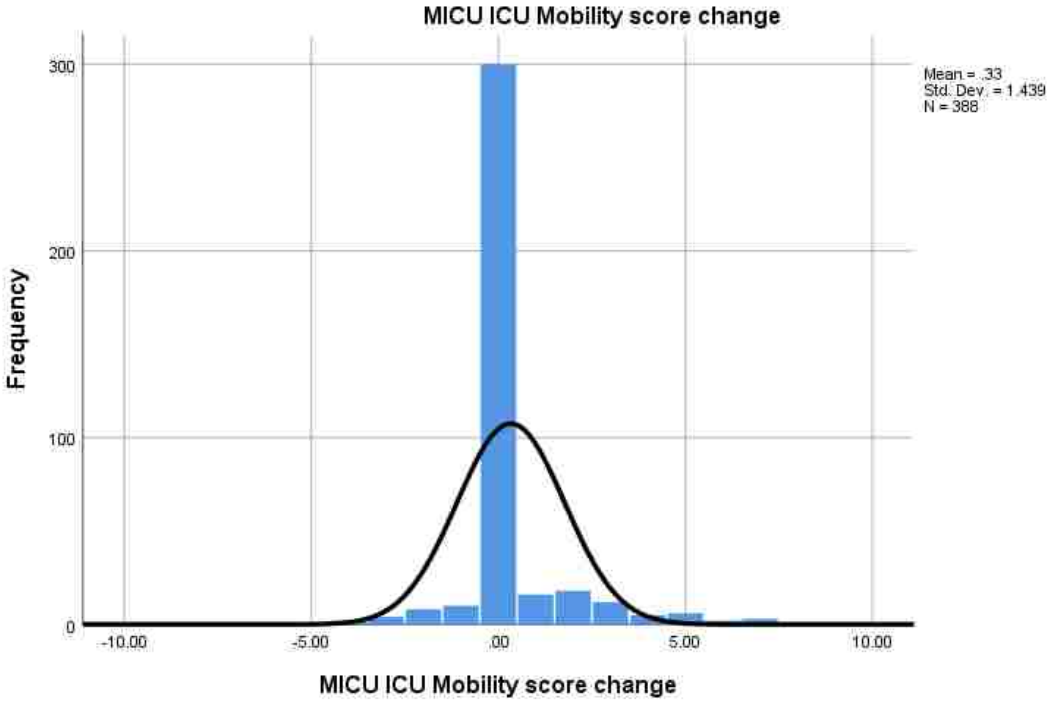


Figure 4. The histogram of the MICU differences shows a not normal distribution.

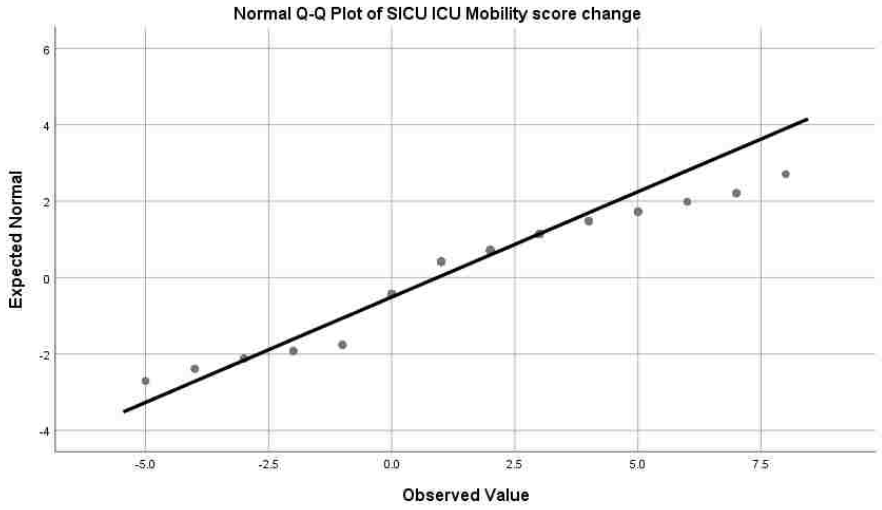


Figure 5. The Q-Q plot of the SICU differences shows that the data points are skewed and are not normally distributed.

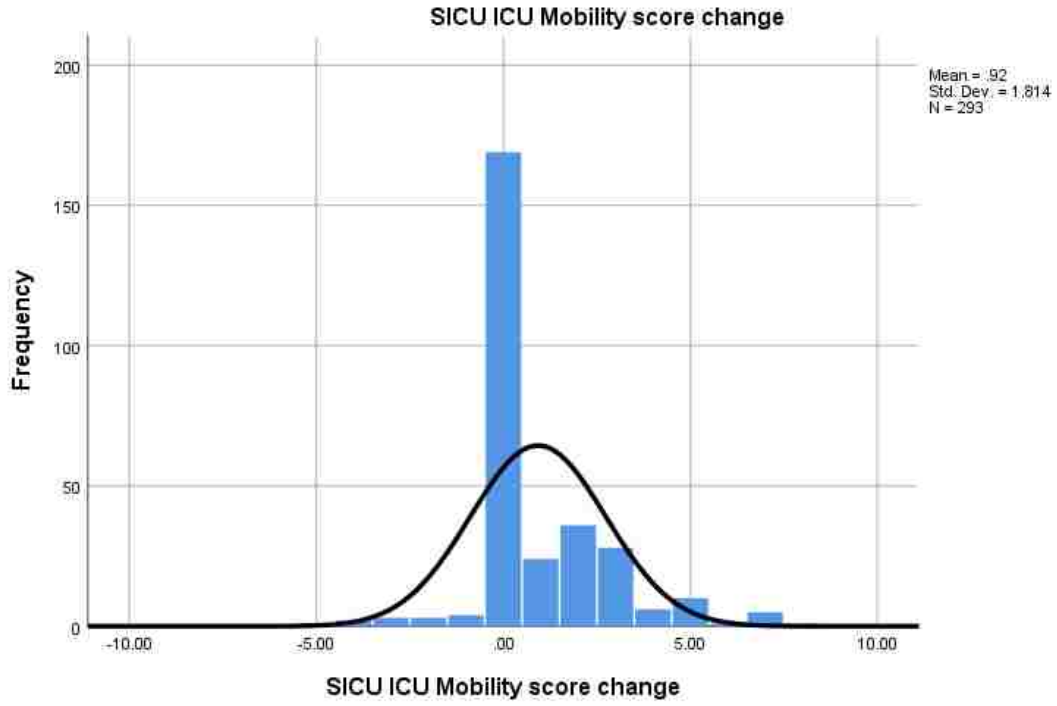


Figure 6. The histogram of the SICU differences shows a not normal distribution.

As shown in Table 6, the mean score for initial ICU mobility scale for MICU was 5.89 (*sd* = 2.60). The mean score for final ICU mobility scale for MICU was 6.22 (*sd* = 2.52).The mean score for initial ICU mobility scale for SICU was 6.18 (*sd* = 2.57). The mean score for final ICU mobility scale for SICU was 7.11 (*sd* = 2.29)

Table 6

Paired Sample Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MICU Final- ICU Mobility scale score	6.22	388	2.523	.128
	MICU Initial- ICU Mobility scale score	5.89	388	2.609	.132
Pair 2	SICU Final- ICU Mobility scale score	7.11	293	2.291	.134
	SICU Initial- ICU Mobility scale score	6.18	293	2.574	.150

Table 7 below shows the output for Pearson's correlation for these data. For MICU *r* =.84, $p < .001$, which is significant. For SICU $r = .72$, $p < .001$, which is significant.

Table 7.

Paired Samples Correlation

		N	Correlation	*p* value
Pair 1	MICU Final- ICU Mobility scale score & MICU Initial- ICU Mobility scale score	388	.843	.000
Pair 2	SICU Final- ICU Mobility scale score & SICU Initial- ICU Mobility scale score	293	.728	.000

Table 8 below shows the paired sample statistics for *t*-test. The null hypothesis for the problem was that there is no difference in the initial and final ICU mobility scale. The alternative hypothesis was that final ICU mobility scale score is more than initial ICU mobility scale after early mobility intervention. ($H_a = \mu_2 > \mu_1$). This is one-tailed. A paired samples *t* test was calculated to compare the mean change in ICU mobility scale score after early mobility intervention. The mean score for initial ICU mobility scale for MICU was 5.89 (*sd* = 2.60). The mean score for final ICU mobility scale for MICU was 6.22 (*sd* = 2.52). A significant increase was found in the final ICU mobility scale score, (*t* (387) = 4.51, *p* < .001, one-tailed). (*p* calculated as .000/2 since this is one-tailed.). The mean score for initial ICU mobility scale for SICU was 6.18 (*sd* = 2.57). The mean score for final ICU mobility scale for SICU was 7.11 (*sd* = 2.29). A significant increase was found in the final ICU mobility scale score, (*t* (292) = 8.71, *p* < .001, one-tailed). (*p* calculated as .000/2 since this is one-tailed.)

Table 8

Paired Samples t- test

		Paired Differences									
					95% Confidence Interval of the Difference						
		Mean	Std. Deviatio	Std. Error Mean	Lower	Upper	*t*	df	*p* value	Effect size	Power
Pair 1	MICU Final-ICU Mobility scale score - MICU Initial-ICU Mobility scale score	.330	1.439	.073	.186	.474	4.51	387	.000	*d* = 0.22 (small)	.99
Pair 2	SICU Final-ICU Mobility scale score - SICU Initial-ICU Mobility scale score	.925	1.814	.106	.716	1.133	8.70	292	.000	*d* = 0.50 (medium)	1.00

Effect size

MICU effect size

$d = t / \sqrt{N}$

$= 4.51/\sqrt{388}$

= 0.22 (This is a small effect size)

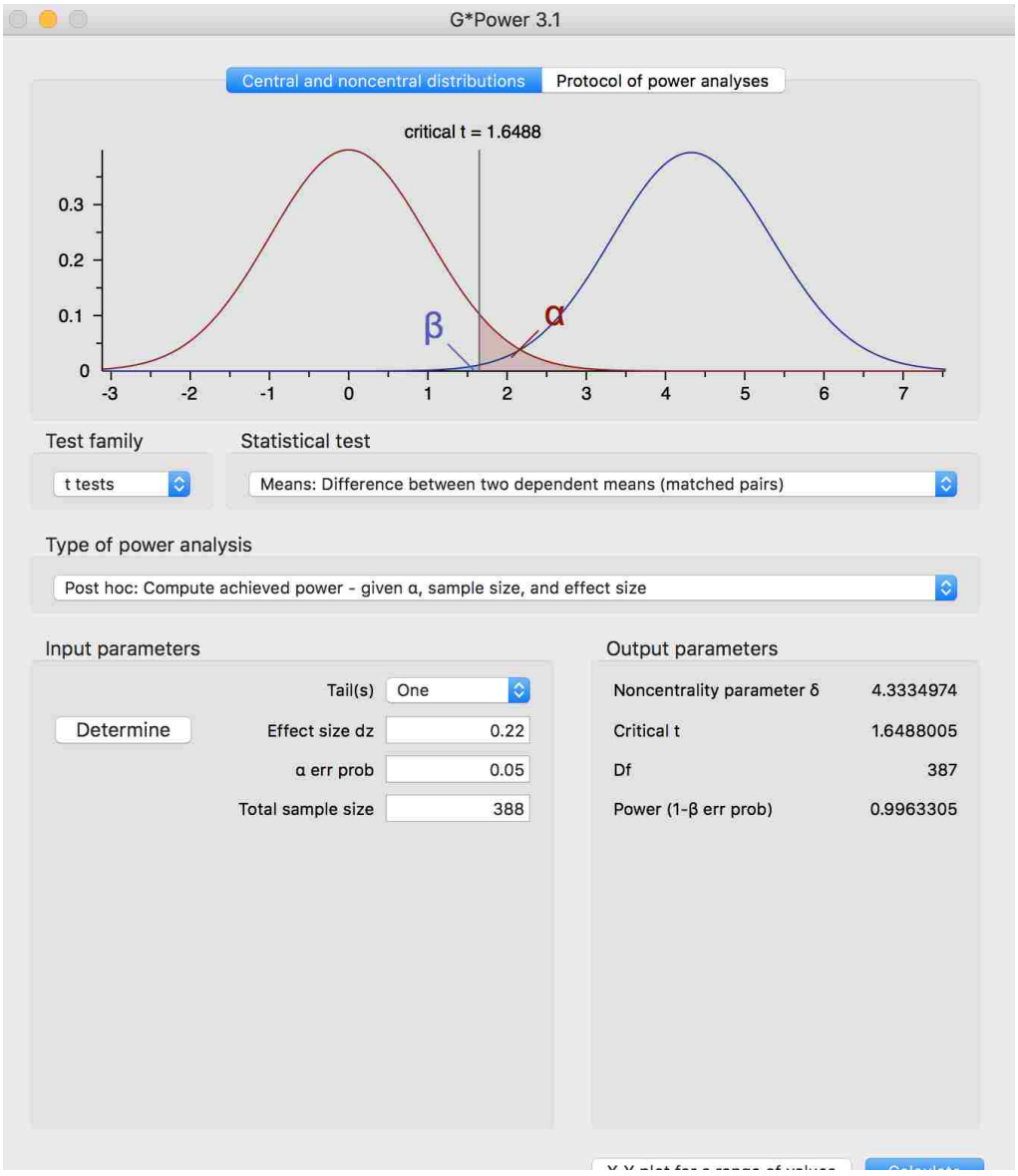


Figure 7. The G-Power post-hoc analysis for the MICU sample shows that power is .99. This exceeds the accepted value of power = .80. The power obtained was sufficient.

SICU Effect size

d = t / √N

= 8.711/√293

= 0.50 (This is a medium effect size)

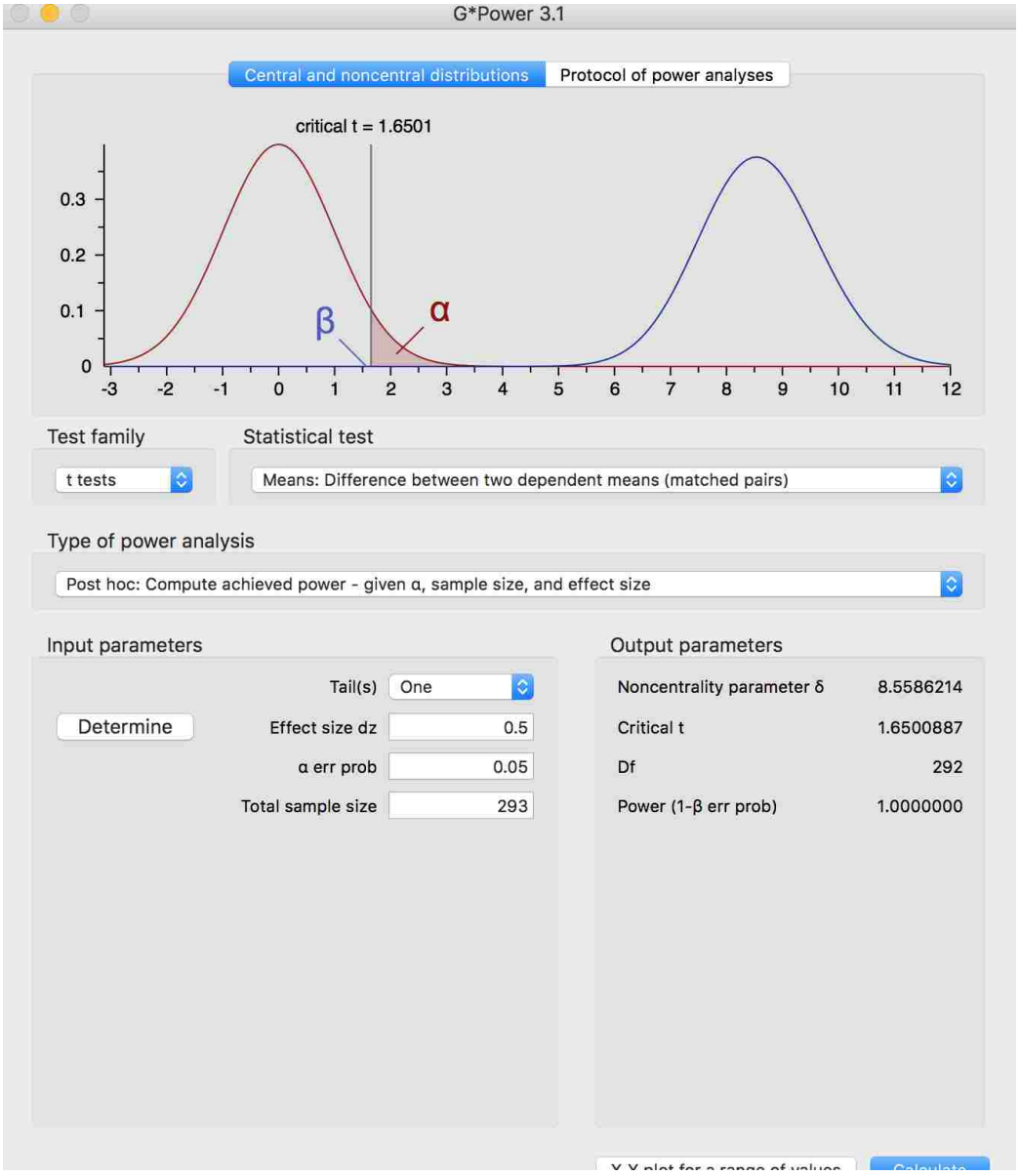


Figure 8. The G-Power post-hoc analysis for the SICU sample shows that power is 1.00. This exceeds the accepted value of power = .80. The power obtained was sufficient.

Primary Research Question- 2: Is standardized early mobilization protocol (Red-Yellow-Green system) administered from ICU admission to discharge effective in improving functional independence of the patient as measured by FSS- ICU scale?

To answer RQ2 a paired samples *t* test was calculated to compare the initial and final functional status score after early mobility intervention. Analysis was performed separately for Medical (MICU) and Surgical (SICU). Following assumptions were checked before the paired *t*-test was conducted. Data were matched pairs: all participants participated in Functional status score scale assessment upon admission and discharge. Assumed to be a random sample. FSS-ICU is measured on the ratio scale. N = 388 for MICU and 293 for SICU, so central limit theorem applies and data are assumed to be normal. However, the normality tests for the paired differences are shown below:

Table 9 shows the values for skewness and kurtosis for functional status score, which can be used to describe the distribution and test for normality. For MICU for the change in FSS score the skew is 2.38, which indicates that the sample is highly positive skewed. The kurtosis value is 8.93, which indicates a leptokurtic distribution. For SICU, for the change in FSS score the skew is .96, which indicates that the sample is moderately positive skewed. The kurtosis value is 2.18, which indicates a leptokurtic distribution.

Table 9

Descriptive Statistics for the Differences

			Statistic	Std. Error
MICU FSS change	Mean		.9974	.17656
	95% Confidence Interval for Mean	Lower Bound	.6503	
		Upper Bound	1.3446	
	5% Trimmed Mean		.6306	
	Median		.0000	
	Variance		12.096	
	Std. Deviation		3.47787	
	Minimum		-10.00	
	Maximum		19.00	
	Range		29.00	

	Interquartile Range		.00	
	Skewness		2.388	.124
	Kurtosis		8.938	.247
SICU FSS change	Mean		2.4846	.28745
	95% Confidence Interval for Mean	Lower Bound	1.9189	
		Upper Bound	3.0504	
	5% Trimmed Mean		2.2254	
	Median		.0000	
	Variance		24.210	
	Std. Deviation		4.92032	
	Minimum		-15.00	
	Maximum		19.00	
	Range		34.00	
	Interquartile Range		4.00	
	Skewness		.964	.142
	Kurtosis		2.187	.284

As shown in Table 10, the sample size is large (n=388 for MICU and n= 293 for SICU), so the Kolmogorov- Smirnov (K-S) test was used to test for normality of data. For MICU, K-S value for the differences is .39, and $p < .001$, which is significant. This means that the data are not normal. For SICU, K-S value for the differences is .24, and $p < .001$, which is significant. This means that the data are not normal. However N > 30 so central limit theorem applies and parametric test (paired sample *t*-test) is utilized (Field, 2013).

Table 10

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	*p* value	Statistic	df	*p* value
MICU FSS change	.394	388	.000	.585	388	.000
SICU FSS change	.243	293	.000	.823	293	.000

a. Lilliefors Significance Correction

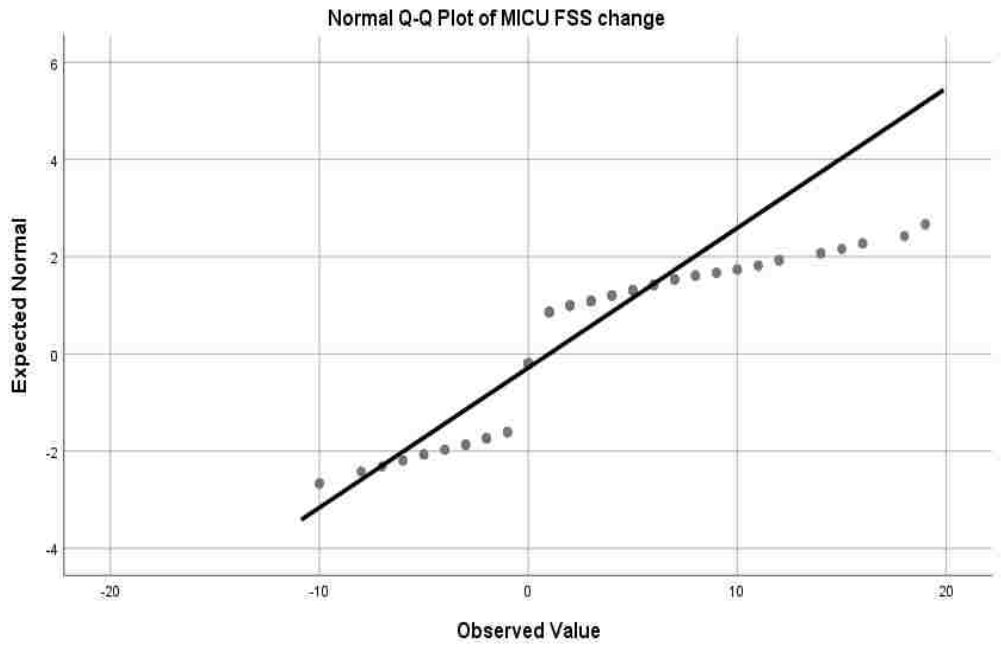


Figure 9. The Q-Q plot of the MICU differences shows that the data points are skewed and are not normally distributed.

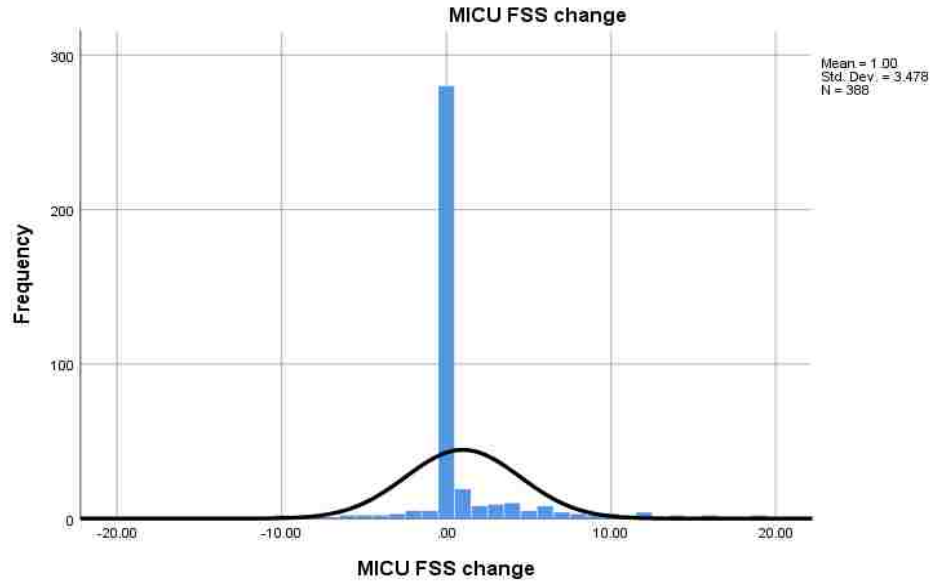


Figure 10. The histogram of the MICU differences shows a not normal distribution.

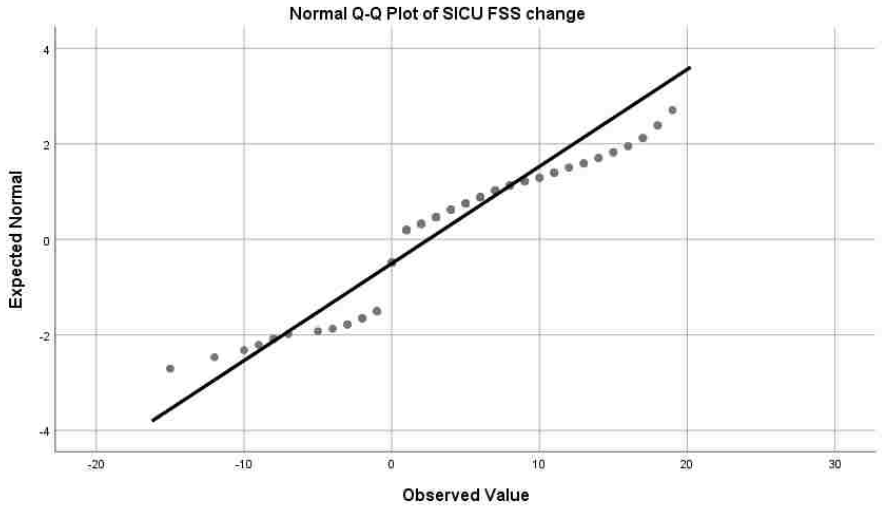


Figure 11. The Q-Q plot of the SICU differences shows that the data points are skewed and are not normally distributed.

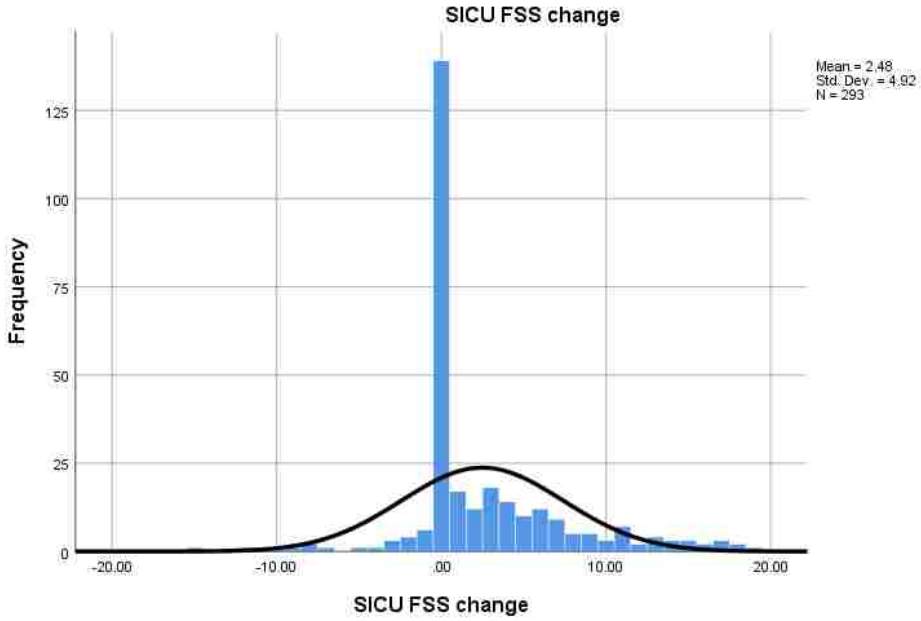


Figure 12. The histogram of the SICU differences shows a not normal distribution.

As shown in table 11, the mean score for initial FSS-ICU scale for MICU was 14.51 (*sd* = 9.17). The mean score for final FSS-ICU scale for MICU was 15.51 (*sd* = 9.10).The mean score for initial FSS-ICU scale for SICU was 16.54 (*sd* = 8.78). The mean score for final ICU mobility scale for SICU was 19.02 (*sd* = 8.83).

Table 11

Paired Sample Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MICU Final-Functional status score-ICU	15.51	388	9.100	.462
	MICU Initial- Functional status score-ICU	14.51	388	9.173	.466
Pair 2	SICU Final-Functional status score-ICU	19.02	293	8.838	.516
	SICU Initial- Functional status score-ICU	16.54	293	8.787	.513

Table 12 below shows the output for Pearson's correlation for these data. For MICU r =.92, $p < .001$, which is significant. For SICU $r = .84$, $p < .001$, which is significant.

Table 12

Paired Samples Correlation

		N	Correlation	*p* value
Pair 1	MICU Final-Functional status score-ICU & MICU Initial-Functional status score-ICU	388	.928	.000
Pair 2	SICU Final-Functional status score-ICU & SICU Initial-Functional status score-ICU	293	.844	.000

Table 13 below shows the paired sample statistics for *t*- test. The null hypothesis for the problem is that there is no difference in the initial and final functional status score scale. The alternative hypothesis is final FSS score is higher than initial FSS scale after early mobility intervention. ($H_a = \mu_2 > \mu_1$). This is one-tailed. A paired samples *t* test was calculated to compare the mean change in FSS-ICU score after early mobility intervention. The mean score for initial FSS-ICU scale for MICU was 14.51 (*sd* = 9.17). The mean score for final ICU mobility scale for MICU was 15.51 (*sd* = 9.10). A significant increase was found in the final FSS-ICU score, (*t* (387) = 5.64, *p* < .001, one-tailed). (*p* calculated as .000/2 since this is one-tailed). The mean score for initial FSS-ICU scale for SICU was 16.54 (*sd* = 8.78). The mean score for final ICU mobility scale for SICU was 19.02 (*sd* = 8.83). A significant increase was found in the final ICU mobility scale score, (*t* (292) = 8.64, *p* < .001, one-tailed). (*p* calculated as .000/2 since this is one-tailed.

Table 13

Paired Samples t- test

		Paired Differences									
					95% Confidence Interval of the Difference						
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	*t*	df	*p* value	Effect size	Power
Pair 1	MICU Final-Functional status score-ICU - MICU Initial-Functional status score-ICU	.997	3.478	.177	.650	1.345	5.64	387	.000	*d* = 0.28 (small)	.99
Pair 2	SICU Final-Functional status score-ICU - SICU Initial-Functional status score-ICU	2.485	4.920	.287	1.919	3.050	8.64	292	.000	*d* = 0.50 (medium)	1.00

MICU Effect size

d = *t* / √N

= 5.64/√388 = 5.64/19.69

= 0.28 (This is a small effect size)

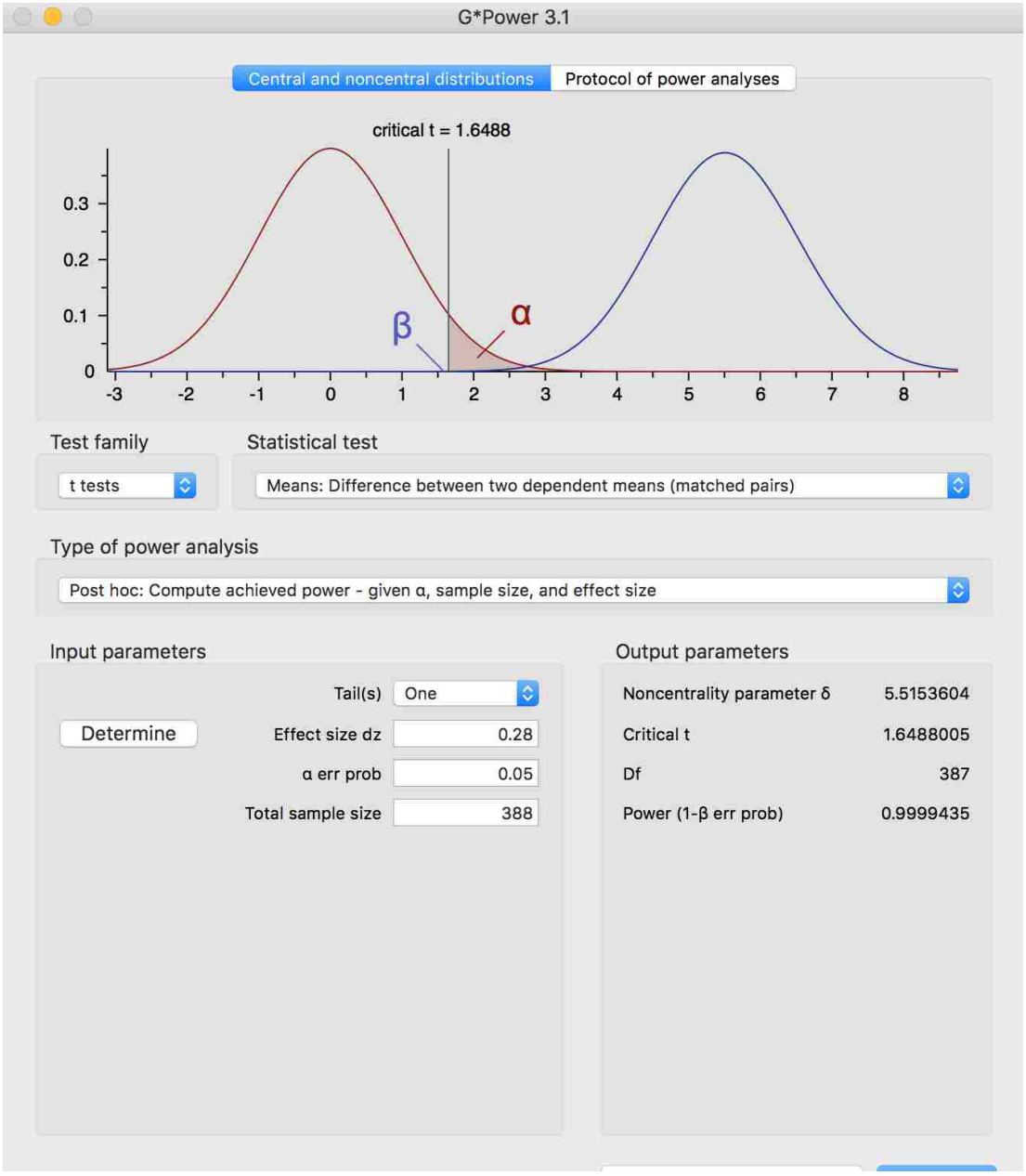


Figure 13. The G-Power post-hoc analysis for the MICU sample shows that power is .99. This exceeds the accepted value of power = .80. The power obtained was sufficient.

SICU Effect size

d = *t* / √N

= 8.64/√293 = 8.64/17.11

= 0.50 (This is a medium effect size)

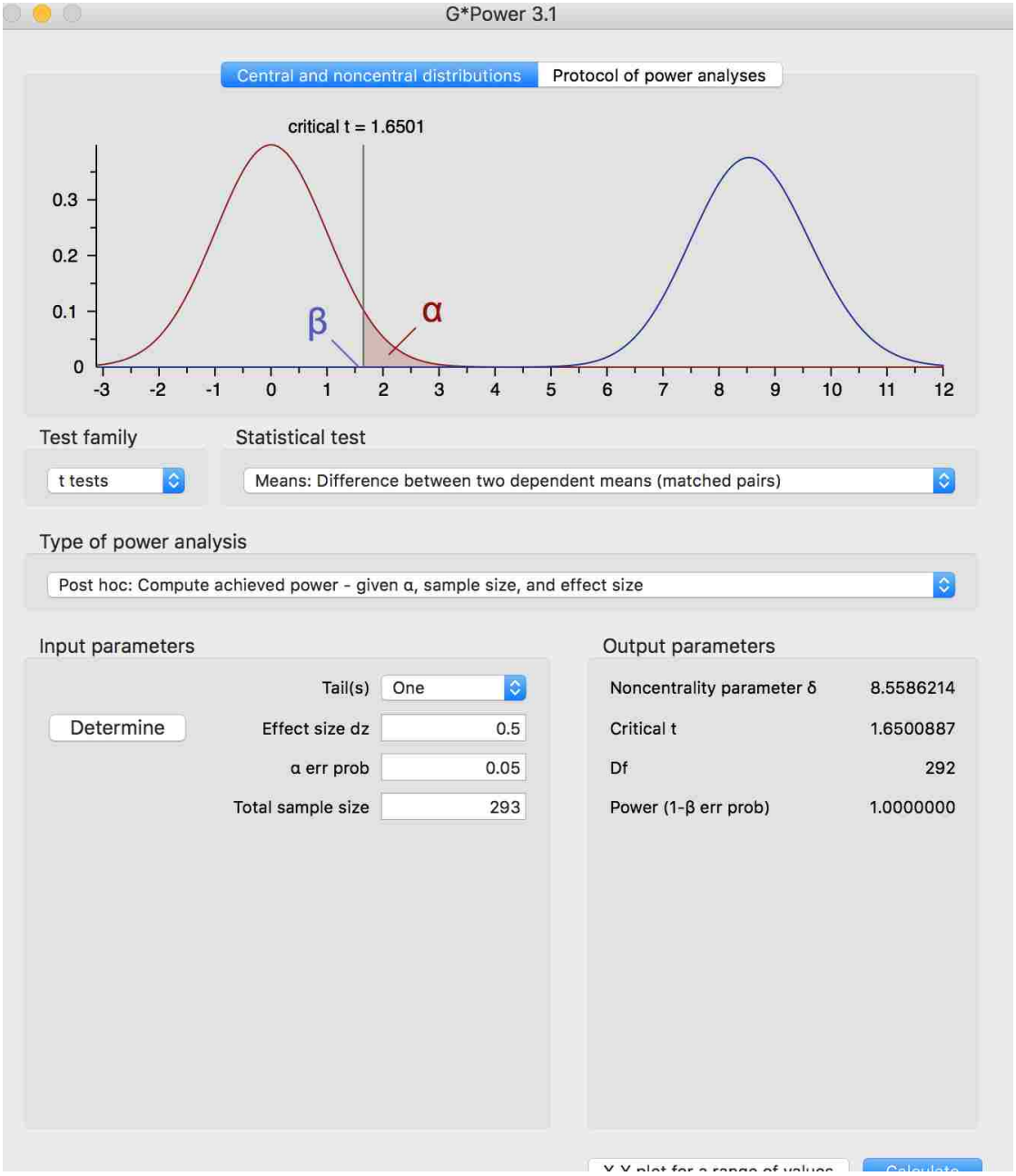


Figure 14. The G-Power post-hoc analysis for the SICU sample shows that power is 1.00. This exceeds the accepted value of power = .80. The power obtained was sufficient.

Research Question- 3: Is standardized early mobilization protocol administered from ICU admission to discharge effective in improving functional independence of the patient as measured by AMPAC basic mobility scale?

To answer RQ3 a paired samples *t* test was calculated to compare the initial and final AMPAC score after early mobility intervention. Analysis was performed separately for Medical (MICU) and Surgical (SICU). Following assumptions were checked before the paired *t*- test was conducted. Data were matched pairs: all participants all participants participated in AMPAC scale assessment upon admission and discharge. Assumed to be a random sample. AMPAC is measured on the ratio scale. N = 388 for MICU and 293 for SICU, so central limit theorem applies and data are assumed to be normal. However, the normality tests for the paired differences are below:

Table 14 shows values for skewness and kurtosis for the AMPAC score change, which can be used to describe the distribution and test for normality. For MICU for the change in AMPAC score the skew is 2.15, which indicates that the sample is highly positive skewed. The kurtosis value is 7.63, which indicates a leptokurtic distribution. For SICU for the change in AMPAC score the skew is 1.13, which indicates that the sample is highly positive skewed. The kurtosis value is 2.24, which indicates a leptokurtic distribution.

Table 14

Descriptive Statistics for the Differences

			Statistic	Std. Error
MICU AMPAC CHANGE	Mean		.4948	.09457
	95% Confidence Interval for Mean	Lower Bound	.3089	
		Upper Bound	.6808	
	5% Trimmed Mean		.3305	
	Median		.0000	
	Variance		3.470	
	Std. Deviation		1.86286	
	Minimum		-6.00	
	Maximum		10.00	
	Range		16.00	

	Interquartile Range		.00	
	Skewness		2.152	.124
	Kurtosis		7.638	.247
SICU AMPAC CHANGE	Mean		1.3857	.16265
	95% Confidence Interval for Mean	Lower Bound	1.0655	
		Upper Bound	1.7058	
	5% Trimmed Mean		1.2165	
	Median		.0000	
	Variance		7.751	
	Std. Deviation		2.78414	
	Minimum		-7.00	
	Maximum		12.00	
	Range		19.00	
	Interquartile Range		2.00	
	Skewness		1.138	.142
	Kurtosis		2.244	.284

As shown in table 15, the sample size is large (n=388 for MICU and n= 293 for SICU), so the Kolmogorov-Smirnov (K-S) test is used to test for normality of data. For MICU, K-S value for the differences is .42, and $p < .001$, which is significant. This means that the data are not normal. For SICU, K-S value for the differences is .31, and $p < .001$, which is significant. This means that the data are not normal. However N > 30 so central limit theorem applies and parametric test (paired sample *t*-test) is utilized (Field, 2013).

Table 15

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	*p* value	Statistic	df	*p* value
MICU AMPAC CHANGE	.437	388	.000	.575	388	.000
SICU AMPAC CHANGE	.291	293	.000	.779	293	.000

a. Lilliefors Significance Correction

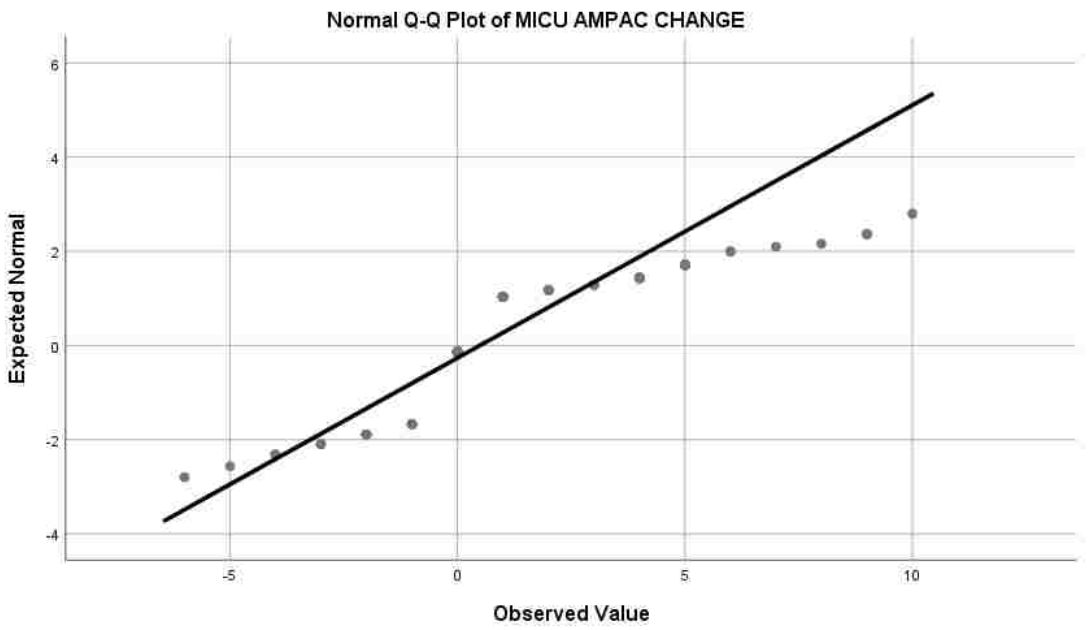


Figure 15. The Q-Q plot of the MICU differences shows that the data points are skewed and are not normally distributed.

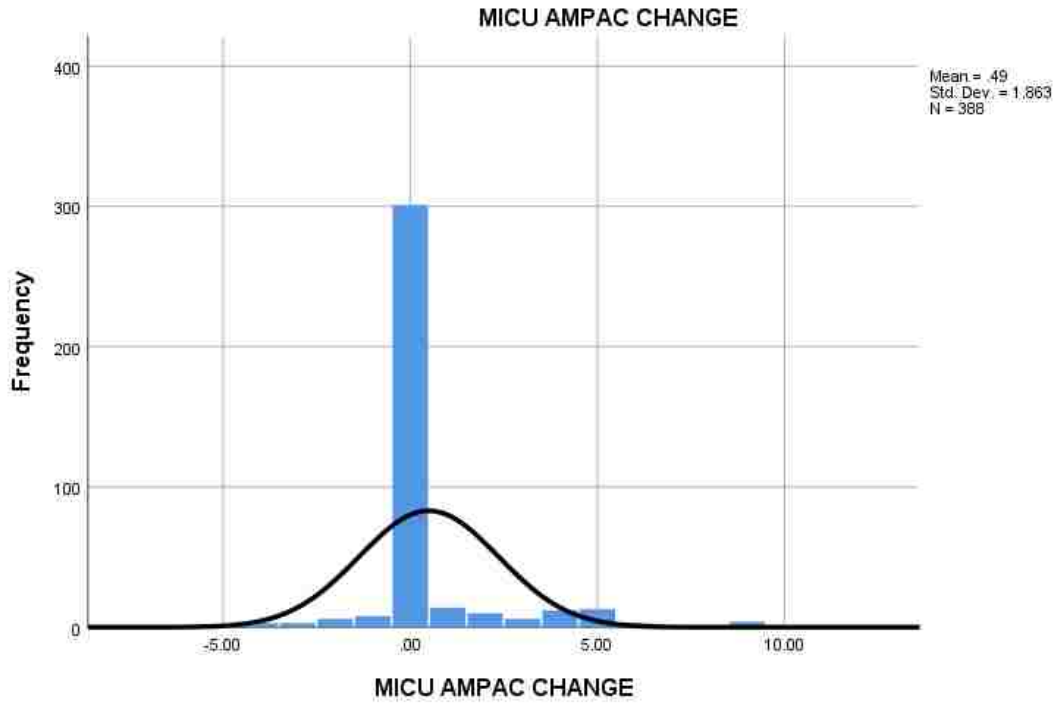


Figure 16. The histogram of the MICU differences shows a not normal distribution.

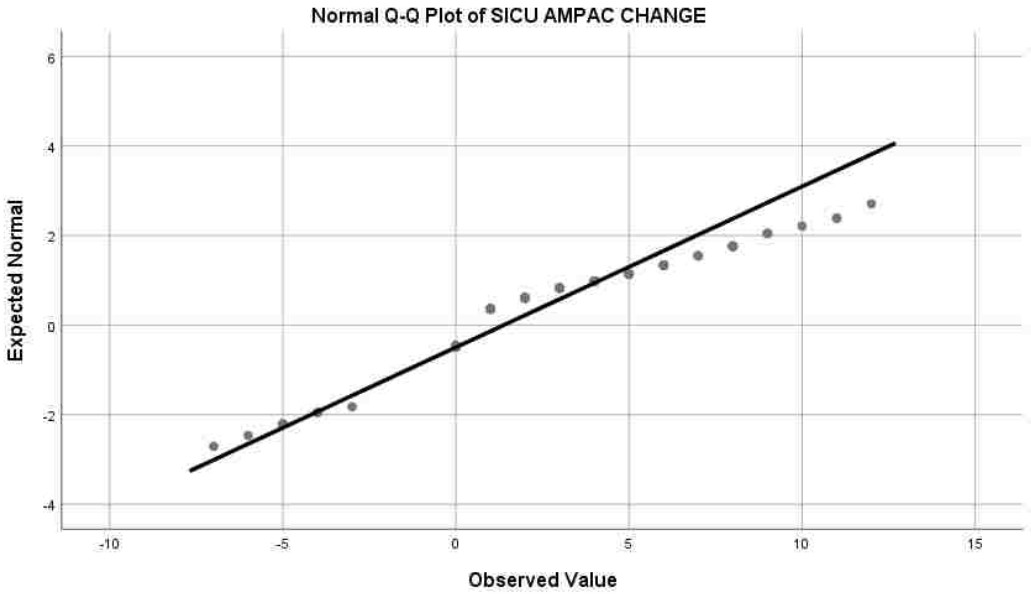


Figure 17. The Q-Q plot of the SICU differences shows that the data points are skewed and are not normally distributed.

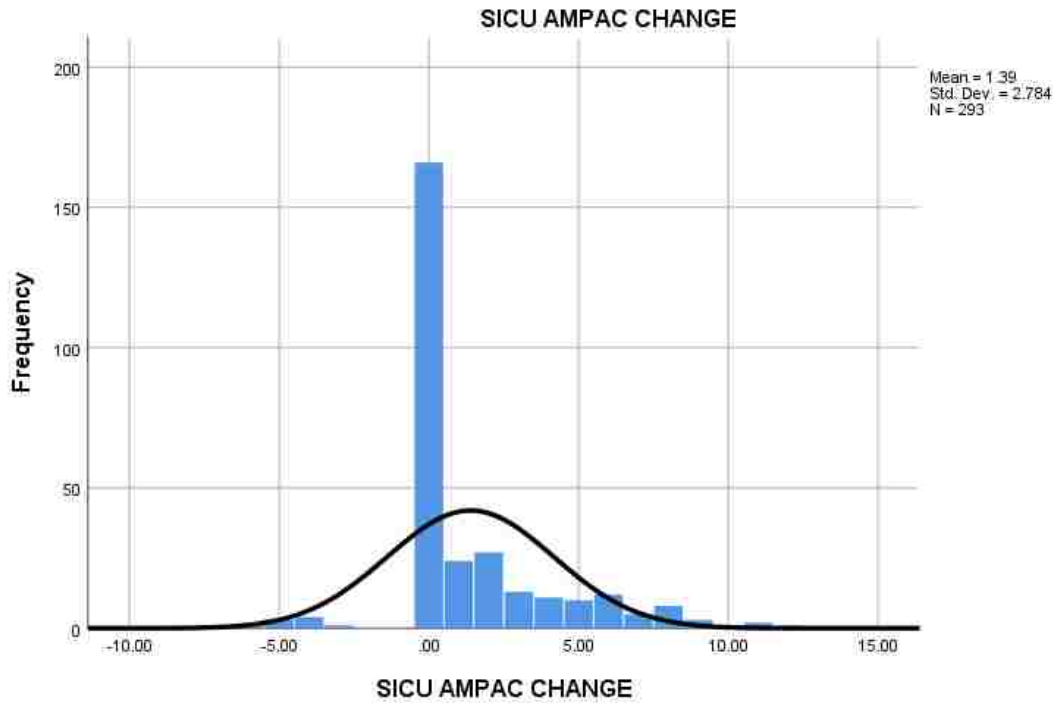


Figure 18. The histogram of the SICU differences shows a not normal distribution.

As shown in table 16, the mean score for initial AMPAC score for MICU was 12.57 (*sd* = 4.78). The mean score for final AMPAC score for MICU was 13.06 (*sd* = 4.75). The mean score for initial AMPAC score for SICU was 13.83 (*sd* = 4.58). The mean score for final AMPAC score for SICU was 15.22 (*sd* = 4.78).

Table 16

Paired Sample Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MICU Final- AMPAC	13.06	388	4.756	.241
	MICU Initial- AMPAC	12.57	388	4.793	.243
Pair 2	SICU Final- AMPAC	15.22	293	4.783	.279
	SICU Initial- AMPAC	13.83	293	4.583	.268

Table 17 below shows the output for Pearson's correlation for these data. For MICU r =.92, $p < .001$, which is significant. For SICU $r = .82$, $p < .001$, which is significant.

Table 17

Paired Samples Correlation

		N	Correlation	*p* value
Pair 1	MICU Final- AMPAC & MICU Initial- AMPAC	388	.924	.000
Pair 2	SICU Final- AMPAC & SICU Initial- AMPAC	293	.824	.000

Table 18 below shows the paired sample statistics for *t*-test. The null hypothesis for the problem was that there is no difference in the initial and final AMPAC score. The alternative hypothesis is final AMPAC score is higher than initial AMPAC score after early mobility intervention. ($H_a = \mu_2 > \mu_1$).This is one-tailed. A paired samples *t* test was calculated to compare the mean change in ICU mobility scale score after early mobility intervention. The mean score for initial AMPAC score for MICU was 12.57 (*sd* = 4.78). The mean score for final AMPAC score for MICU was 13.06 (*sd* = 4.75). A significant increase was found in the final AMPAC score, (*t* (387) = 5.23, *p* < .001, one-tailed). (*p* calculated as .000/2 since this is one-tailed.). Hence we can reject the null hypothesis. The mean score for initial AMPAC score for SICU was 13.83 (*sd* = 4.58). The mean score for final AMPAC score for SICU was 15.22 (*sd* = 4.78). A significant increase was found in the final ICU mobility scale score, (*t* (292) = 8.51, *p* < .001, one-tailed). (*p* calculated as .000/2 since this is one-tailed.). Hence we can reject the null hypothesis

Table 18

Paired Samples t- test

		Paired Differences									
					95% Confidence Interval of the Difference						
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	*t*	Df	*p* value	Effect size	Power
Pair 1	MICU Final-AMPAC - MICU Initial-AMPAC	.495	1.863	.095	.309	.681	5.23	387	.000	*d* = 0.26 (small)	.99
Pair 2	SICU Final-AMPAC - SICU Initial-AMPAC	1.386	2.784	.163	1.066	1.706	8.51	292	.000	*d* = 0.49 (small)	1,00

MICU Effect size

d = *t* / √N

= 5.23/√387

= .26 (This is a small effect size.)

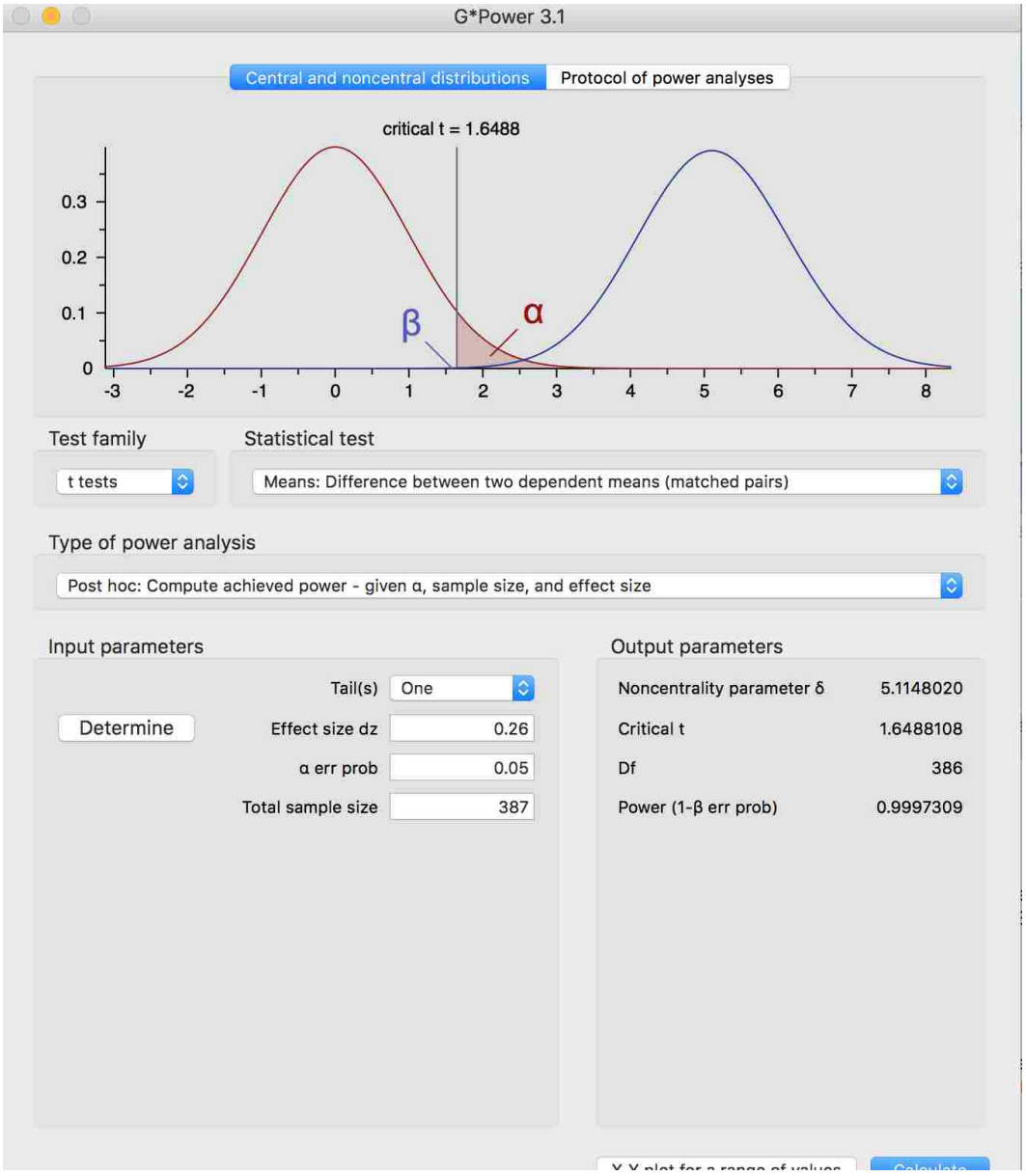


Figure 19. The G-Power post-hoc analysis for the MICU sample shows that power is .99. This exceeds the accepted value of power = .80. The power obtained was sufficient.

SICU effect size

d = *t* / √N

= 8.51/√292

= 0.49 (This is a medium effect size.)

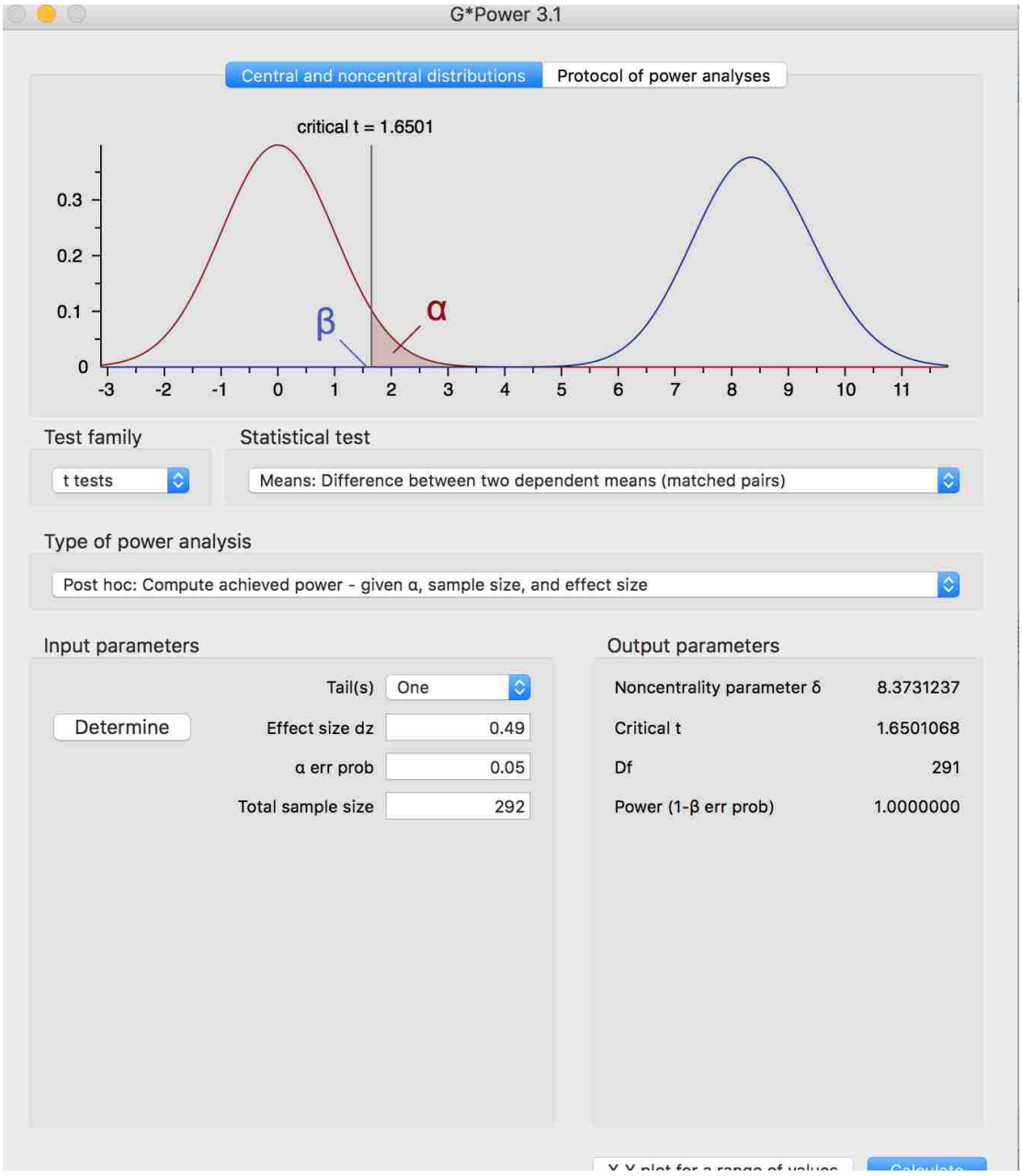


Figure 20. The G-Power post-hoc analysis for the SICU sample shows that power is 1.00. This exceeds the accepted value of power = .80. The power obtained was sufficient.

Primary Research Question- 4 Is standardized early mobilization protocol (Red-Yellow-Green system) administered from ICU admission to discharge effective in decreasing agitation and sedation in ICU patients as measured by Richmond agitation and sedation scale- RASS?

To answer RQ 5 non parametric test the Wilcoxon Signed- Rank test is used to determine whether the final RASS score is different from the initial RASS score. Analysis was performed separately for Medical (MICU) and Surgical (SICU). Following assumptions were checked before the Wilcoxon test was conducted. Wilcoxon Signed- Rank test requires that the data are, "at least ordinal" (Cronk, 2014, p. 105). For this problem, initial and final RASS scores meet this assumption. I initial and final RASS scores are paired sample and the sample data have been randomly selected. The differences between initial and final RASS score has a distribution that is not approximately symmetric, this assumption is violated which can be observed in the box plot below (Figure 21 and Figure 22)

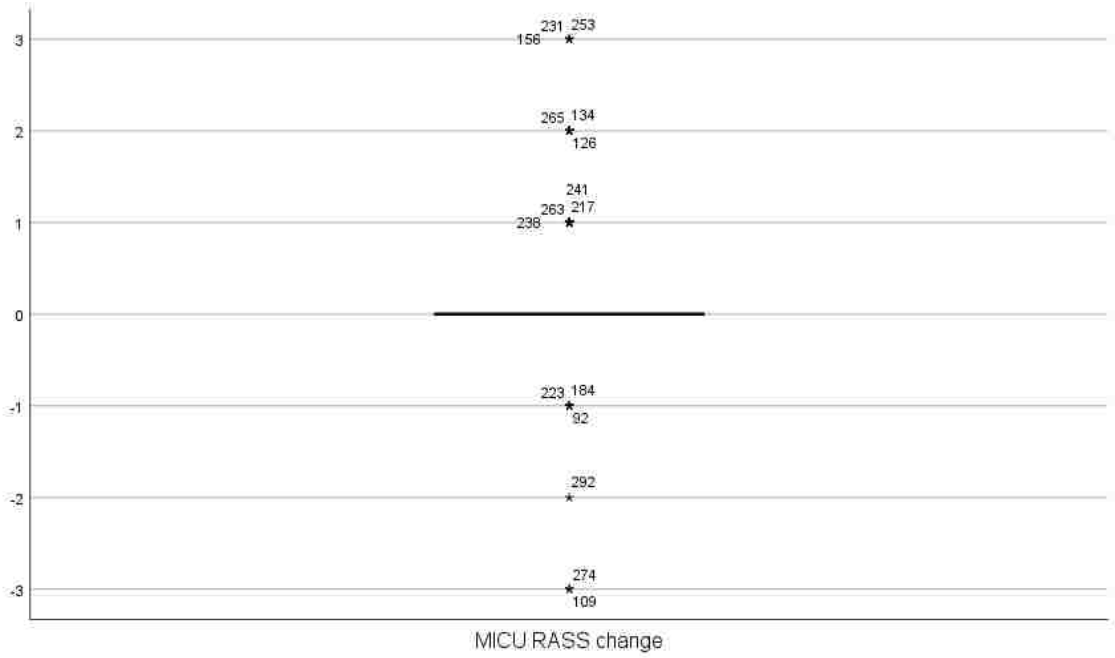


Figure 21. The box plot for the difference in RASS score for MICU is not symmetric and there are outliers

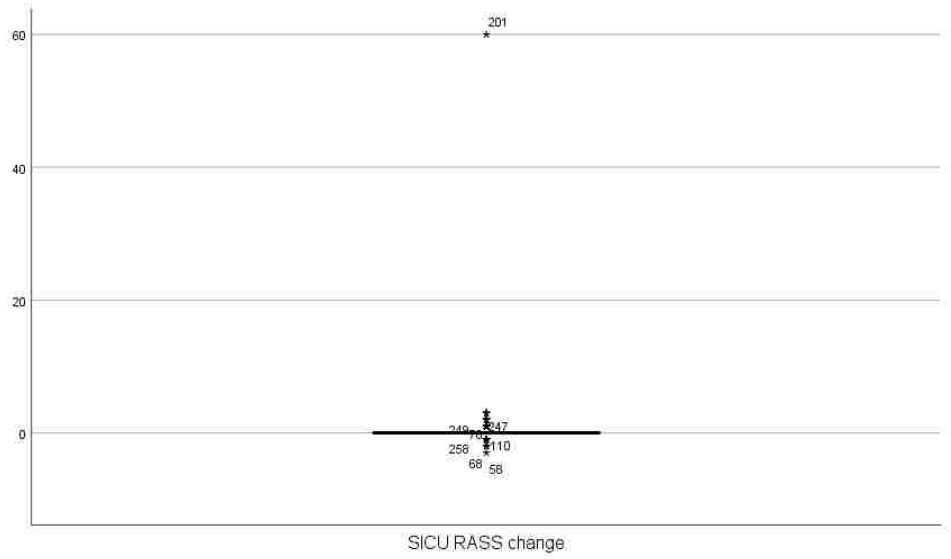


Figure 22. The box plot for the difference in RASS score for SICU is not symmetric and there are outliers

As per table 19, for MICU, the mean median for the Initial RASS score (n=388) was -.27 and the standard deviation was .91. The mean median for the Final RASS score (n=388) was -.21 and the standard deviation was .84. For SICU, the mean median for the Initial RASS score (n=293) was -.17 and the standard deviation was .69. The mean median for the Final RASS score (n=293) was .10 and the standard deviation was 3.54.

Table 19

Descriptive Statistics for the initial and Final RASS score of both MICU and SICU

	N	Mean	Std. Deviation	Minimum	Maximum
MICU Initial- RASS	388	-.27	.911	-5	4
SICU Initial- RASS	293	-.17	.699	-5	2
MICU Final- RASS	388	-.21	.846	-5	4
SICU Final- RASS	293	.10	3.544	-5	60

As shown in table 20, a Wilcoxon signed ranks test examined the results of the initial and final RASS score. For MICU significant difference was found in the results (Z = -2.27, p = .023). Initial RASS scores were significantly different from the final RASS scores. For SICU non-significant difference was found in the results (Z = -1.83, p = .067). Initial RASS scores were not significantly different from the final RASS scores.

Table 20

Wilcoxon Signed-Rank Test Summary

	MICU Final- RASS - MICU Initial- RASS	SICU Final- RASS - SICU Initial- RASS
Z	-2.272[b]	-1.832[b]
Asymp. Sig. (2-tailed)	.023	.067

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

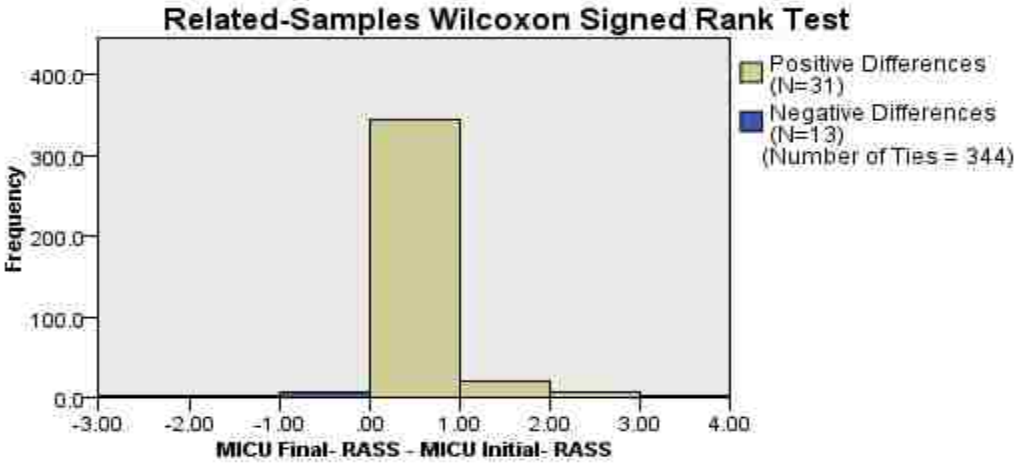
Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The median of differences between MICU Initial- RASS and MICU Final- RASS equals 0.	Related-Samples Wilcoxon Signed Rank Test	.023	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Figure 23. The null hypothesis for this problem is that the initial and final RASS score are the same. H_0 is $\mu_1 = \mu_2$. The alternative hypothesis for this problem is that final RASS scores are different than the initial RASS scores. The H_a is $\mu_1 \neq \mu_2$, which indicates a two tailed test. This figure below shows the two-tailed significance level obtained from the Wilcoxon signed rank test. The results show that the two-tailed p = .023, is significant at the $p < .05$ level. Therefore,

the null hypothesis is rejected. That is, there is significant difference in MICU initial and final RASS scores.



Total N	388
Test Statistic	682.500
Standard Error	82.534
Standardized Test Statistic	2.272
Asymptotic Sig. (2-sided test)	.023

Figure 24. A Wilcoxin test examined the results of the initial and final RASS score A significant difference was found in the results (Z= 2.27, $p < .05$). Final RASS score (Mean median= -.21, SD .84) were different than the initial RASS score (Mean median= -.27, SD .91)

Effect size:

r = Z/√n

= -2.27/√388

= 0.11(absolute value). This is a small effect size

Figure 25. The G-Power post-hoc analysis for the sample shows that power is .56. This is below the accepted value of power = .80. This sample size was not large enough.

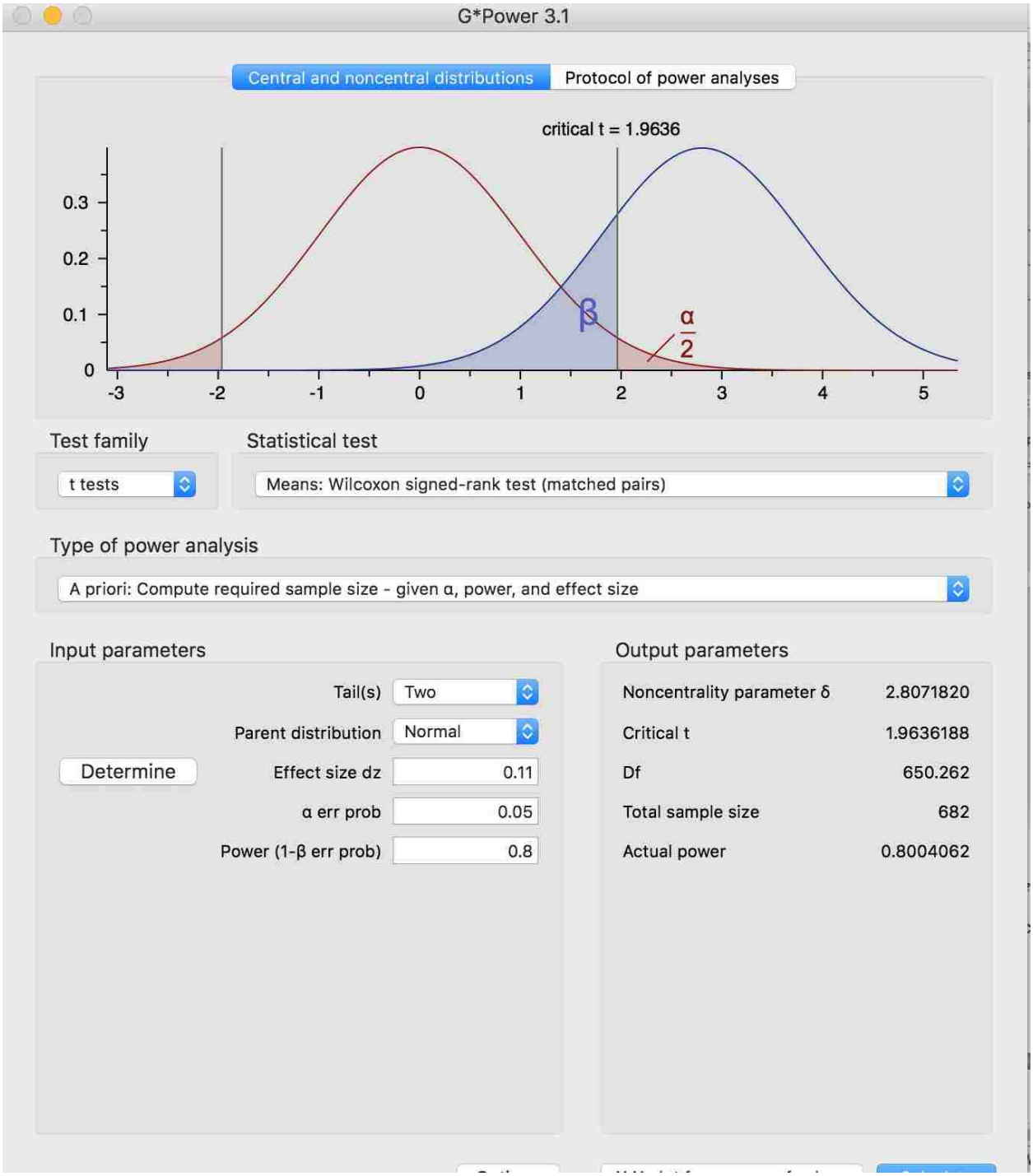


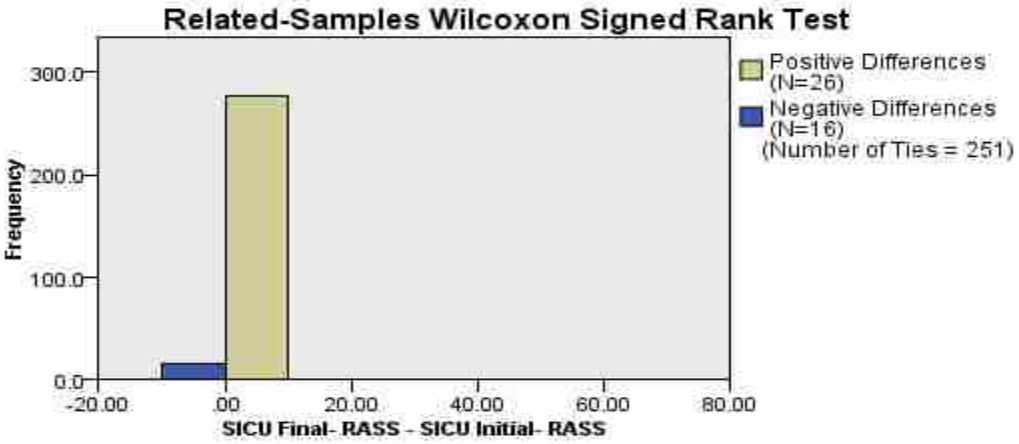
Figure 26. The G-Power A priori analysis shows that much larger samples were needed to achieve the accepted value of power =. 80. To achieve actual power of .80, the study required a total sample size of 682.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The median of differences between SICU Initial- RASS and SICU Final-RASS equals 0.	Related-Samples Wilcoxon Signed Rank Test	.067	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Figure 27. The null hypothesis for this problem is that the initial and final RASS score are the same. H_0 is $\mu_1 = \mu_2$. The alternative hypothesis for this problem is that final RASS scores are different than the initial RASS scores. The H_a is $\mu_1 \neq \mu_2$, which indicates a two tailed test. This figure below shows the two-tailed significance level obtained from the Wilcoxon signed rank test. The results show that the two-tailed $p = .067$, which is not significant at the $p < .05$ level. Therefore, the null hypothesis is retained and fails to be rejected. That is, there is no significant difference in SICU initial and final RASS scores.



Total N	293
Test Statistic	592.500
Standard Error	76.984
Standardized Test Statistic	1.832
Asymptotic Sig. (2-sided test)	.067

Figure 28. A Wilcoxin test examined the results of the SICU initial and final RASS score A non-significant difference was found in the results (Z= 1.83, p = .067). For SICU, final RASS score (Mean median= .10, SD 3.54) were not significantly different than the initial RASS score Mean median= -.17, SD .69)

Effect size:

$r = Z/\sqrt{n}$

$= -1.83/\sqrt{293}$

= 0.10 (absolute value). This is a small effect size.

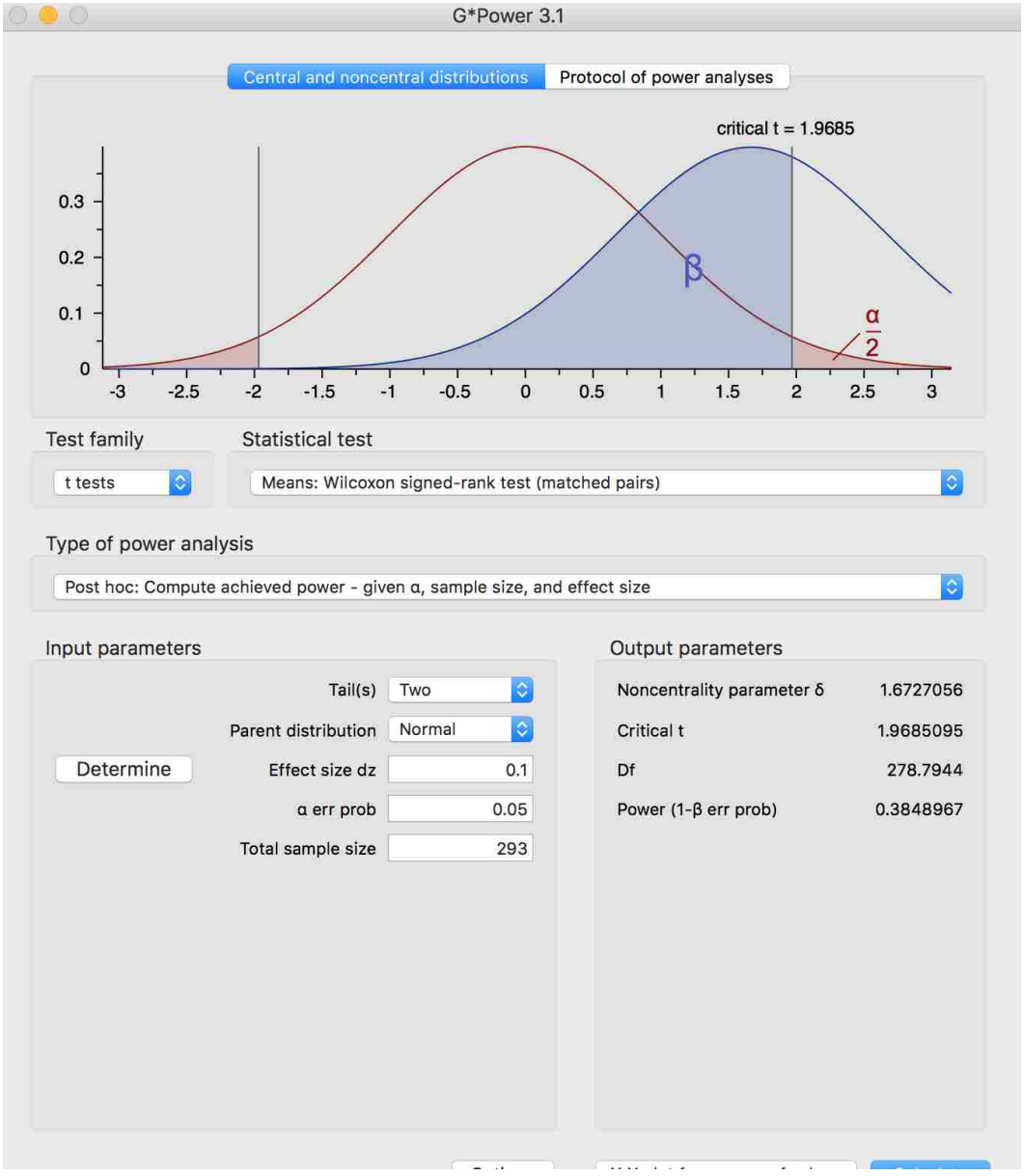


Figure 29. The G-Power post-hoc analysis for the sample shows that power is .38. This is below the accepted value of power = .80. This sample size was not large enough.

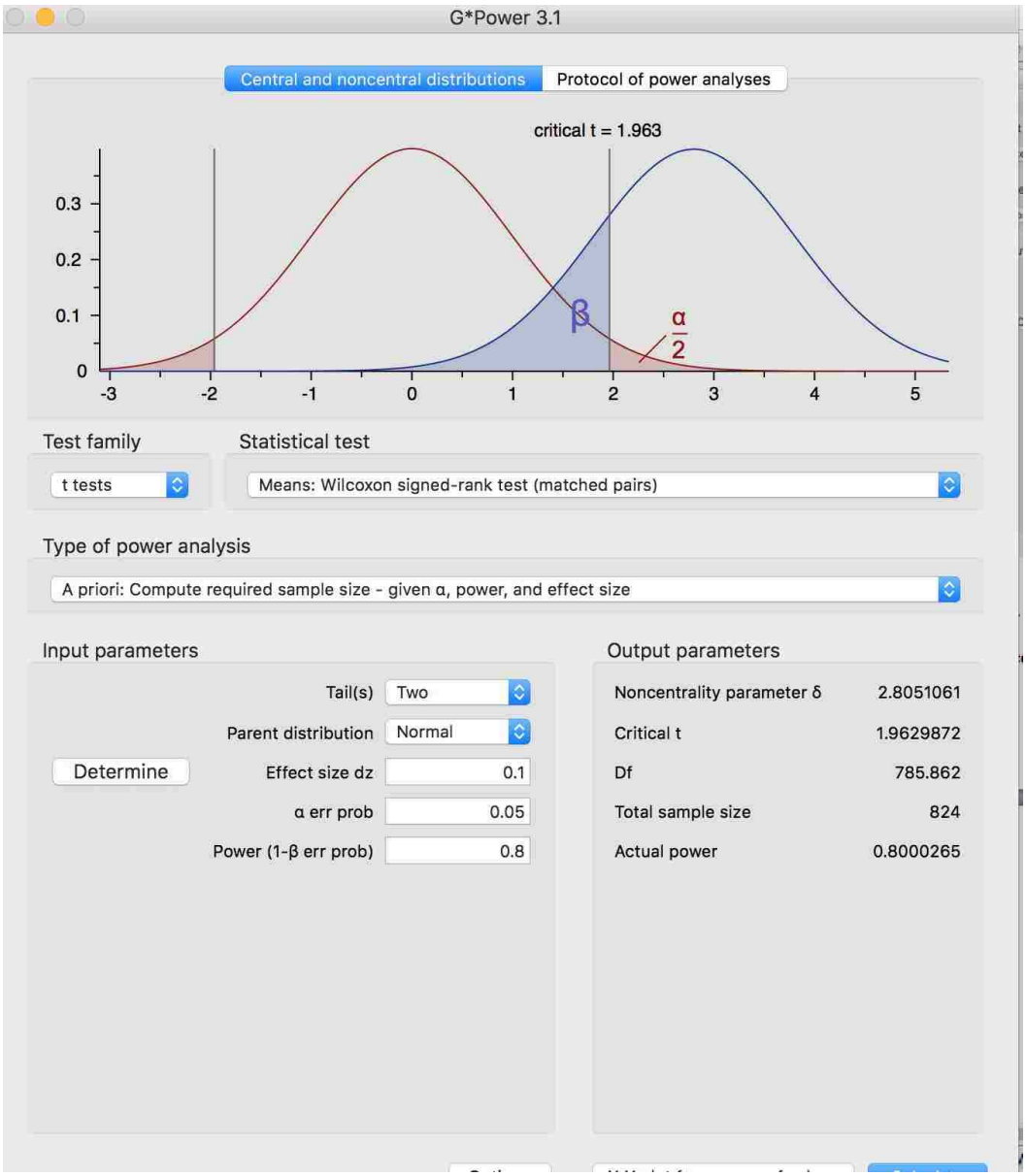


Figure 30. The G-Power A priori analysis shows that much larger samples were needed to achieve the accepted value of power =. 80. To achieve actual power of .80, the study required a total sample size of 824.

Final Interpretation:

A Wilcoxon signed ranks test examined the results of the initial and final RASS score. For MICU significant difference was found in the results. Final RASS scores (Mdn = - .21) were

significantly lower than the initial RASS score (Mdn = -.27), z = -2.27, p = .023, r = 0.11. For SICU no significant difference was found in the results. Final RASS scores (Mdn = .10) were not significantly different than the initial RASS score (Mdn = -.17), z = -1.83, p = .067, r = 0.10

To further analyze each category of RASS score, crosstabs were conducted for both MICU and SICU. Because RASS is a positive and negative scale where positive number means patients are agitated and the negative numbers means patients are sedated, it was hypothesized that upon discharge due less sedation requirements to participate in early mobilization more patients will have RASS score clustered in the middle at the score of 0 (alert and calm) which can be observed in the clustered chart below for both MICU and SICU:

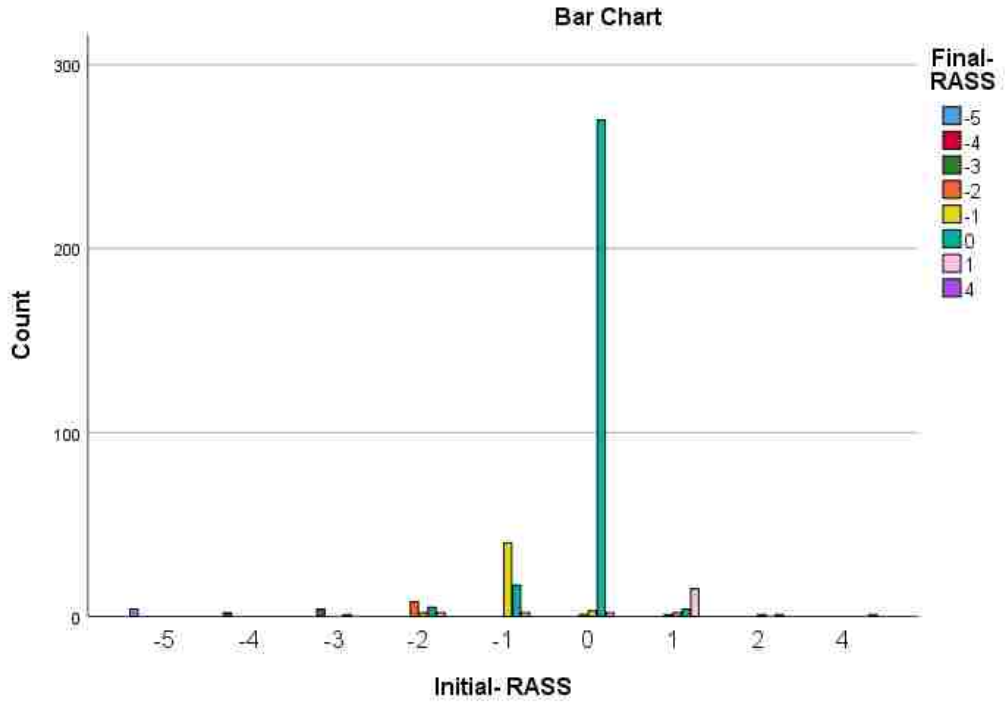


Figure 31. MICU clustered bar chart indicating the majority of the RASS score clustered towards middle at score 0. Which means upon discharge majority of the patients were alert and calm?

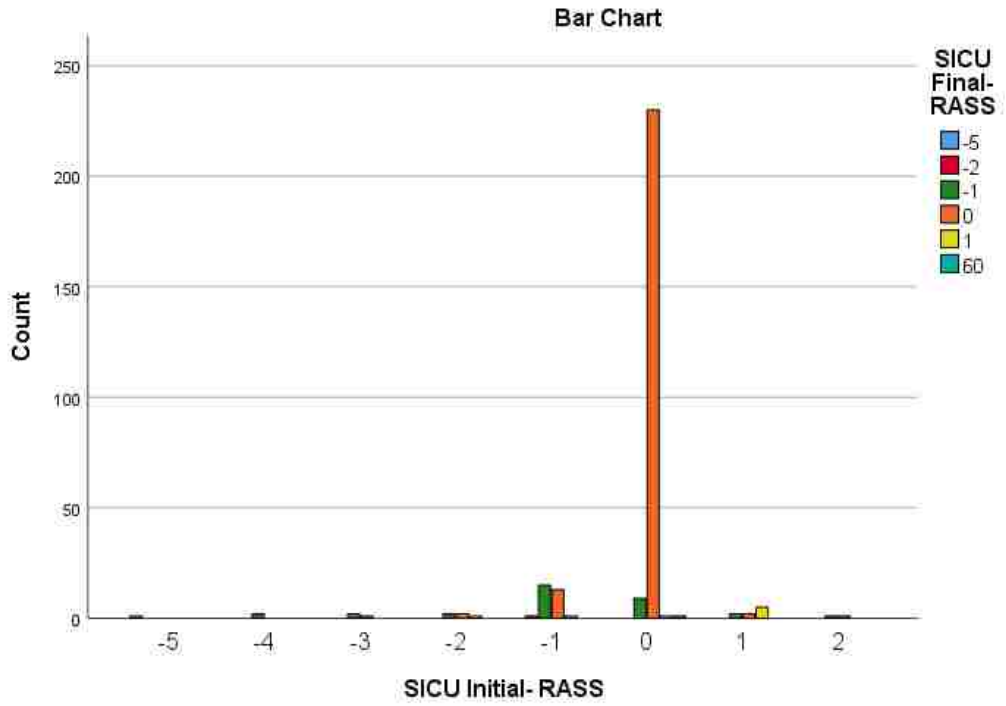


Figure 32. SICU clustered bar chart indicating the majority of the RASS score clustered towards middle at score 0. Which means upon discharge majority of the patients were alert and calm.

Research Question- 5: Is standardized early mobilization protocol (Red-Yellow-Green system) administered from ICU admission to discharge effective in decreasing ICU acquired delirium as measured by CAM- ICU?

To answer RQ6 the McNemar test is used to determine whether the proportion of participants with negative score on initial CAM-ICU assessment is different from the proportion of participants with negative score for final CAM-ICU assessment. Analysis was performed separately for Medical (MICU) and Surgical (SICU). McNemar test is used to test the hypothesis if the proportion of patients with negative CAM-ICU score (less confusion) is different upon final CAM-ICU assessment compared to initial CAM-ICU assessment. Following assumptions were checked before the McNemar test was conducted. McNemar test requires that the data are Nominal. For this question the initial and final CAM-ICU score meets this assumption. There is one categorical dependent variable with two categories (i.e. dichotomous variable) and one categorical independent variable with two related groups (Initial and final CAM ICU assessment). Here the initial and final CAM-ICU scores have 2 categories (positive and negative). The two groups of the dependent variable must be mutually exclusive.

As per table 21, for MICU, the mean proportion for the Initial CAM-ICU score (n=388) is 1.65 and the standard deviation is .47. The mean proportion for the Final CAM-ICU score (n=388) is 1.81 and the standard deviation is .39. For SICU, the mean proportion for the Initial CAM-ICU (n=293) is 1.83 and the standard deviation was .37. The mean proportion for the Final CAM-ICU score (n=293) is1.82 and the standard deviation is .38.

Table 21.

Descriptive statistics for the initial and final CAM-ICU score for MICU and SICU

		MICU Initial-CAM-ICU	MICU Final-CAM-ICU	SICU Initial-CAM-ICU	SICU Final- CAM-ICU
N	Valid	388	388	293	293
	Missing	0	0	95	95
Mean		1.65	1.81	1.83	1.82
Std. Error of Mean		.024	.020	.022	.023

Median	2.00	2.00	2.00	2.00
Mode	2	2	2	2
Std. Deviation	.478	.391	.377	.386
Variance	.228	.153	.142	.149
Skewness	-.629	-1.602	-1.760	-1.667
Std. Error of Skewness	.124	.124	.142	.142
Kurtosis	-1.613	.570	1.105	.783
Std. Error of Kurtosis	.247	.247	.284	.284
Range	1	1	1	1
Minimum	1	1	1	1
Maximum	2	2	2	2

As shown in table 22, in MICU, 98.4% of the patients that did not have pretest confusion, they did not have posttest confusion as well. 49.3% of the patients that did have pretest confusion, did not have post test confusion.

Table 22

MICU Crosstabulation

			MICU Final- CAM-ICU		
			POSITIVE	NEGATIVE	Total
MICU Initial- CAM-ICU	POSITIVE	% within MICU Initial- CAM-ICU	50.7%	49.3%	100.0%
		% within MICU Final- CAM-ICU	94.5%	21.3%	35.1%
	NEGATIVE	% within MICU Initial- CAM-ICU	1.6%	98.4%	100.0%
		% within MICU Final- CAM-ICU	5.5%	78.7%	64.9%
Total		% within MICU Initial- CAM-ICU	18.8%	81.2%	100.0%
		% within MICU Final- CAM-ICU	100.0%	100.0%	100.0%

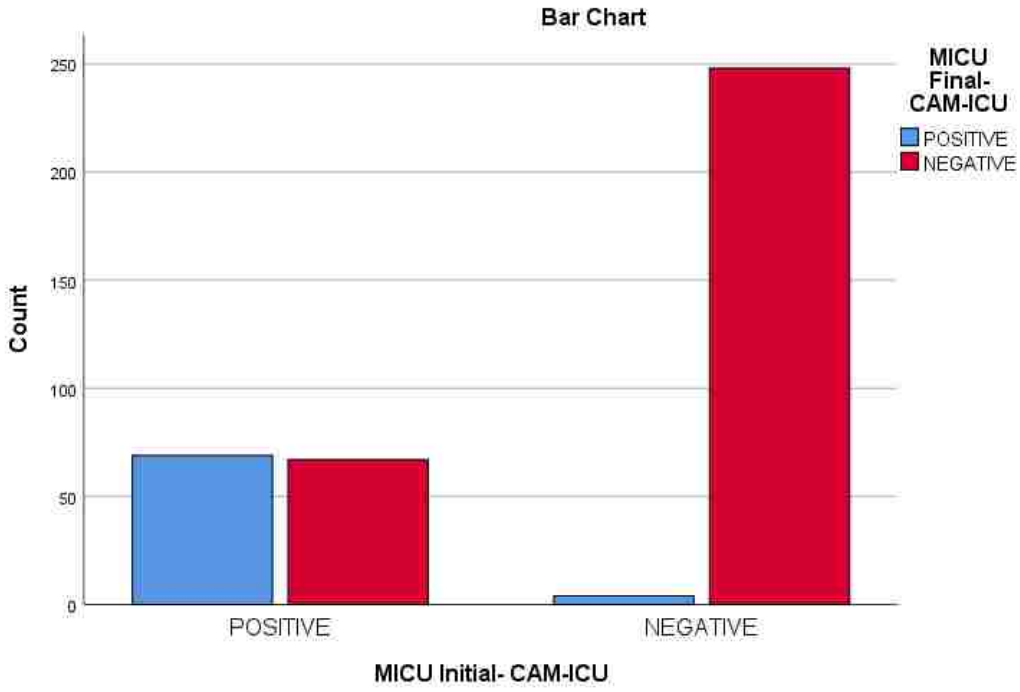


Figure 33. Visual representation of the clustered bar chart showing that upon discharge more patients scored negative in CAM –ICU indicating that patients had less confusion upon discharge.

As per table 22, out of 388 patients, 71 patient's scores changed during the final CAM-ICU assessment compared to initial assessment. Of these, significantly more patients (n= 67) changed their score from positive to negative, than from negative to positive (n=4).

Table 23

MICU initial and final CAM ICU contingency table

	MICU Final- CAM-ICU	
MICU Initial- CAM-ICU	POSITIVE	NEGATIVE
POSITIVE	69	67
NEGATIVE	4	248

The table 24 shows that $\chi 2$ (1, N=388) = 54.14, $p < .001$ which is less than 0.05. Hence we can reject the null hypothesis. There is a significant difference between MICU initial and final CAM-ICU scores. The proportion of patients with negative CAM ICU (no confusion) is significantly different during the ICU discharge compared to ICU admission.

Table 24

MICU McNemar Test summary (Chi- Square Tests)

	Value	Exact Sig. (2-sided)
McNemar Test		.000[a]
N of Valid Cases	388	

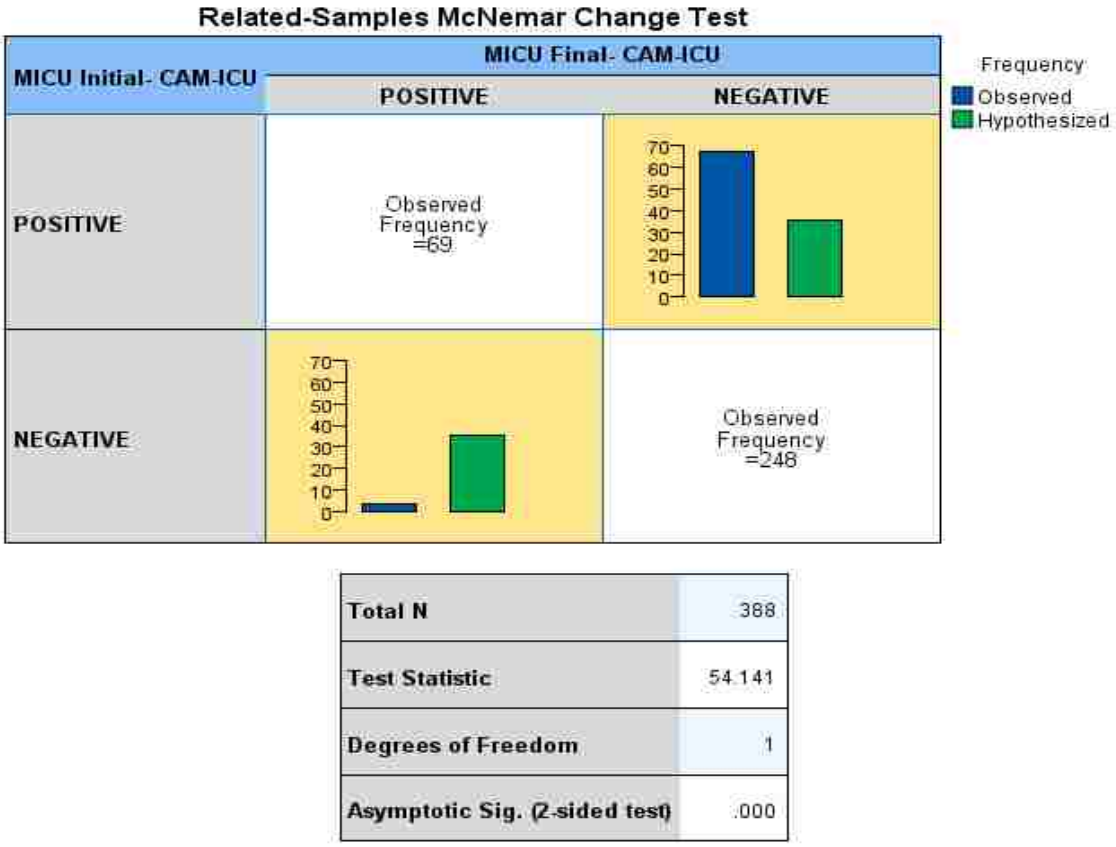
a. Binomial distribution used.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distributions of different values across MICU Initial- CAM-ICU and MICU Final- CAM-ICU are equally likely.	Related-Samples McNemar Test	.000	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Figure 34. For MICU the null hypothesis for this problem is that there is no significant difference in the proportion of the patients that scored negative in CAM upon ICU discharge compared to ICU admission. H_0 is $\mu_1 = \mu_2$. The alternative hypothesis for this problem is that there is significant difference at the two measurement points. The H_a is $\mu_1 \neq \mu_2$, which indicates a two-tailed test. This figure shows the two-tailed significance level obtained from the McNemar test. The results show that the two-tailed $p < .001$, is significant at the $p < .05$ level. Therefore, the null hypothesis is rejected. That is, there is significant difference in MICU initial and final CAM ICU scores



Total N	388
Test Statistic	54.141
Degrees of Freedom	1
Asymptotic Sig. (2-sided test)	.000

Figure 35. A Mc Nemar test examined the results of initial and final CAM-ICU scores. A significant difference was found in the results (Z= 54.14, $p < .001$). The proportion of the patients with negative CAM- ICU score were significantly different during ICU discharge than the admission.

Effect size

$r = Z/\sqrt{n}$

$= 54.14/\sqrt{388}$

= 2.74 (This is a large effect size)

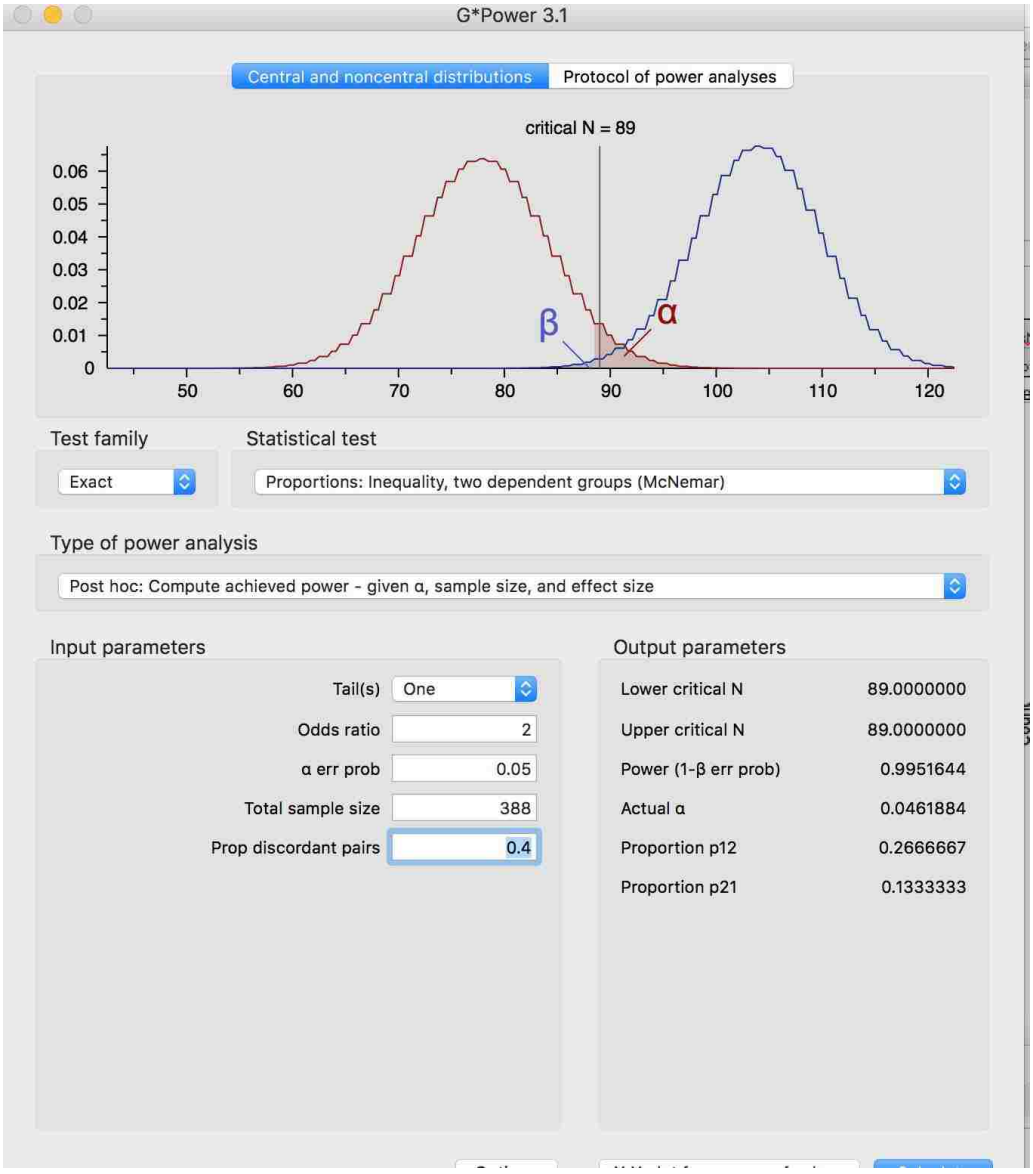


Figure 36. The G-Power post-hoc analysis for the MICU sample shows that power is 0.99. This exceeds the accepted value of power = .80. The power obtained was sufficient.

SICU analyses

As shown in table 25, in SICU, during admission for the initial CAM ICU assessment, 94.2 % of the patients that did not have pretest confusion, they did not have posttest confusion as well. 22 % of the patients that did have pretest confusion, did not have posttest confusion

Table 25

SICU Crosstabulation

			SICU Final- CAM-ICU		
			POSITIVE	NEGATIVE	Total
SICU Initial-CAM-ICU	POSITIVE	% within SICU Initial-CAM-ICU	78.0%	22.0%	100.0%
		% within SICU Final-CAM-ICU	73.6%	4.6%	17.1%
	NEGATIVE	% within SICU Initial-CAM-ICU	5.8%	94.2%	100.0%
		% within SICU Final-CAM-ICU	26.4%	95.4%	82.9%
Total		% within SICU Initial-CAM-ICU	18.1%	81.9%	100.0%
		% within SICU Final-CAM-ICU	100.0%	100.0%	100.0%

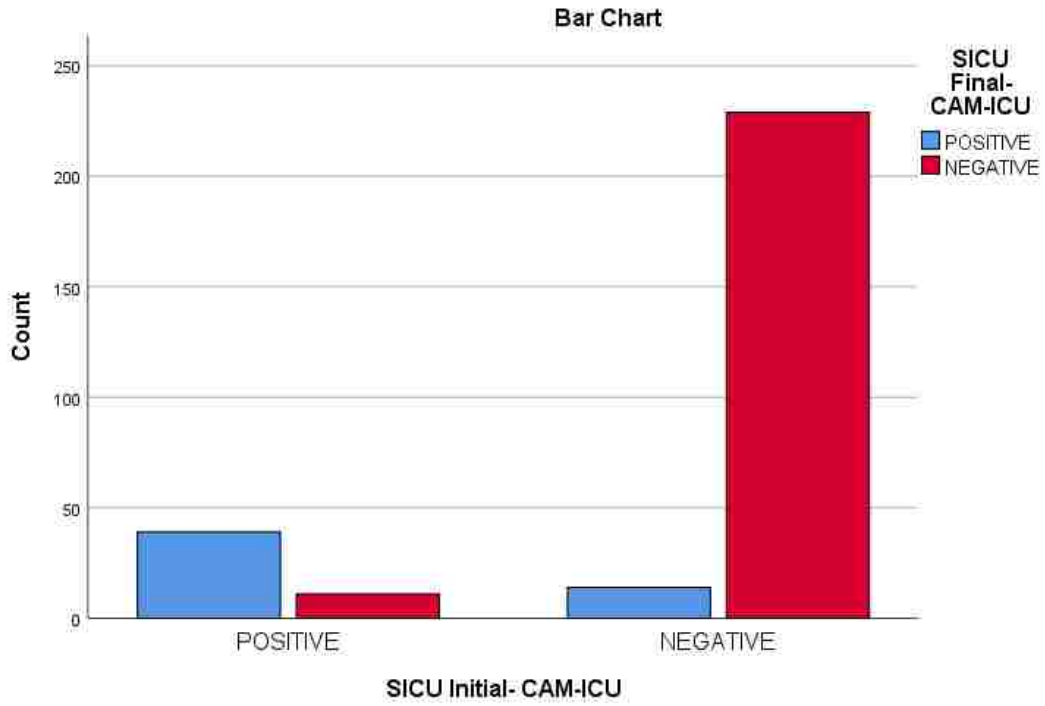


Figure 37. Visual representation of the clustered bar chart showing that upon discharge more patients scored negative in CAM –ICU indicating that patients had less confusion upon discharge.

As per table 26, out of 293 patients, 25 patient's scores changed during the final CAM-ICU assessment compared to initial assessment. Of these, less patients (n= 11) changed their score from positive to negative, than from negative to positive (n=14)

Table 26

SICU initial and final CAM ICU contingency table

	SICU Final- CAM-ICU	
SICU Initial- CAM-ICU	POSITIVE	NEGATIVE
POSITIVE	39	11
NEGATIVE	14	229

The table 27 shows that $\chi 2$ (1, N=293) = 0.16, p = .690 which is more than 0.05. Hence we fail to reject the null hypothesis. There is no significant difference between SICU initial and final CAM-ICU scores. The proportion of patients with negative CAM ICU (no confusion) is not significantly different during the ICU discharge compared to ICU admission.

Table 27

SICU McNemar test summary (Chi-square tests)

	Value	Exact Sig. (2-sided)
McNemar Test		.690[a]
N of Valid Cases	293	

a. Binomial distribution used.

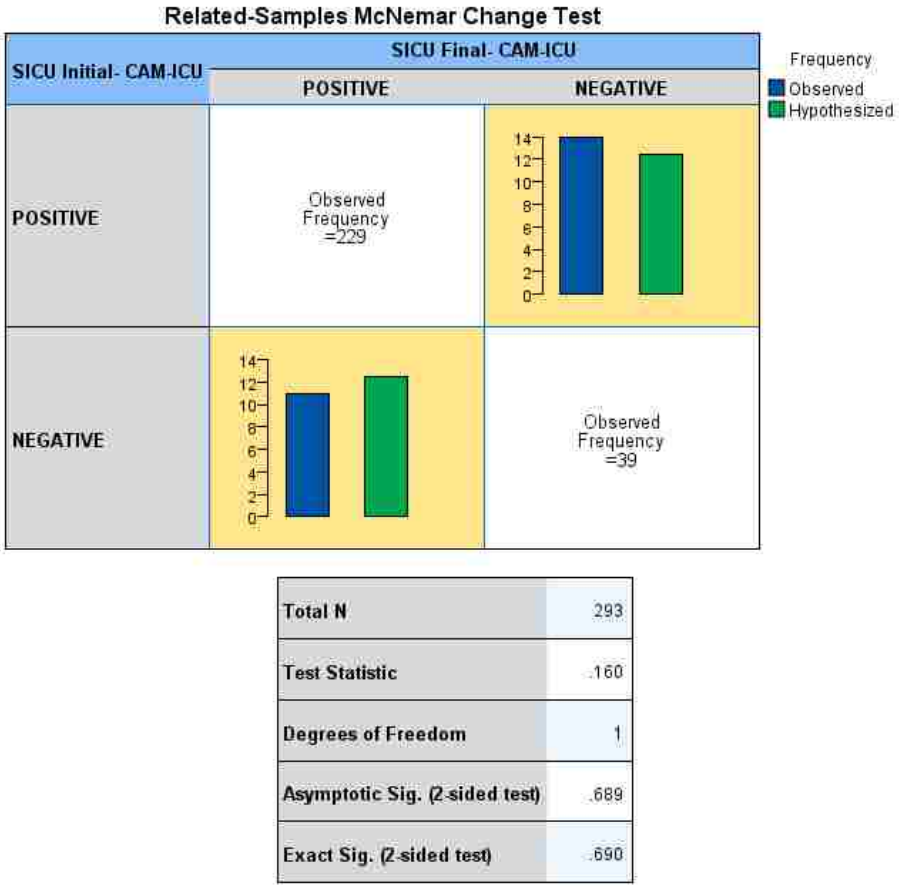
Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distributions of different values across SICU Initial- CAM-ICU and SICU Final- CAM-ICU are equally likely.	Related-Samples McNemar Test	.690[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1] Exact significance is displayed for this test.

Figure 38. For SICU the null hypothesis for this problem is that there is no significant difference in the proportion of the patients that scored negative in CAM upon ICU discharge compared to ICU admission. H_0 is $\mu_1 = \mu_2$. The alternative hypothesis for this problem is that is that there is significant difference at the two measurement points. The H_a is $\mu_1 \neq \mu_2$, which indicates a two-tailed test. This figure shows the two-tailed significance level obtained from the McNemar test. The results show that the two-tailed p = .690, which is not significant at the $p < .05$ level. Therefore, we fail to reject the null hypothesis. That is, there is no significant difference in SICU initial and final CAM ICU scores



Total N	293
Test Statistic	.160
Degrees of Freedom	1
Asymptotic Sig. (2-sided test)	.689
Exact Sig. (2-sided test)	.690

1. The exact p-value is computed based on the binomial distribution because there are 25 or fewer records.

Figure 39. A McNemar test examined the results of initial and final CAM-ICU scores. A non-significant difference was found in the results (Z= .160, p = .690). The proportion of the patients with negative CAM- ICU score were not significantly different during discharge than the admission

Effect size

$r = Z/\sqrt{n}$

$= .160/\sqrt{293}$

= 0.009 (This is a very small effect size)

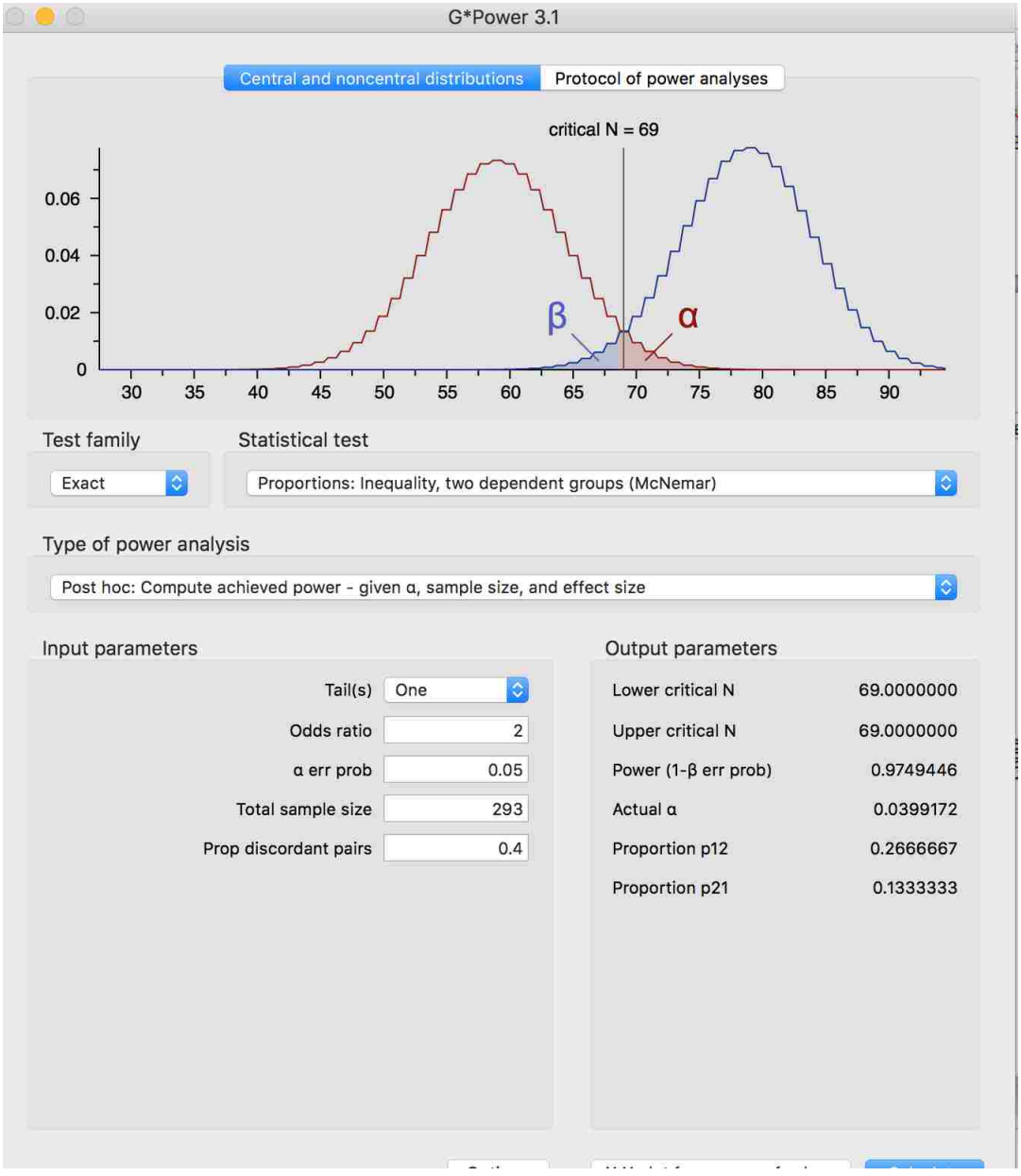


Figure 40. The G-Power post-hoc analysis for the MICU sample shows that power is 0.97. This exceeds the accepted value of power = .80. The power obtained was sufficient.

Primary Functional Outcomes Summary Table:

Table 28 below summarizes the statistical analysis for MICU for functional and behavioral outcomes.

Table 28.

Medical ICU Functional and Behavioral Measures during the Early Mobilization Period (Pretest- post test data)

MICU Outcome Measures	**Initial Score n = 388**	**Final Score n = 388**	**Mean change**	**Test statistic/ *p* Value**	**Effect size**	**Power**
Functional Measures						
ICU mobility scale (IMS)	5.89 (sd = 2.60)	6.22 (sd = 2.52).	.33 (sd = 1.43)	$t(387) = 4.51$, $p < .001$	$d = 0.22$ (small)	.99
Functional status score-ICU (FSS-ICU)	14.51 (sd = 9.17)	15.51 (sd = 9.10).	.99 (sd = 3.47)	$t(387) = 5.64$, $p < .001$	$d = 0.28$(small)	.99
AMPAC Mobility Scale	12.57 (sd = 4.78)	13.06 (sd = 4.75).	0.49 (sd = 1.86)	$t(387) = 5.23$, $p < .001$	$d = 0.26$(small)	.99
Behavioral Measures						
RASS	-.27 (sd = .91)	-.21 (sd = .84)	-0.06	$Z = -2.27$, $p = .023$	$r = 0.11$ (small)	0.56
CAMICU – Percent negative	1.65 (sd= .47) 49.3% negative	1.81(sd =.39 78.7% negative	29.4% improvement	$\chi 2$ (1, N=388) = 54.14, $p < .001$	$r = 2.74$ (large)	0.99

Table 29 below summarizes the statistical analysis for SICU for functional and behavioral outcomes.

Table 29.

Surgical ICU Functional and Behavioral Measures during the Early Mobilization Period (Pretest- post test data)

SICU Outcome Measures	**Initial Score n = 293**	**Final Score n = 293**	**Mean change**	**Test stastistic/ *p* Value**	**Effect size**	**Power**
Functional Measures						
ICU mobility scale (IMS)	6.18 (*sd* = 2.57).	7.11 (*sd* = 2.29).	.92 (sd = 1.81)	*t*(292) = 8.71, *p* < .001	*d= 0.50 (medium)*	*1.00*
Functional status score-ICU (FSS-ICU)	16.54 (*sd* = 8.78)	19.02 (*sd* = 8.83).	2.48 (sd = 4.92)	*t*(292) = 8.64, *p* < .001	*d= 0.50 (medium)*	1.00
AMPAC Mobility Scale	13.83 (*sd* = 4.58)	15.22 (*sd* = 4.78)	1.38 (sd = 2.78)	*t* (292) = 8.51, *p* < .001	*d= 0.49(medium)*	1.00
Behavioral Measures						
RASS	-.17 (sd = .69)	.10(sd= 3.54)	-0.27	Z = -1.83, *p* = .067	*r* =1.10 (small)	0.38
CAMICU – Percent negative	1.83 (sd= .37) 22.0 % negative (	1.82 (sd=.38) 95.4 % negative.	73.4 % improvement	$\chi 2$ (1, N=293) = 0.16, *p* =.690	*r* = 0.009 (very small)	0.97

Secondary outcomes data analysis: Between group analysis was conducted between early mobilization and historical comparison group to answer research question 6 and 7.

Patient's demographics

For MICU, the total sample size from early mobilization group was N= 388, with the average age of 71.2 years. 51.03 % (n= 198) of the sample was male and 48.96% (n= 190) was female. The total sample size from comparison group was N= 480, with the average age of 69.2 years. 46.25 % (n= 222) of the sample was male and 53.75% (n= 258) was female. For SICU, the total sample size from early mobilization group was N= 293, with the average age of 65.2 years. 57.33 % (n= 168) of the sample was male and 42.66% (n= 125) was female. The total sample size from comparison group was N= 291, with the average age of 64.4 years. 58.07 % (n= 169) of the sample was male and 41.92% (n= 122) was female. Proportions of the primary diagnosis for both MICU and SICU patients for early mobilization and comparison group is listed in the table 30 below.

Table 30.

Demographic Variables of Patients

Characteristic	Comparison group* - n (%)	Early Mobilization* - n (%)
N	MICU- 480 SICU – 291	MICU- 388 SICU- 293
Age (yr.) Mean	MICU- 69.2 SICU- 64.4	MICU – 71.2 SICU- 65.2
MICU Gender	Male- 222 (46.25%) Female- 258 (53.75 %)	Male- 198 (51.03 %) Female- 190 (48.96%)
SICU Gender	Male-169 (58.07 %) Female-122 (41.92 %)	Male-168 (57.33%) Female-125 (42.66 %)
MICU Primary diagnosis – n (%)	Pulmonary conditions- 192 (40%) Cardiac conditions- 188 (39.16 %)	Pulmonary conditions- 181 (46.64 %) Cardiac conditions- 124 (31.95 %)

	Neurological- 32 (6.66 %) Trauma- 4 (0.83 %) Post- operative- 6 (1.25 %) Other- 58 (12.08%)	Neurological- 18 (4.63 %) Trauma- 5 (1.28 %) Post- operative- 4 (1.03 %) Other- 56 (14.43%)
SICU Primary diagnosis – n (%)	Pulmonary conditions-12 (4.12 %) Cardiac conditions- 6 (2.06 %) Neurological- 98 (33.67 %) Trauma- 62 (21.30%) Post- operative- 78 (26.80 %) Other- 35 (12.02 %)	Pulmonary conditions- 10 (0.34%) Cardiac conditions- 2 (0.68 %) Neurological- 102 (34.81 %) Trauma- 82 (37.98%) Post- operative- 74 (25.25%) Other- 23 (7.84 %)

Research Question- 6: Is standardized early mobilization protocol administered in the ICU effective in decreasing ICU length of stay compared to the usual care historical comparison group from prior year?

To answer RQ6 an independent samples *t* test was calculated to compare the ICU length of stay for the early mobility group and the historical comparison group. Analysis was performed separately for Medical (MICU) and Surgical (SICU). Following assumptions were checked before the independent t- test was conducted. The two samples were independent- since each participant provided data for only one sample. The two groups (Early mobility group and comparison group) being compared were independent to each other. The two samples were random samples. The 2 samples were relatively equal in size. For MICU: Early mobility group n= 388 and historical comparison group n= 480; For SICU: Early mobility group n= 293 and historical comparison group n= 291. The dependent variable, length of stay (days) is measured is a ratio scale. The independent variable, MICU group has two discrete levels (historical comparison group and early mobility group). Since n > 30, we can assume normality of the dependent variable based on central limit theory. However, the normality tests are below:

MICU analyses

Table 31 shows values for skewness and kurtosis for the MICU LOS, which can be used to describe the distribution and test for normality. For historical comparison group the skewness is 1.33 which indicates that the sample is highly positive skewed. The kurtosis value is .28 which indicates a leptokurtic distribution. For Early mobility group the skewness is 2.14, which indicates that the distribution is highly positive skewed. The kurtosis value is 5.38, which indicates a leptokurtic distribution.

Table 31

Descriptive Statistics for the Sample

	MICU GROUPS			Statistic	Std. Error
MICU LOS-Days	HISTORICAL COMPARISON GROUP	Mean		2.94	.024
		95% Confidence Interval for Mean	Lower Bound	2.90	
			Upper Bound	2.99	
		5% Trimmed Mean		2.91	
		Median		2.93	
		Variance		.265	
		Std. Deviation		.515	
		Minimum		3	
		Maximum		4	
		Range		1	
		Interquartile Range		0	
		Skewness		1.335	.111
		Kurtosis		.289	.222
	EARLY MOBILITY GROUP	Mean		2.51	.110
		95% Confidence Interval for Mean	Lower Bound	2.30	
			Upper Bound	2.73	
		5% Trimmed Mean		2.23	
		Median		2.00	
		Variance		4.726	
		Std. Deviation		2.174	

	Minimum	1	
	Maximum	15	
	Range	14	
	Interquartile Range	2	
	Skewness	2.141	.124
	Kurtosis	5.389	.247

As shown in table 32, the sample size was large (n=480) so the Kolmogorov-Smirnov (K-S) test was used to test for normality of data. The K-S value for MICU LOS for the historical comparison is .32, and p <.001, which is significant. This means that historical control group data were assumed to be not normal. The K-S value for MICU LOS for the Early mobility group is .26, and p=.000 which is significant. The early mobility group data were also assumed to be not normal. The data did show some skew and kurtosis deviations and the K-S tests show that both samples did not met the normality assumption. However n>30 so as per central limit theorem normality is assumed (Fields, 2013). Therefore, an independent sample *t*-test may be used. The final assumption, homogeneity of variance, was tested via Levene's test when we ran the *t*-test.

Table 32

Tests of Normality for Historical comparison and Early mobility group

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	MICU GROUPS	Statistic	df	*p* value	Statistic	df	*p* value
MICU LOS- Days	HISTORICAL COMPARSION GROUP	.326	480	.000	.697	480	.000
	EARLY MOBILITY GROUP	.266	388	.000	.716	388	.000

a. Lilliefors Significance Correction

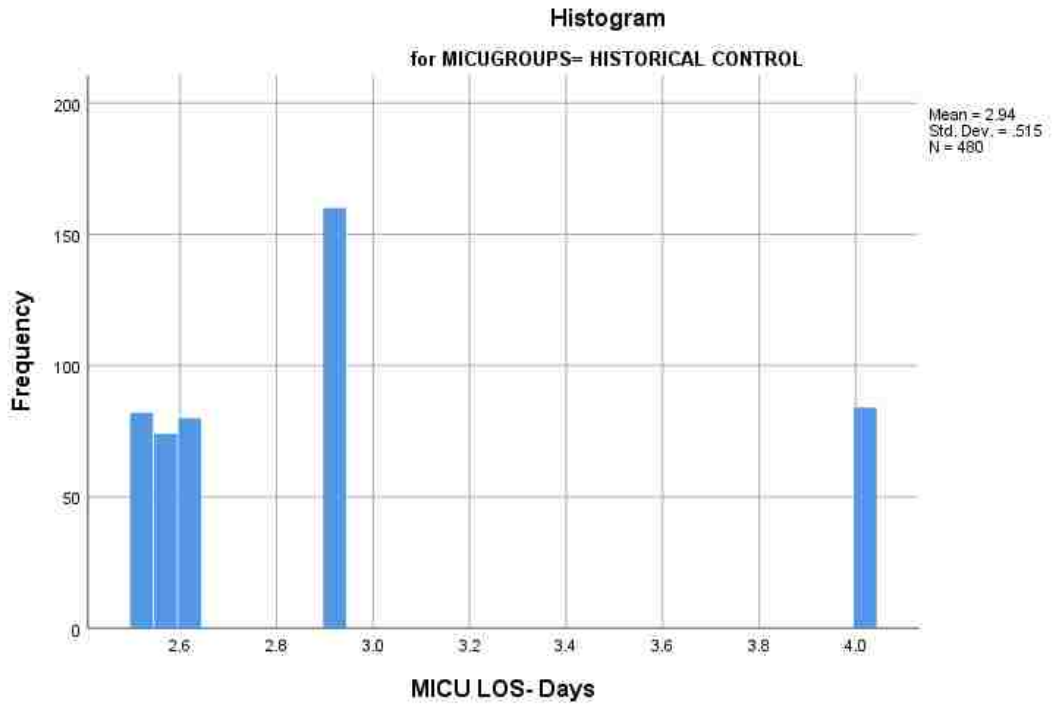


Figure 41. The histogram for historical comparison group shows positive skew and a leptokurtic distribution.

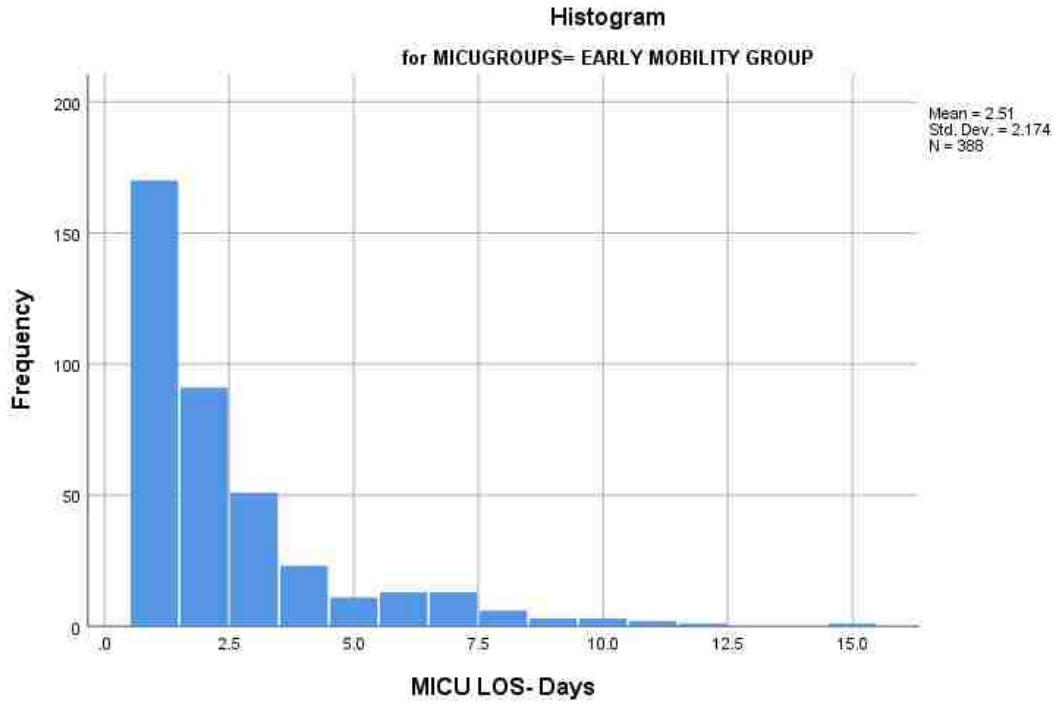


Figure 42. The histogram for the early mobility group shows positive skew and a leptokurtic distribution.

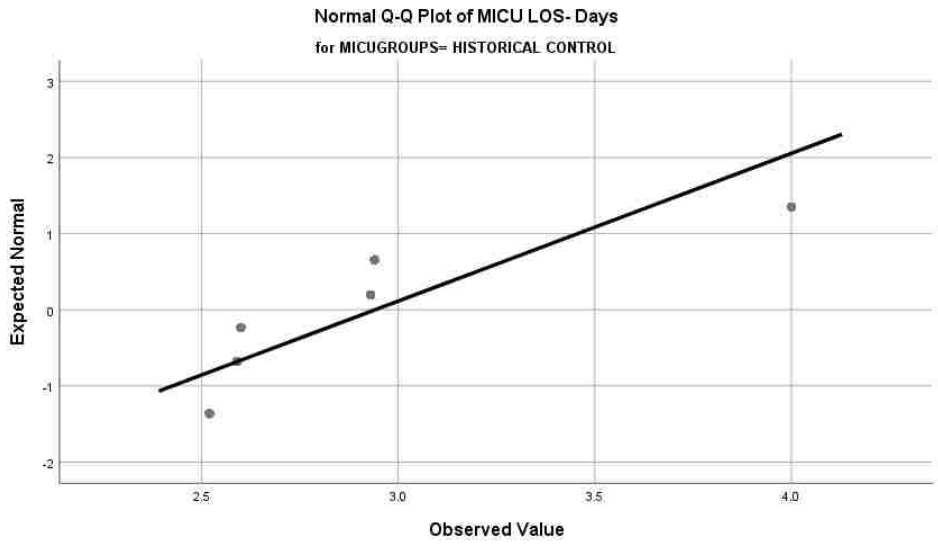


Figure 43. The Q-Q plot for the historical comparison group shows that the observed quantile points fall away from the expected quantiles (diagonal lines) indicating that the data points were skewed and not normally distributed

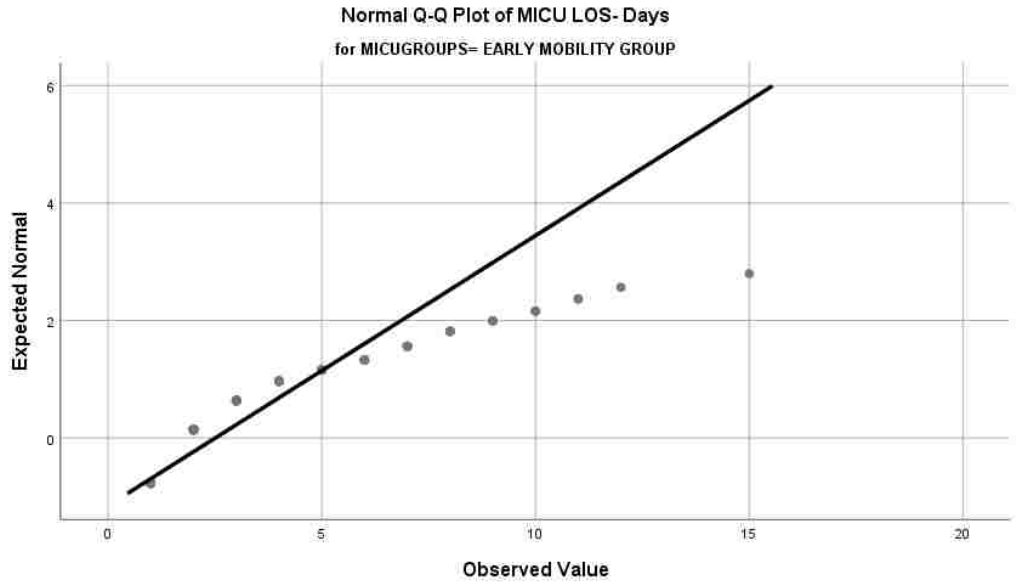


Figure 44. The Q-Q plot for the early mobility group shows that the observed quantile points fall away from the expected quantiles (diagonal lines) indicating that the data points were skewed and not normally distributed.

As per table 33, for MICU LOS mean of the historical comparison group was (M= 2.94, sd .51) and the mean of the Early mobility group was (M=2.51, sd= 2.17)

Table 33

Group Statistics for Historical comparison and Early mobility group

	MICU GROUPS	N	Mean	Std. Deviation	Std. Error Mean
MICU LOS- Days	HISTORICAL COMPARISON GROUP	480	2.94	.515	.024
	EARLY MOBILITY GROUP	388	2.51	2.174	.110

Table 34 shows the output for the indepenent sample *t*- test. To check the final assumption for homogenetity of variance, Levene's test was used. For this variable, the *p* value is significant ($p < .05$) which means the variances were not homogenous, F (480,388) = 283.16, p <.001. Hence the row "equal variances not assumed" was used to interpret the data.

The null hypothesis for this question was there is no significant difference in the MICU LOS mean between the historical comparison group and early mobility group. The alternative hypothesis for this problem was μ1>μ2 (MICU LOS of the historical comparison group is more than MICU LOS of the early mobility group). Therefore, it is a one tailed test. An independent-samples *t* test was calculated comparing the mean LOS days for the historical comparison group and early mobility group. Significant difference was found, t (422.2) = 3.79, $p < .001$ (p calculated as .000/2 since this is a one-tailed test). Hence we can reject the null hypothesis. The mean of the historical comparison group (M= 2.94, sd .51) was significantly higher than the mean of the Early mobility group (M=2.51, sd= 2.17)

Table 34

Output for Independent Samples t- test

		Levene's Test for Equality of Variances		t-test for Equality of Means							
									95% Confidence Interval of the Difference		
		F	*p* value	*t*	df	*p* value	Mean Difference	Std. Error Difference	Lower	Upper	Effect size	Power
MICU LOS-Days	Equal variances assumed	283.16	.000	4.17	866	.000	.429	.103	.227	.630		
	Equal variances not assumed			3.79	422.24	.000	.429	.113	.207	.650	*d* = 0.8 (large)	1.00

Effect size (*d*)

Here n1 is not equal to n2. Hence effect size is calculated by using Cohen's formula by using the pooled standard deviation.

d = mean1-mean2 / pooled standard deviation (standard deviation of control group)

$d = (x_1 - x_2) / sd$

= 0.43 / 0.51

= 0.84

This is a large effect size.

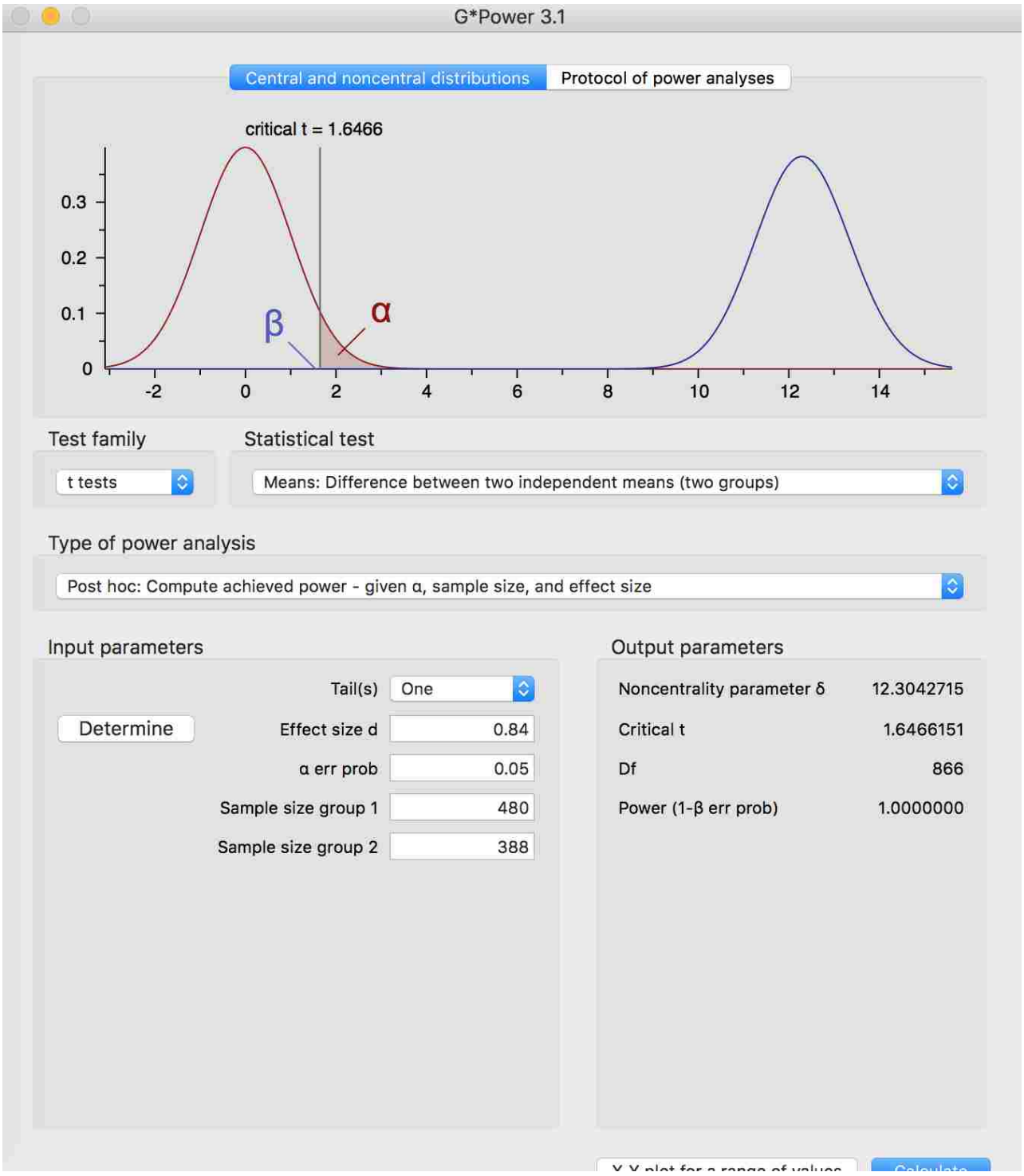


Figure 45. The effect size, *d*, was calculated as .84 (0.43/ 0.51). The G-Power post-hoc analysis for the sample shows that power is 1. This is above the accepted value of power = .80. This sample size was large enough.

SICU analyses

Table 35 shows values for skewness and kurtosis for the SICU LOS, which can be used to describe the distribution and test for normality. For historical comparison group the skewness is .174 which indicates that the sample is mildly positive skewed. The kurtosis value is -1.79 which indicates a platykurtic distribution. For early mobility group the skewness is 2.49 which indicates that the distribution is highly positive skewed. The kurtosis value is 7.33, which indicates a leptokurtic distribution.

Table 35

Descriptive Statistics for the Sample

	SICU GROUPS			Statistic	Std. Error
SICU LOS- Days	HISTORICAL COMPARISON GROUP	Mean		5.88	.082
		95% Confidence Interval for Mean	Lower Bound	5.72	
			Upper Bound	6.05	
		5% Trimmed Mean		5.87	
		Median		5.31	
		Variance		1.940	
		Std. Deviation		1.393	
		Minimum		4	
		Maximum		8	
		Range		3	
		Interquartile Range		3	
		Skewness		.174	.143
		Kurtosis		-1.798	.285
	EARLY MOBILITY GROUP	Mean		3.77	.251
		95% Confidence Interval for Mean	Lower Bound	3.28	
			Upper Bound	4.27	
		5% Trimmed Mean		3.14	
		Median		2.00	
		Variance		18.478	
		Std. Deviation		4.299	
		Minimum		1	

	Maximum	27	
	Range	26	
	Interquartile Range	3	
	Skewness	2.494	.142
	Kurtosis	7.332	.284

a. There are no valid cases for SICU LOS- Days when SICU GROUPS = .000. Statistics cannot be computed for this level.

As shown in table 36, the sample size was large (n=291for historical group and 293 for control group), so the Kolmogorov-Smirnov (K-S) test was used to test for normality of data. The K-S value for SICU LOS for the historical group is .261, and $p < .001$, which is significant. This means that the LOS data for the historical comparison group were assumed to be not normal. The K-S value for SICU LOS for early mobility group is .264, and $p < .001$, which is significant. The LOS data for the early mobility group were also assumed to be not normal. The data did show some skew and kurtosis deviations and the K-S tests did show that both samples did not met the normality assumption. However n > 30 so central limit theory applies and normality is assumed for the sample (Fields, 2013). Therefore, an independent sample t-test may be used. The final assumption, homogeneity of variance, will be tested via Levene's test when we run the t-test.

Table 36

Tests of Normality for the Historical comparison group and Early mobility group

		Kolmogorov-Smirnov[b]			Shapiro-Wilk		
	SICU GROUPS	Statistic	df	*p* value	Statistic	df	*p* value
SICU LOS- Days	HISTORICAL COMPARISON GROUP	.261	291	.000	.785	291	.000
	EARLY MOBILITY GROUP	.264	293	.000	.674	293	.000

a. There are no valid cases for SICU LOS- Days when SICU GROUPS = .000. Statistics cannot be computed for this level.

b. Lilliefors Significance Correction

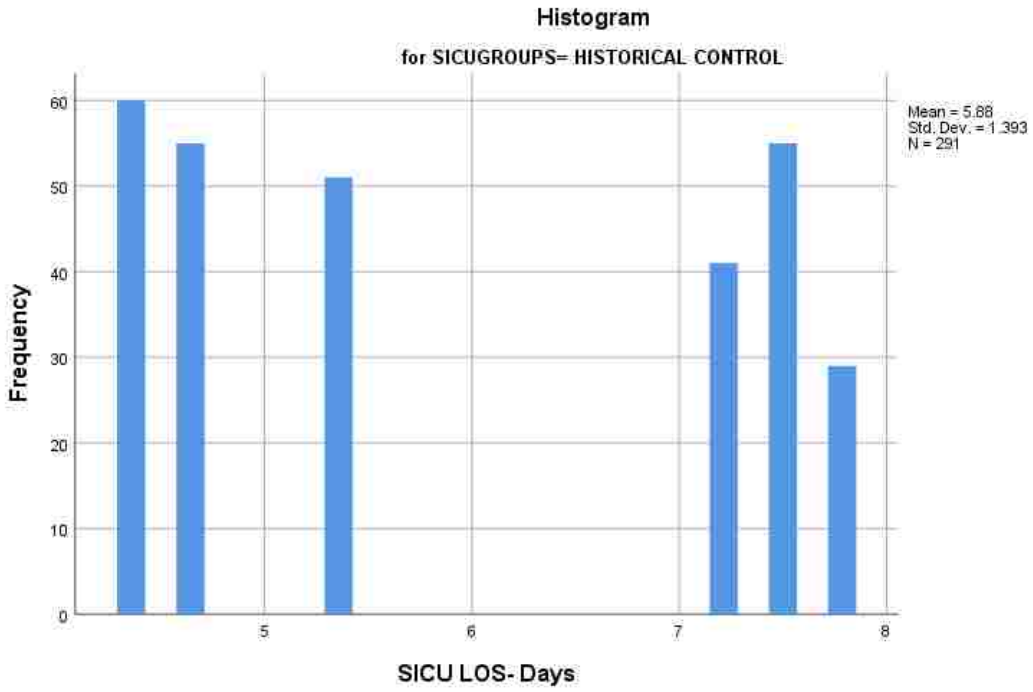


Figure 46. The histogram for historical comparison group shows positive skew and a platykurtic distribution.

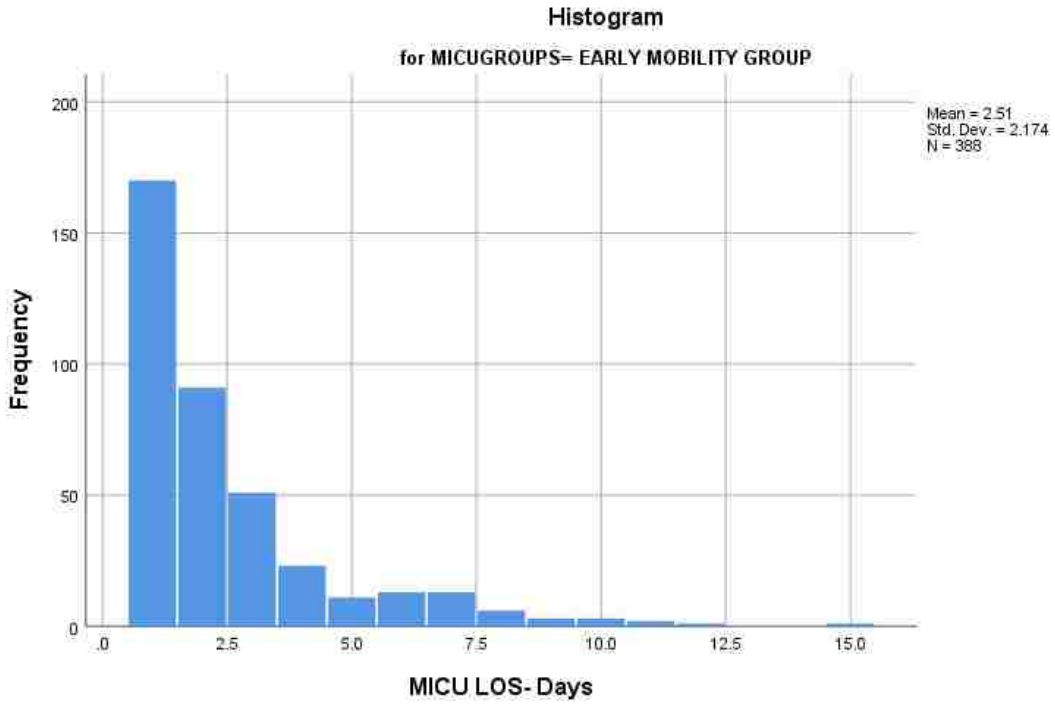


Figure 47. The histogram for the early mobility group shows positive skew and a leptokurtic distribution.

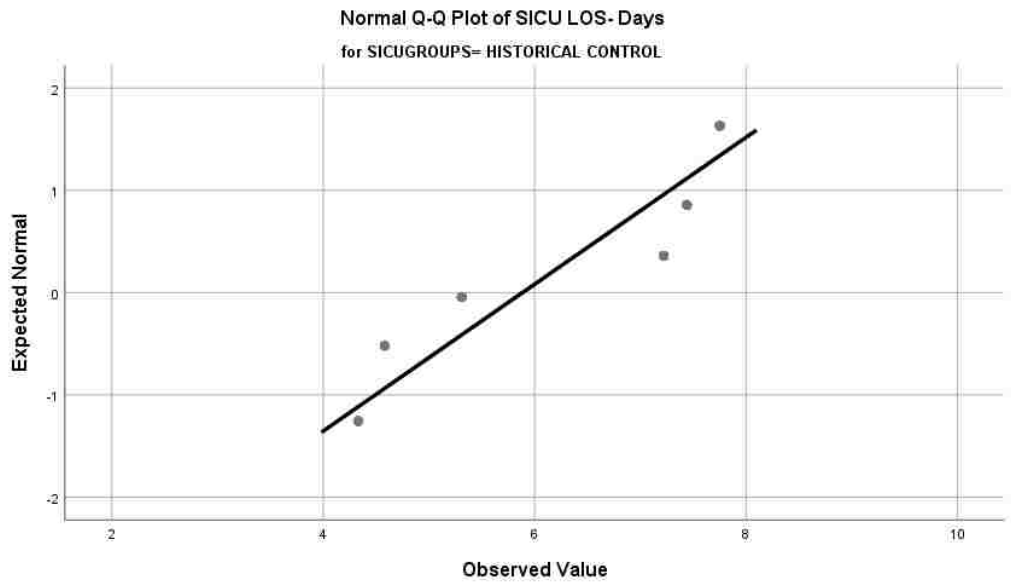


Figure 48. The Q-Q plot for the historical comparison group shows that the observed quantile points fall slightly away and snakes around the expected quantiles (diagonal lines) indicating that the data points were skewed and not normally distributed.

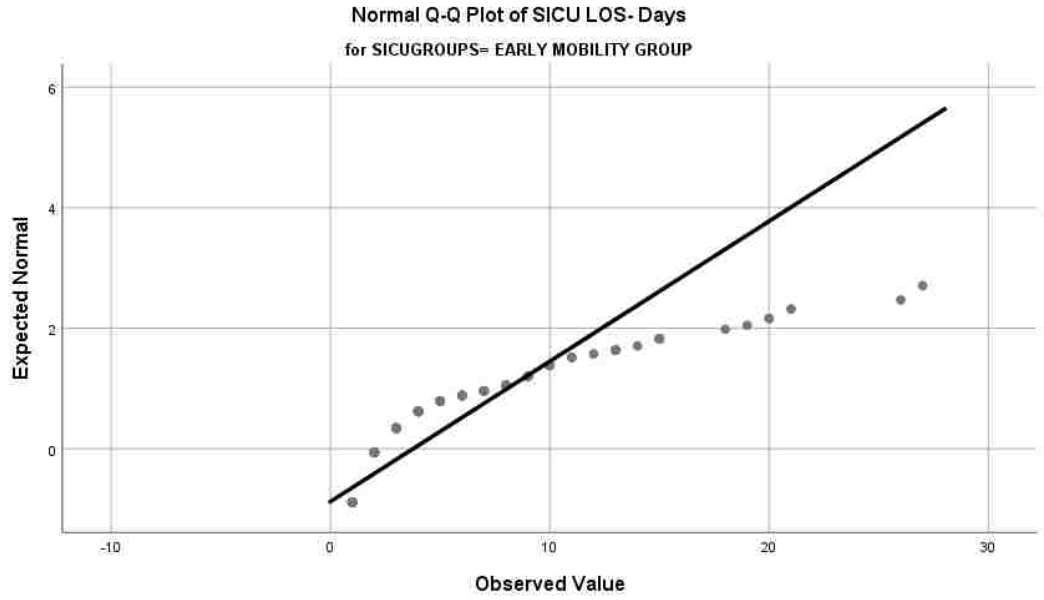


Figure 49. The Q-Q plot for the early mobility group shows that the observed quantile points fall slightly away and snakes around the expected quantiles (diagonal lines) indicating that the data points were skewed and not normally distributed.

As per table 37, for SICU LOS mean of the historical comparison group was (M= 5.88, sd 1.39) and the mean for the early mobility group was (M=3.77, sd 4.29).

Table 37

Group Statistics for Historical comparison group and Early mobility group

	SICU GROUPS	N	Mean	Std. Deviation	Std. Error Mean
SICU LOS- Days	HISTORICAL COMPARISON GROUP	291	5.88	1.393	.082
	EARLY MOBILITY GROUP	293	3.77	4.299	.251

Table 38 shows the output for the independent sample *t*- test. To check the final assumption for homogeneity of variance, Levene's test was used. For this variable, the *p* value is significant ($p < .05$) which means the variances were not homogenous, F (291,293) = 78.97, $p < .001$.

The null hypothesis for this question was there is no significant difference in the SICU LOS mean between the historical comparison group and early mobility group. The alternative hypothesis for this problem was $\mu 1 > \mu 2$ (SICU LOS of the historical comparison group is more than SICU LOS of the early mobility group). Therefore, it is a one tailed test. An independent-samples *t* test was calculated comparing the mean LOS days for the historical comparison group and early mobility group. Significant difference was found, t (353.01) = 8.004, $p < .001$ (p calculated as .000/2 since this is a one-tailed test). Hence we can reject the null hypothesis. The mean of the historical comparison group (M= 5.88, sd 1.39) was significantly higher than and the mean of the early mobility group (M=3.77, sd 4.29).

Table 38

Output for Independent Samples t- test

		Levene's Test for Equality of Variances		t-test for Equality of Means							
								95% Confidence Interval of the Difference			
		F	*p* value	t	df	*p* value	Mean Difference	Std. Error Difference	Lower	Upper	Effect size	Power
SICU LOS-Days	Equal variances assumed	78.973	.000	7.981	582	.000	2.113	.265	1.593	2.634		
	Equal variances not assumed			8.004	353.01	.000	2.113	.264	1.594	2.633	*d*=1.51 (Large)	1.00

Effect size (d)

Here n1 is not equal to n2. Hence effect size is calculated by using Cohen's formula by using the pooled standard deviation.

d = mean1-mean2 / pooled standard deviation (standard deviation of control group)

$d = (x_1 - x_2) / sp$

= 2.11 / 1.39

= 1.51

This is a large effect size.

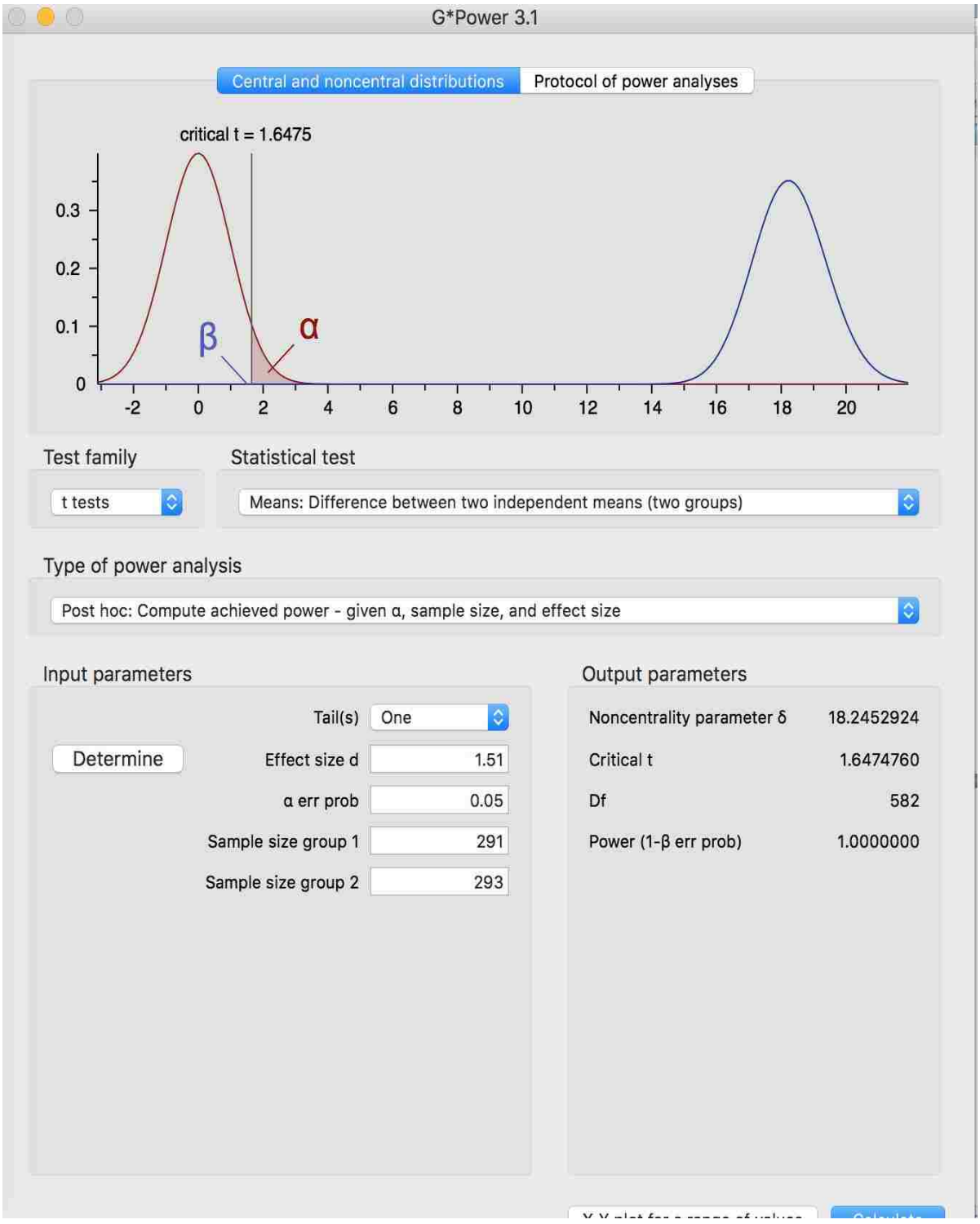


Figure 50. The effect size, d, was calculated as 1.51 (2.11/1.39). The G-Power post-hoc analysis for the sample shows that power is 1.00. This is above the accepted value of power = .80. This sample size was large enough.

<u>Research Question- 7</u>: Is standardized early mobilization protocol administered from ICU admission to discharge effective in increasing discharge to community after discharge from hospital

To answer RQ7 a chi squared test of association was conducted to determine if there is correlation between discharge destination (discharge to community vs. discharge to other facilities) and the ICU group patients belong to (Early mobility group and historical comparison group). It was hypothesized that due to early mobility intervention more patients were discharged to the community and return to their prior level of function and they were less likely to be discharged to the other facilitates for further continuum of care. Analysis was performed separately for Medical (MICU) and Surgical (SICU). Following assumptions were checked before the chi squared test of association was conducted. Nominal level variables were used to answer this research question. Random sampling was assumed for the problem. Expected frequency in all cells is ≥ 5. This is shown in Table 39 below.

MICU data analysis

As shown in table 39, from MICU discharges total 440 (50.7% of the total) patients were discharged to community of which 211 (48%) patients belonged to historical group and 229 (52 %) patients belonged to early mobility group. Further total 428 (49.3% of the total) patients were discharged to other facilities of which 269 (62.9%) patients belonged to historical group and 159 (37.1 %) patients belonged to early mobility group

Table 39

MICU Crosstabulation

		MICU GROUPS		
		HISTORICAL COMPARISON GROUP	EARLY MOBILITY GROUP	Total
	Count	211	229	440

MICU DISCHARGE DESTINATION	DISCHARGE TO COMMUNITY	% within MICU DISCHARGE DESTINATION	48.0%	52.0%	100.0%
		% within MICU GROUPS	44.0%	59.0%	50.7%
		% of Total	24.3%	26.4%	50.7%
	DISCHARGE TO OTHER FACILITIES	Count	269	159	428
		% within MICU DISCHARGE DESTINATION	62.9%	37.1%	100.0%
		% within MICU GROUPS	56.0%	41.0%	49.3%
		% of Total	31.0%	18.3%	49.3%
Total		Count	480	388	868
		% within MICU DISCHARGE DESTINATION	55.3%	44.7%	100.0%
		% within MICU GROUPS	100.0%	100.0%	100.0%
		% of Total	55.3%	44.7%	100.0%

Table 40 shows that χ^2 (1, N = 868) = 19.47, $p < .001$ Here $p < .05$ and hence we can say that a significant relationship was found and we can reject the null hypothesis. There is a correlation between the discharge destination and the ICU group the patient belong to.

Table 40

Chi-Square Test

	Value	df	*p* value	Effect size	Power
Pearson Chi-Square	19.475[a]	1	.000	*w* = .14 (small)	0.98
N of Valid Cases	868				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 191.32.

b. Computed only for a 2x2 table

Table 41 reports the effect size for MICU. For the 2 x 2 contingency, Phi is used as a measure of association, Φ = -.150 (small effect size)

Table 41

Effect Sizes (Symmetric Measures)

		Value	Approximate *p* value
Nominal by Nominal	Phi	-.150	.000
	Cramer's V	.150	.000
N of Valid Cases		868	

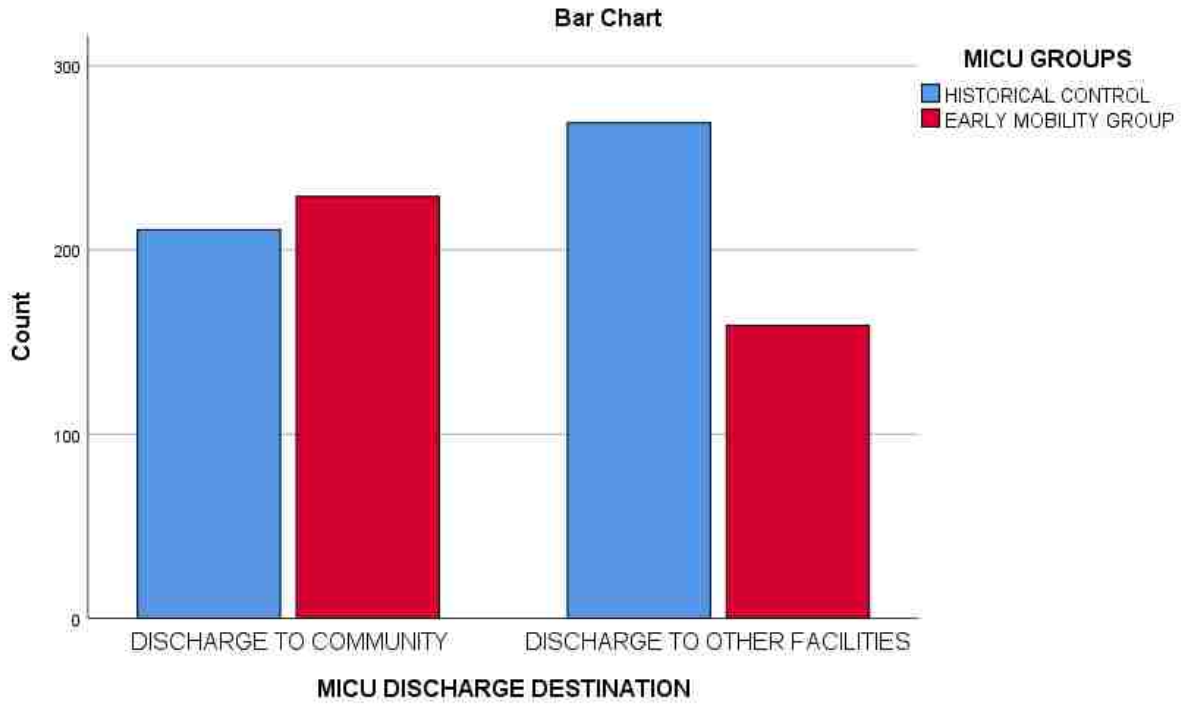


Figure 51. From the clustered bar chart we can comment that for early mobility group more patients were discharged to community and for the historical comparison group more patients were discharged to other facilities

Results

A chi square test of association was calculated comparing the discharge destination (discharge to community vs discharge to other facility) and the type of ICU group they belong to (Historical control group vs. early mobility group). χ^2 (1, N = 868) = 19.47, $p < .001$. Here $p < .05$ and hence we can say that a significant relationship was found and we can reject the null hypothesis. There is a correlation between the discharge destination and the ICU group the patient belong to. The significant values indicate that there is a significant dependence of one variable on the other and that the discharge destination (community vs. other facility) differed across early mobility and the historical comparison group. 52% of the patients who belonged to early mobility group were discharged to community compared to historical control group where only 48% were discharged to community.

Effect size:

The effect size, w was calculated as:

$w = \sqrt{\chi^2}/N$

$w = \sqrt{19.47}/ 868$

w =.14 (Small effect size)

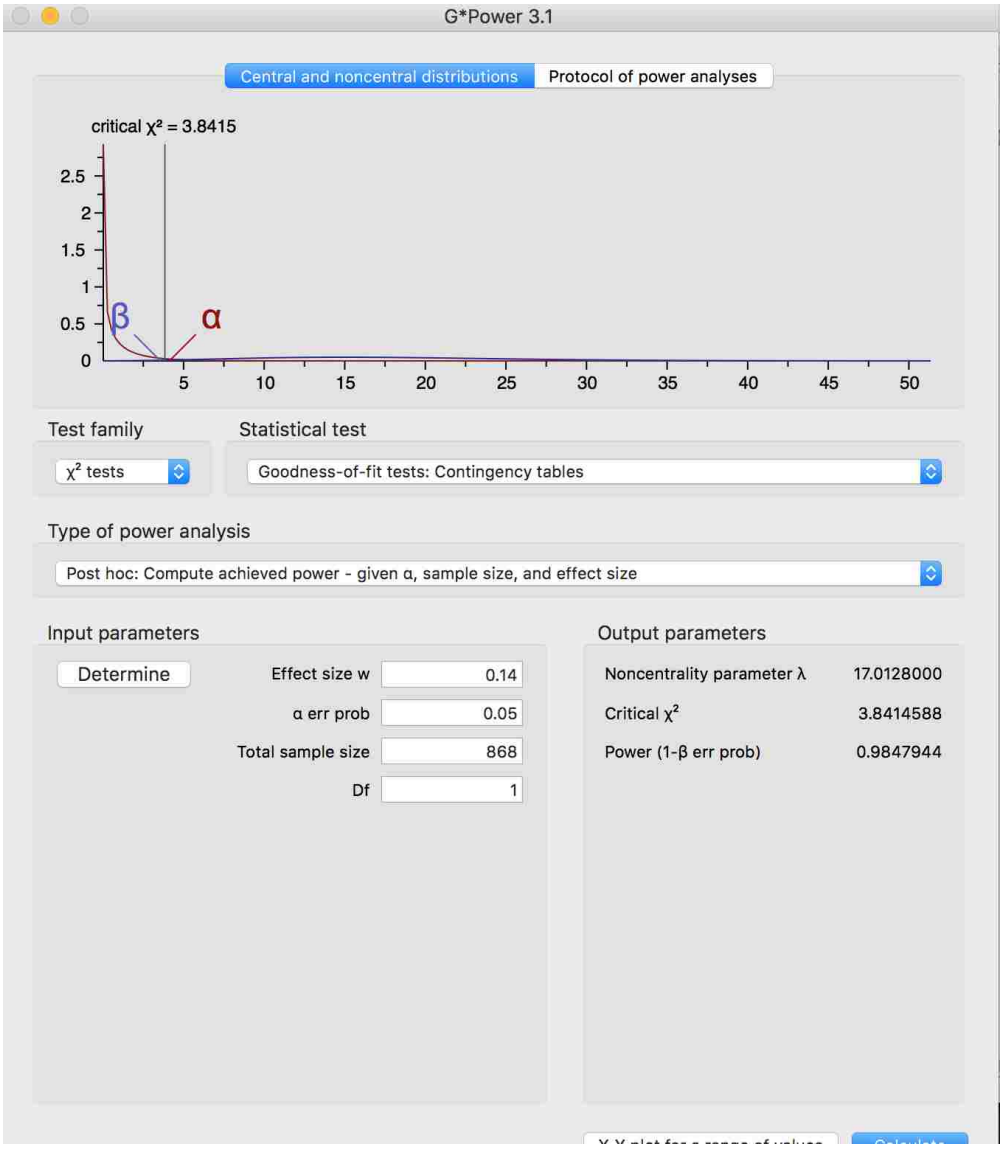


Figure 52. The G-Power post-hoc analysis for the sample with effect size w = .14. The calculated power is 0.98. This is above the accepted value of power = .80. This sample size was large enough.

SICU analyses

As shown in table 42**,** from SICU discharges total 288 (49.3% of the total) patients were discharged to community of which 115 (39.9%) patients belonged to historical comparison group and 173 (60.1 %) patients belonged to early mobility group. Further total 296 (50.7% of the total) patients were discharged to other facilities of which 176 (59.5%) patients belonged to historical comparison group and 120 (40.5 %) patients belonged to early mobility group

Table 42

SICU Crosstabulation

			SICU GROUPS		
			HISTORICAL COMPARISON GROUP	EARLY MOBILITY GROUP	Total
SICU DISCHARGE DESTINATION	DISCHARGE TO COMMUNITY	Count	115	173	288
		% within SICU DISCHARGE DESTINATION	39.9%	60.1%	100.0%
		% within SICU GROUPS	39.5%	59.0%	49.3%
		% of Total	19.7%	29.6%	49.3%
	DISCHARGE TO OTHER FACILITIES	Count	176	120	296
		% within SICU DISCHARGE DESTINATION	59.5%	40.5%	100.0%
		% within SICU GROUPS	60.5%	41.0%	50.7%
		% of Total	30.1%	20.5%	50.7%
Total		Count	291	293	584
		% within SICU DISCHARGE DESTINATION	49.8%	50.2%	100.0%
		% within SICU GROUPS	100.0%	100.0%	100.0%
		% of Total	49.8%	50.2%	100.0%

Table 43 shows that χ^2 (1, N = 584) = 22.26, p < 001. Here p < .05 and hence we can say that a significant relationship was found and we can reject the null hypothesis. There was a correlation between the discharge destination and the ICU group the patient belong to.

Table 43

Chi-Square Tests

	Value	Df	*p* value	Effect size	Power
Pearson Chi-Square	22.269[a]	1	.000	*w* = .19 (small)	0.99
N of Valid Cases	584				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 143.51.

b. Computed only for a 2x2 table

Table 44 reports the effect size for SICU. For the 2 x 2 contingency table, Phi is used as a measure of association, Φ = -.195 (small effect size)

Table 44.

Effect Size (Symmetric Measures)

		Value	Approximate *p* value
Nominal by Nominal	Phi	-.195	.000
	Cramer's V	.195	.000
	Contingency Coefficient	.192	.000
N of Valid Cases		584	

c. Correlation statistics are available for numeric data only.

For the 2 x 2 contingency table, Phi is used as a measure of association, Φ = -.195 (small effect size)

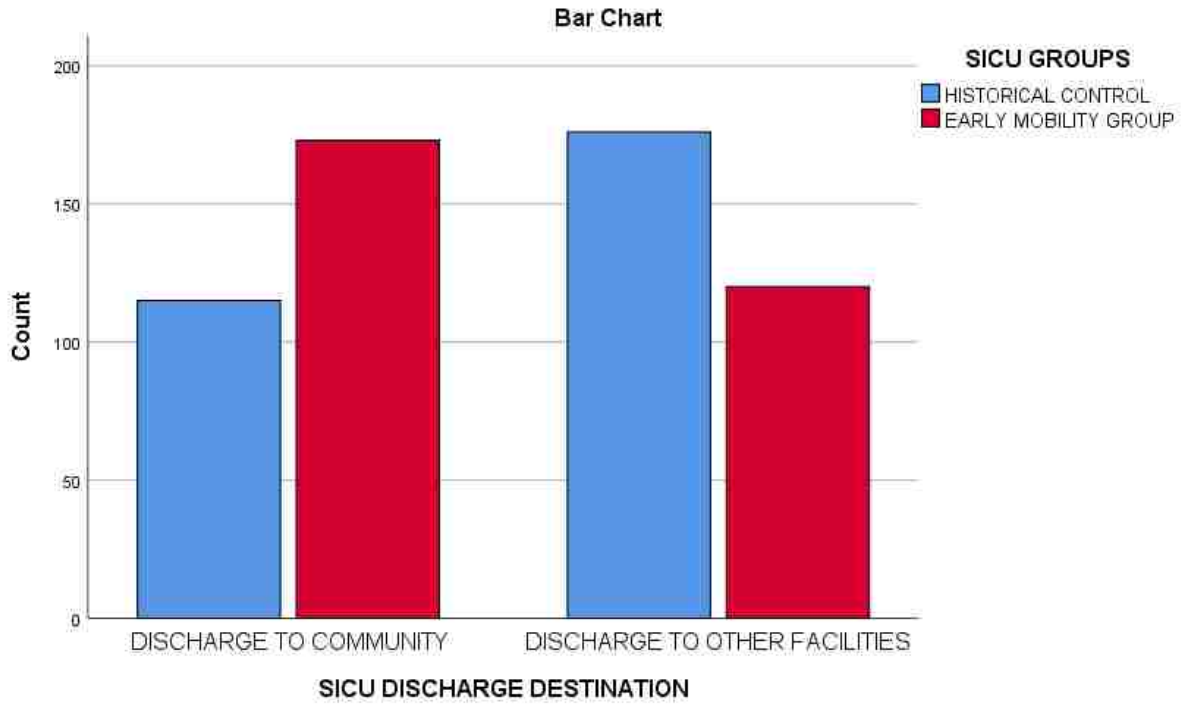


Figure 53. From the clustered bar chart we can comment that for early mobility group more patients were discharged to community and for the historical comparison group more patients were discharged to other facilities

Results

A chi square test of association was calculated comparing the discharge destination (discharge to community vs discharge to other facility) and the type of ICU group they belong to (Historical comparison group vs. early mobility group). χ^2 (1, N = 584) = 22.26, $p < .001$. Here $p < .05$ and hence we can say that a significant relationship was found and we can reject the null hypothesis. There is a correlation between the discharge destination and the ICU group the patient belong to. The significant values indicate that there is a significant dependence of one variable on the other and that the discharge destination (community vs. other facility) differed across early mobility and the historical comparison group. 60.1% of the patients who belonged to early mobility group were discharged to community compared to historical comparison group where only 39.9% were discharged to community.

Effect size:

The effect size, w was calculated as:

$w = \sqrt{\chi^2}/N$

$w = \sqrt{22.26}/584$

w = .19 (This is a small effect size).

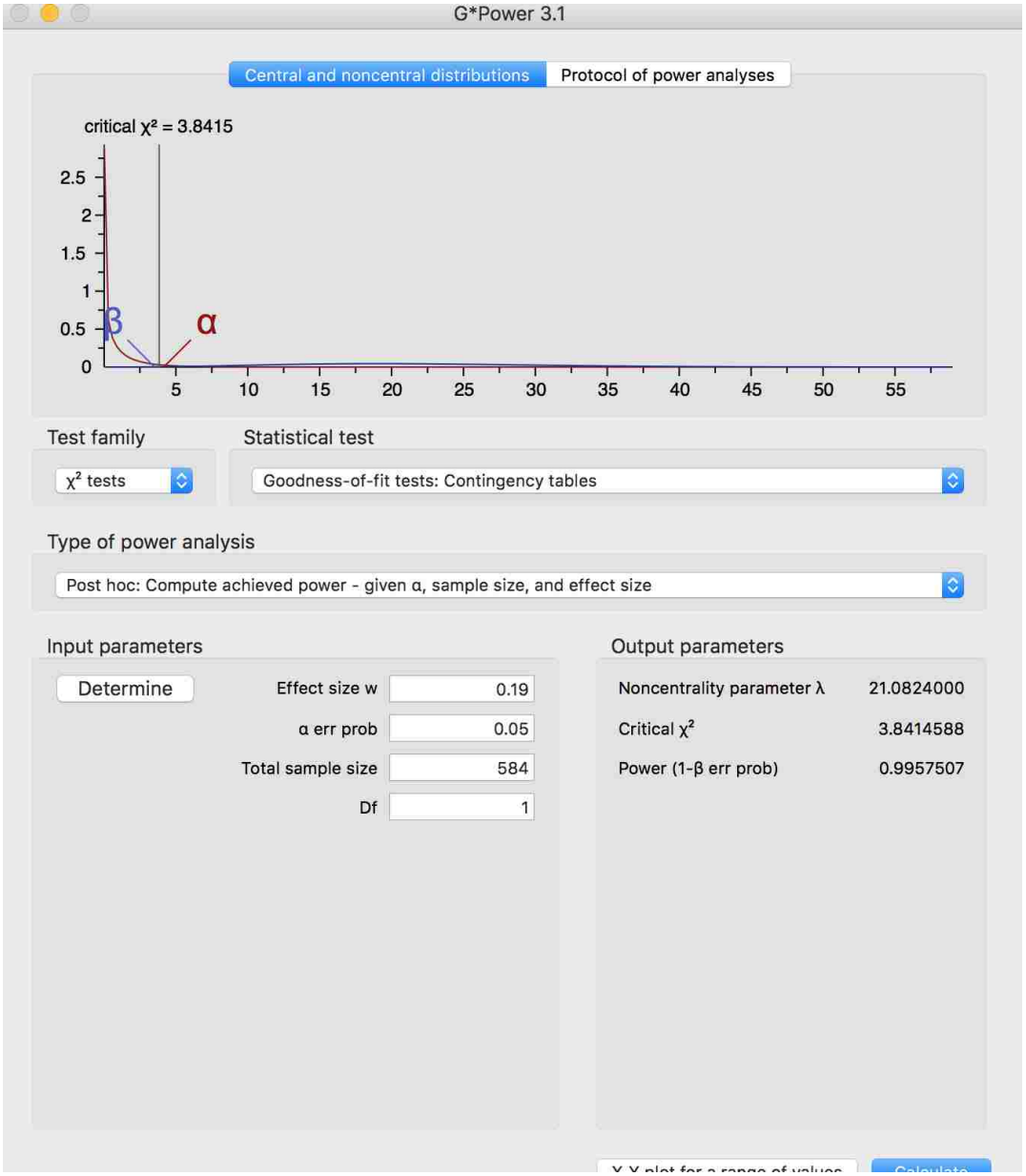


Figure 54. The G-Power post-hoc analysis for the sample, w = .19. The calculated power is .99. This exceeds the accepted value of power =.80.

Secondary Outcomes Summary Table:

Table 45 below summarizes the statistical analysis for the secondary outcomes (Length of stay and discharge disposition) for historical comparison group and early mobility group.

Table 45

Comparison of historical comparison and all patients during early mobilization period

Characteristic	Historical Comparison Period	Early Mobilization Period	*p* value	Effect size	Power
MICU Length of stay – mean (SD)	M= 2.94, (sd= .51)	M=2.51, (sd= 2.17)	$t(422.2) = 3.79$, $p < .001$	$d = 0.84$ (large effect size)	1.00
SICU Length of stay – mean (SD)	M= 5.88, (sd =1.39)	M=3.77, sd 4.29	$t(353.01) = 8.004$, $p < .001$	$d = 1.51$ (large effect size)	1.00
MICU Discharge disposition – n (%)	Discharge to community- 211 (48%) Discharge to other facilities- 269 (62.9%)	Discharge to community- 229 (52 %) Discharge to other facilities - 159 (37.1 %)	χ^2 (1, N = 868) = 19.47, $p < .001$	$w = .14$ (small effect size)	0.98
SICU Discharge disposition – n (%)	Discharge to community-115 (39.9%) Discharge to other facilities- 176 (59.5%)	Discharge to community - 173 (60.1 %) Discharge to other facilities - 120 (40.5 %)	χ^2 (1, N = 584) = 22.26, $p < .001$	$w = .19$ (small effect size)	0.99

Exploratory Outcomes Summary Table:

Table 46 below reports the exploratory outcomes including hospital length of stay and discharge disposition categories for historical comparison group and early mobility group.

Table 46

Other Exploratory outcomes

Characteristic	Historical Comparison* - n (%)	Early Mobilization* - n (%)
MICU Hospital length of stay – mean (days)	10.6	8.4
SICU Hospital length of stay – mean (days)	12.0	9.03
MICU Discharge disposition – n (%)	Home- 211 (48 %) Skilled nursing (20%) Rehabilitation facility (10%) Short- term care (2%) Long-term acute care (0%) Death (12%) Hospice (2%) Other (6%)	Home- 229 (52%) Skilled nursing (14%) Rehabilitation facility (8%) Short- term care (1%) Long-term acute care (3%) Death (10%) Hospice (8%) Other (4%)
SICU Discharge disposition – n (%)	Home 115 (39.9 %) Skilled nursing (20.1%) Rehabilitation facility (21%) Short- term care (0%) Long-term acute care (5%) Death (10%) Hospice (3%) Other 1%	Home 173 (60.1 %) Skilled nursing (13.9%) Rehabilitation facility (13%) Short- term care (1%) Long-term acute care (0%) Death (6%) Hospice (4%) Other 2%

Values are expressed as n (%) unless otherwise indicated. Totals for each category indicate the number of patients with valid data in that category.

DISCUSSION

Historically, we have seen that early mobilization of patients in ICU has not been practiced in the US and throughout the world because of safety and feasibility concerns. While, a review of the literature demonstrated the existence of QI projects addressing early mobilization globally in the healthcare system, multiple barriers were identified that have prevented the implementation of early mobilization within the ICU. Recognizing the importance and potential benefits of early mobilization in the ICU to patient's quality of life, NYU Langone hospital-Brooklyn embracked upon a QI project to infuse and assess the safety and feasibility of a specific early mobilization protocol in the ICU. The protocol was based upon Hodgson et al (2014) published consensus recommendations for safe active mobilization of mechanically ventilated critically ill adults. Since Hodgson's recommendations were published, no study has described how to operationalize and implement the Red-Yellow-Green protocol system they recommend. To our knowledge, this project was the first and only, that implemented early mobilization in the Medical and Surgical ICUs by operationalizing the Red-Yellow-Green system described in Hodgson et al. The Translating Research Into Practice (TRIP) model and a multidisciplinary team approach were used as conceptual frameworks to guide the evidence-based strategic approach taken.

A retrospective analysis was conducted to analyze the outcome of this quality improvement project and assess the safety and feasibility of using the early mobilization protocol (Red-Yellow-Green system described in Hodgson et al.) to enhance overall patient quality of life while, ensuring that a financial burden specific to implementing the protocol for initiating "early mobilization" in ICU was not observed. Specifically, the purpose of the study was to evaluate the effectiveness of the NYU Langone hospital-Brooklyn early mobilization protocol to improve patient's functional status, improve behavior with less sedation/agitation, decrease ICU acquired delirium, decrease ICU/hospital length of stay and increase community discharge. Based upon this purpose and the study results presented previously the following discussion will address each outcome measure category independently to provide the reader with clear insight as to the impact of the protocol on patients quality of life.

Outcome measures:

1. **Functional outcomes:** The degree of functionality of ICU patients was assessed via use of the ICU Mobility Scale (IMS), Functional Status Score - ICU (FSS-ICU) and the AMPAC mobility scale. For the first 3 research questions, the research hypothesis can be accepted because there was significant improvement in functional scores for both MICU and SICU patients. MICU patients demonstrated improvement in mean functional scores after the early mobility intervention via all scales with an increase of 0.3 on the IMS (t (387) = 4.51, p < .001), 1 on the FSS-ICU (t (387) = 5.64, p < .001), and 0.5 on the AMPAC scale (t (387) = 5.23, p < .001). In SICU patients, this improvement was markedly increased by 0.9 on the IMS (t (292) = 8.71, p < .001), 2.5 on the FSS-ICU (t (292) = 8.64, p < .001) and 1.4 on the AMPAC scale (t (292) = 8.51, p < .001). Mean change for ICU mobility scale during this study was .92. Minimal important difference (MID) for IMS listed in the literature is 0.89-1.40 (Tipping et al., 2018). Mean change for Functional status score during the study was 2.48. MID for FSS listed in the literature is 2-5 (Huang et al., 2016). Mean change for AMPAC score during the study was 1.38. MID for basic mobility section of AMPAC is 4.28 (Latham et al., 2008). Improvement in the functional scales is consistent to what is documented in the literature.

   Parry et al (2015) noted that lower FSS-ICU and IMS score is seen during ICU-acquired weakness (ICU-AW) and higher FSS-ICU and IMS scores were predictive of discharge to home upon ICU discharge. As noted by Hough & Needham (2007), ICU-AW severely inhibits patients' ability to be discharged to home due to difficulty with activities of daily living, diffuse muscle weakness, and diffuse muscle wasting. Furthermore, they also observed that ICU-AW affected between 25% and 57% of patients depending on the ICU population being studied with an association between ICU-AW and increased duration of mechanical ventilation, increased length of stay in the ICU and hospital, greater costs per patient and increased 1–year mortality. This study demonstrated appreciable increase in ICU patients' functionality post early mobilization, which can be extrapolated to conclude that the increase in functionality will produce a decrease in instances of ICU-AW.

2. **Behavioral outcomes**: ICU patients were also assessed for changes in behavior via the Richmond Agitation Sedation Scale (RASS) and the Confusion Assessment Method (CAM-ICU).

RASS score is an instrument to assess sedation and agitation in adult ICU patients. It has discrete criteria and sufficient levels for sedative medication titration and agitation evaluation. During research question- 4 analyses, MICU patients showed statistically significant reduction in the RASS score ($Z = -2.27$, $p = .023$) during the pre-test post-test analyses. SICU patients on the other hand showed a non-significant change in RASS score during pretest post-test analyses ($Z = -1.83$, $p = .067$). To further understand the data crosstabulation was performed for both MICU and SICU. The clustered bar chart demonstrated that the majority of the RASS score clustered towards middle at score 0. Which means upon discharge majority of the patients were alert and calm. The non-significant change in SICU is attributable to the patient population that requires less sedation to begin with based on the diagnosis categories (majority of the patients are post- surgical patients with less co morbidities). Hence, the initial and final scores are very similar resulting into non-significant change in mean score. Overall, as demonstrated by the clustered bar chart in figure majority of the patients in both ICU were alert and calm (score of 0) upon discharge from the ICU. This decrease in use of sedation can be attributed to the medical team's decision to adhere to ABCDEF bundle and focusing on titrating the sedation medication down as early as possible to ensure the requirement for alertness for the mobilization protocol. The reduction in sedation further lead to better compliance and performance of mobility exercises which could reduce patient's risk of acquiring ICU-associated delirium. Kim et al (2019) noted that interventions aimed at improving functional recovery may not only minimize or improve physical function but may also affect cognitive processing, and emotional health.

CAM-ICU is an instrument to assess incidence and recorded episodes of acute delirium. During research question- 5 analyses, MICU patients showed statistically significant difference between MICU initial and final CAM-ICU scores ($\chi 2$ (1, N=388) = 54.14, $p < .001$). In MICU, during admission for the initial CAM ICU assessment 49.3 % of participants scored negative (no confusion). During discharge for the final CAM ICU assessment, majority of the participants 78.7% were negative. Clustered bar chart showed that significantly more patients (n= 67) changed their score from positive to negative, than from negative to positive

(n=4). Upon discharge more patients scored negative in CAM –ICU indicating that patients had less confusion upon discharge. On contrary, SICU patients showed a non-significant change in CAM-ICU score during pretest post-test analyses ($\chi 2$ (1, N=293) = 0.16, p =.690). Out of 388 patients only 25 patient's scores changed during the final CAM-ICU assessment compared to initial assessment. Of these, less patients (n= 11) changed their score from positive to negative, than from negative to positive (n=14). However the clustered bar chart demonstrates that the majority of the patients scored negative upon SICU discharge. Majority of the SICU patients were not confused to begin with (only 22% of patients had confusion during the initial assessment), hence the initial and final scores are very similar resulting into non-significant change. Overall, as demonstrated by the clustered bar chart in figure majority of the patients in both ICU score negative in CAM-ICU assessment upon discharge from the ICU indicating less delirium upon discharge from the ICU. Schweickert et al. (2009) noted that ICU acquired delirium was associated with increased mortality, longer ICU and hospital stay and increased duration of ventilation with a tremendous financial burden of approximately $4 to $16 billion nationally. The early mobilization program could be an impressive instrument in combating ICU-associated delirium and its side effects. Barr et al (2013) recommended that performing early mobilization of adult ICU patients whenever feasible helps to reduce the incidence and duration of delirium (Level 1B recommendation)

3. **Length of Stay:** The implementation of the early mobilization protocol decreased length of stay in both MICU and SICU as well as the overall hospital length of stay. During research question – 6 analysis, both MICU (t (422.2) = 3.79, $p < .001$) and SICU (t (353.01) = 8.004, $p < .001$) patients demonstrated statistically significant decline in ICU length of stay during early mobility period compared to the historical comparison period. MICU length of stay decreased from 2.94 days to 2.51 days. Also the overall hospital length of stay for MICU patients decreased from 10.6 to 8.4 days. Similarly, SICU length of stay decreased from 5.88 days to 3.77 days and the overall hospital length of stay for SICU patients decreased from 12 days to 9.3 days. This decrease in stay has significant financial ramifications not only for hospitals but also for patients and their families as there are multiple out-of-pocket expenses. Healthcare costs have been projected to increase by 5.5% annually from $3.6 trillion in 2018 to almost $ 6.0 trillion by 2027 (CMS, 2018). Out of pocket and hospital spending have

increased up to 4.8 % and 5.1% respectively. The Society of Critical Care Medicine states that the annual CCM cost was $108 billion in 2010 with an estimated daily ICU cost to be $4,300 (SCCM). Based on the above data, the reduction in length of stay during the quality improvement project leads to approximate MICU cost saving equal to 0.4 (days) x 388 (n) x 4300 ($) = $ 667,360 and approximate SICU cost saving = 2.1(days) x 293(n)x 4300 ($)= $ 2.6 million. On average, patients are responsible for 20% of this cost out-of-pocket amounting to over $800 daily. A decrease in an ICU patients' length of stay from 12 days to 9.3 days would decrease the patient's cost from over $10,000 to $8,000. This reduction in costs would greatly benefit patients and their families by reducing their financial burdens. It is also noteworthy that length of stay is the biggest driver of cost to a hospital due to its fixed payment amount system for caring for patients with specific diagnoses. Lord et al (2013) conducted early rehabilitation within the ICU and noted its impact upon net cost to the hospital. It was noted that 22% decrease in length of ICU stay yielded a net cost savings over $800,000. This findings were similar to what was reported by Robert et al (2013). Investment in an ICU early rehabilitation program can generate net financial savings for U.S. hospitals. Even under the most conservative assumptions, the projected net cost of implementing such a program is modest relative to the substantial improvements in patient outcomes demonstrated by ICU early rehabilitation programs (Robert et al., 2013).

4. **Discharge to community**: During research question – 7 analysis, both MICU (χ^2 *(1, N = 868) = 19.47, p < .001*) and SICU (χ^2 *(1, N = 584) = 22.26, p <.001*) patients demonstrated statistically significant improvement in discharge to community during early mobility period compared to the historical control period. In MICU, 52% of the patients who belonged to early mobility group were discharged to community compared to historical control group where only 48% were discharged to community. In the SICU, 60.1% of the patients who belonged to early mobility group were discharged to community compared to historical control group where only 39.9% were discharged to community. This increase greatly impacts patient welfare in terms of finances and quality of life. Patients experience better outcomes when they are able to return to their activities and daily routine sooner. Kim et al (2019) observed that "maximum level of mobility achieved in the MICU" was strongly associated with discharge home among MICU patients who were admitted from the community. They further concluded

that this factor would facilitate early mobilization protocols to increase patients' discharges home after ICU stay. One important factor of patients' long term recovery was the ability to be discharged to community to ensure improved mental health. As Hough and Herridge (2012) observed, although patients could show improvement in depressive symptoms over time, moderate- to-severe symptoms persisted in 19% of the patients, 5 years after ICU discharge with psychiatrist-diagnosed PTSD being reported among 44% of ARDS patients at hospital discharge, 25% at 5 years post-discharge, and 24% at 8 years post-discharge from the ICU (Davydov, Desai and Needham, 2008). Family support is crucial for a patient's mental health post discharge by providing for emotional and physical needs, encouraging compliance and providing feedback to caregivers. By facilitating discharge to home with family, early mobilization may be able to reduce the instances of mental illness after ICU discharge and improve patients' quality of life.

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CHAPTER V

SUMMARY AND CONCLUSIONS

Summary

Based upon this retrospective review, the Interdisciplinary VBM Early Mobilization Team implementing the protocol consistently and effectively implement the Hodgson Red Yellow Green Mobilization system. With no adverse events reported during the study, early mobilization can be considered safe and feasible to implement in this ICU by this team. Accurate identification of candidates for early mobilization yielded statistically robust outcomes for several functional and behavioral outcome measures. Behavioral improvements included a decrease in use of sedation medication resulting into fewer side effects to drugs. Fewer patients were confused upon discharge and had less delirium. The results from the QI project showed that, in addition to reducing ICU and hospital LOS, early ICU intervention enables more patients to discharge to community instead of post-acute care facilities. This demonstrates the need for the routine application of early mobilization in the ICU.

For the full potential of the mobilization system to be realized, the following must be addressed; need for cultural shifts across all healthcare settings, standardized training in the early mobilization protocol and further testing of the protocols inter and intra reliability and validity. A hospital wide cultural change is essential to unleash the full potential of early mobilization which should be implemented consistently across the hospitals service continuum. A protocol such as the one studied here, is simple and feasible and can further support the achievement of quality healthcare and patient's quality of life.

To translate the protocol effectively into practice, a multidisciplinary team effort of the standardized must be employed. This translation must be supported by standardized training in protocol for all team members. Finally, as healthcare professionals who provide team based care we must acknowledge the protocol is only advantageous when there is coordination amongst the patient's care team. Therefore, consistent and effective communication practices must be employed across team members.

In order to positively translate the protocol into ICU practice, we propose that each hospital engages in a staff-wide assessment of current ICU mobilization procedures, explores current guidelines for ICU, acknowledges the pitfalls of the current guidelines, explores the rationale for increasing patient mobilization, and evaluates ease, efficiency and barriers of various mobilization procedures. While, remembering that staff buy in and feedback along the process improves trust in adopting new practices effectively such as the Hodgson Red Yellow Green Mobilization Consensus Recommendations implemented in the Medical and Surgical ICU reported in this study.

Limitations

As with all research, this study had limitations. The non-experimental and retrospective nature of the study had threats to both internal and external validity.

Internal validity considerations:

Even though all the providers were trained in the form of in-service regarding the use of the mobility checklist and the mobility codes, interrater reliability amongst providers were not established. Many extraneous factors could have contributed to the study's findings. There might be other simultaneous projects occurring in the ICU during the QI project period that might have contributed to decrease in length of stay in the ICU.

There were no strict sampling requirements for the study. Because of the intention to treat nature of the study, all the patients that were admitted in ICU were included in the study if they met the inclusion criteria. A selection effect could have occurred resulting in confounding variables with the research group that were not identified or controlled for.

Another internal validity threat comprises of both equivalency of groups and contamination. Even though to have seasonal consideration historical comparison group from the same time period of the previous year was used for comparing data, both groups were not matched exactly for age and gender variables. There were a variety of diagnoses within ICU admissions ranging from strokes, general surgeries, cardiac stents and respiratory failures. Each diagnosis may have a different course of disease progression and prognosis and that was not taken into consideration during the current study.

As a retrospective clinically based study, the environment was not well controlled. While all the patients were treated on the same MICU or SICU, it is likely that the overall unit milieu (E.g. presence of other patients in the area, therapist treating the patients, noise level, etc.) varied for each subject. In addition, there are other extraneous variables that were not controlled for or analyzed, including the patients' psychiatric diagnosis, behaviors, medical comorbidities or medications (Gilner, Morgan & Leech 2009).

External validity considerations:

Population external validity was reduced due to sampling bias; only the subjects admitted to the NYU Brooklyn Medical and surgical ICU were included. Also, only the subjects that were referred to physical therapy during ICU admission and who had at least one mobility session were included. It is possible, that the final sample was not a good representation of the theoretical populations, namely all the ICU patients in United States. This limits the generalizability of the findings. However, as a clinically-based study retrospective chart review was completed for the patients who were treated in the natural conditions of the two ICUs of NYU Langone Brooklyn campus which means that this research did have a medium to high level of ecological external validity.

Conclusions

The findings from this study support the use of the protocol developed, which was based upon the Hodgson Red Yellow Green Mobilization Consensus Recommendations in a Medical and Surgical ICU. Early mobilization of patients in the ICU can aid patient's functional and behavioral abilities thus impacting quality of life and also reduces the patient's ICU and hospital LOS. Long term deficits that impact quality of life resulting from lack of early mobilization or continued immobilization while in the hospital setting can be minimized and thus positively impact burden of care on the family and the society as more patients may be discharged to the community with a greater quality of life and independence.

Future Research

The results presented here form the foundation for future research which can address the known limitations of this study design. While the prospective design would produce a stronger study design, it is important to know how to inspire confidence amongst providers and to build the culture change. Most notably, it is important for providers to understand the results of the current QI project including the feasibility and safety of early mobilization programs and its positive outcomes on patient functionality and behavioral outcomes.

It is also recommended for future studies to have larger sample sizes. This would improve the likelihood that analyses would meet normality assumptions and allow for the use of the more powerful parametric statistical tests. Larger samples could be achieved through the extension of the length of the study to include more ICU admissions, multiple ICUs and greater geographical variability within the United States.

Other studies in the literature, identfy that the lack of post-ICU follow-up of study participants was a potential concern and requires further exploration. This could be similarly suggested based upon the QI project reported here. Although, patients had robust results because they were mobilized intensely in ICU with routine follow- up, after admission to the floors after ICU discharge, follow-up was lacking and lead to some decline in their function. There were also increased complaints from the patients and family members regarding patients not receiving equal intensity of therapy post-ICU discharge. Having a standardized post-ICU follow-up routine might increase staffing needs and demands however might be helpful in decreasing overall hospital LOS and possible readmission.

Increasing the intensity and duration of intervention in ICU can also be implemented by the use of twice a day (BID) treatments and the incorporation of interventions by other disciplines likes occupational therapists and speech pathologists. Further research involving multiple disciplines and increasing therapy frequency can assist in operationalizing optimal dosage of intervention required for ICU population.

Involving patients and family by incorporating tools like ICU diaries may have additional buy-in from patients' family members. Studies observing the effects of increased family involvement should be included in the future to show additional benefits of the early mobilization protocol.

Studies incorporating participation level outcome measures to determine overall patient satisfaction and experience might give additional insights to improve the overall outcome of early mobilization from patient's perspective.

Studies including outcome measures related to staff perceptions and staff experience while treating this complex caseload will help to analyze the effectiveness of the program from the staffing perspective and may guide to alter the protocol that is more clinically acceptable by the staff, which in turn can aide with culture shift and long-term adherence to the program.

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Appendix A

Approval to Conduct Research Letters at Performance Sites (Dr. Jeffery Fine- Director of Rehabilitation medicine at NYU Langone Hospital- Brooklyn)

NYU Langone Health

Rusk Rehabilitation Medicine
NYU Langone Hospital Brooklyn

From the desk of Jeffrey S. Fine, MD
Vice Chairman NYU Langone Brooklyn &
Rusk Rehabilitation Network Development

To: To whom it may concern
From: Jeffrey S. Fine, MD
Regarding: Swati Patel, DPT
Date: 7/19/2019

The Department of Rehabilitation Medicine spearheaded a quality improvement project to initiate therapeutic exercise and ambulation for patients newly admitted to medical and surgical ICI settings. The project is titled "Implementing the Hodgson Red Yellow Green Mobilization Consensus Recommendations in a Medical and Surgical ICU."

Swati Patel, PT, DPT, NCS, is a participating clinician in the program, and is responsible for aggregating clinical and outcome data for our project. As such she is approved to complete chart reviews in Epic to gather the necessary metrics.

We have filled out the appropriate paperwork for NYU Langone Health to indicate that this quality improvement project is in accord with NYU School of Medicine IRB policy. As such, this project does not require further IRB review in order to be presented or published outside the institution.

Please call or email for any questions,

Jeffrey S. Fine, MD

Diplomate AAPM&R- Physical Medicine and Rehabilitation, Spinal Cord Medicine, Pain Management, Brain Injury Medicine
Chief, Department of Physical Medicine & Rehabilitation Medicine NYU Langone Hospital - Brooklyn
Vice Chairman, NYU Rusk Rehabilitation Brooklyn and Rusk Rehabilitation Network Development
(718) 630-7303

JEFFREY.FINE3@NYUMC.ORG

NYU Langone Health - Rusk Rehabilitation Medicine Brooklyn
150 55th Street, Suite 3-06 Brooklyn, NY 11220
Tel 718-630-7425 Fax 718-630-7604

Appendix B

Approval of IRB where researcher is full-time employed if that institution is engaged in research through his/her activity (Kell Julliard, Director of Clinical research at NYU Langone hospital- Brooklyn)

July 9, 2019

To whom it may concern:

This email is to verify that the project "Implementing the Hodgson Red Yellow Green Mobilization Consensus Recommendations in a Medical and Surgical ICU," of which Swati Patel, PT, DPT, NCS, is a co-author, is a quality improvement project. We have filled out the appropriate paperwork for NYU Langone Health to indicate that this is accords with NYU School of Medicine IRB policy. As such, this project does not require further IRB review in order to be presented or published outside the institution. If there are questions or concerns about the above, please feel free to contact me.

Sincerely,

Kell Julliard

Kell Julliard, MA

Director of Clinical Research
Family Health Centers at NYU Langone

Clinical Research Office
Family Health Centers at NYU Langone, 5800 3rd Ave, Room 357, Brooklyn, NY 11220
Telephone (718) 630-6332 • Fax (718) 759-5807 • E-mail kell.julliard@nyulangone.org

Appendix C

NYU Langone Self- certication form for QI project

INSTRUCTIONS: Complete the following section to help you determine if your proposed activity falls in the realm of QI. If a statement is true, check off **YES**. If all of your responses to the below statements are positive (i.e., checked off **YES**), then your proposed activity constitutes QI that does not require IRB review or oversight.

	QI Certification Statements	YES	NO
1	Your activity's primary objective is to produce an improvement in safety or care that will be sustained over time at the local institution or within a particular program at the local institution. ***NOTE:*** *If the intended outcome is simply to report on what happened at the local institution/program, it does not indicate research design or intent as it may not be generalizable outside of the local institution.*	x☒	☐
2	Your activity does **NOT** use a fixed protocol for the duration of the proposed work. ***NOTE:*** *If frequent adjustments are needed, your answer should be "YES."*	x☑	☐
3	Your activity does **NOT** involve an intervention that may pose risks greater than those presented by routine clinical care.	x☒	☐
4	There will be minimal delays in implementing changes from results.	x☒	☐
5	All individuals involved in key project roles have on-going commitment to the improvement of the local care situation.	x☒	☐
6	Your activity is **NOT** funded by an outside organization with commercial interest in the use of the results. ***NOTE:*** *The purpose of this statement is to determine if the project has received funding to be conducted as a research study.*	x☒	☐
7	Your activity is **NOT** part of a multi-center project that involves non-NYUL Health sites. ***NOTE:*** *If it is being conducted in a multi-site context with a common protocol across sites, then the results may be generalizable and thus constitute research.*	x☒	☐

Certification for the **Project Leader**	
Date	7/19/2014
Print Name	Jeffrey Fine, MD
Signature	7/19/14 MD *I certify that the information provided above is accurate*

NOTE: If the results of this form indicate your proposed activity is considered QI and not research involving human subjects, consistent with the federal regulations governing human subject research, IRB review or oversight is not required.

Appendix D

Seton Hall University IRB approval

SETON HALL UNIVERSITY

1 8 5 6

September 26, 2019

Swati Patel

Re: Study ID# 2020-002

Dear Ms. Patel,

Please accept our apologies for communicating that your human subjects research training was expired in the correspondence dated September 26, 2019. Based on this being the only outstanding requirement from the initial review of your application entitled, "Implementing the Hodgson Red Yellow Green Mobilization Consensus Recommendations in a Medical and Surgical ICU: A Retrospective Study Exploring the Effectiveness of an Early Mobilization Decision Protocol in ICU" at the September 25, 2019 meeting, your study is now approved. This memo serves as official notice of the aforementioned study's approval.

The Institutional Review Board approval of your research is valid for a one-year period from the date of this letter. During this time, any changes to the research protocol or study team must be reviewed and approved by the IRB prior to their implementation.

You will receive a communication from the Institutional Review Board at least 1 month prior to your expiration date requesting that you submit an Annual Progress Report to keep the study active, or a Final Review of Human Subjects Research form to close the study. In all future correspondence with the Institutional Review Board, please reference the ID# listed above.

Thank you for your cooperation.

Sincerely,

Mara Pashey

Mara C. Pashey, PhD, OTR
Associate Professor
Co-Chair, Institutional Review Board

Office of the Institutional Review Board
President's Hall · 400 South Orange Avenue · South Orange, New Jersey 07079 · Tel: 973.275.4654 · Fax 973.275.2978 ·
www.shu.edu

WHAT GREAT MINDS CAN DO