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Virtual reality utilization in stroke motor neurorehab

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VIRTUAL REALITY UTILIZATION IN STROKE MOTOR NEUROREHABILITATION

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ABSTRACT

The burden of strokes on the healthcare system is tremendous. Strokes are one of the leading causes of long-term morbidity and mortality in the United States[1]. In addition, strokes have a huge economic burden that lasts long after the actual stroke has occurred and has been medically stabilized. Thus, there is a desire to prevent strokes, as well as treat those who have experienced stroke. As technology has and continues to advance, there is the potential for the inclusion of new technologies to become integrated into the healthcare system. One such example is the inclusion of virtual reality in the rehabilitation of patients who have experienced a stroke.

The current process of stroke rehabilitation focuses upon returning a patient as close as possible to their baseline level of function. This is generally through the use of repetitive activity to help the brain reroute neuro signaling pathways around damaged areas of the brain. With the inclusion of virtual reality into the process of rehab, it may be possible to better control the environment around a patient and create activities to help better simulate activities of daily life. Through the inclusion of current generation virtual reality into modern rehabilitation regiments it may be possible to better the outcomes of patients who have undergone a stroke with physical deficits.

With the current burden of stroke on the medical system it is important to find ways to treat patients as efficiently as possible. By incorporating virtual reality into stroke

rehabilitation, there may be better outcomes for patients which will allow them to live better and more capable lives. Much of the research that has been conducted on the matter has shown promise but has lacked large sample sizes and often uses outdated technology. More research must be conducted using more modern technologies and larger sample sizes to show a true benefit in its utilization.

The proposed study in this thesis will be a two-armed randomized control trial to assess the efficacy of virtual reality in stroke rehabilitation. The Fugl-Meyer assessment of motor recovery after stroke will be used to evaluate the physical motor benefits of implementation of virtual reality in stroke rehab. The potential benefit of virtual reality into stroke rehab could profoundly impact how we take care of patients who have experienced a stroke. It can create an effective new means to help patients regain their pre-stroke level of function, thus better helping return individuals to their normal lives. This in turn can help decrease costs on the healthcare system by decreasing the number of people living with long term disability.

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LIST OF ABBREVIATIONS

BBS…….Berg Balance Scale

BU ..... Boston University

CDC……Center for Disease Control

FMA……..…Fugyl-Meyer Assessment

MMT…….Manual Muscle Test

MOCA……....Montreal Cognitive Assessment

NIH……...……. National Institute of Health

SSS……...Simulation Sickness Syndrome

TIA..... Transient Ischemic Attack

VRBR.……...……. Virtual Reality Based Rehabilitation

INTRODUCTION

Background

Strokes are a leading cause of long-term disability in the Unites States. The CDC estimated that, in 2011, the chronic care of stroke patients cost 71.6 billion dollars[2]. Every year approximately 795,000 individuals will have a stroke[3]. The longer a stroke lasts and, thus, longer duration of time without oxygen leads to neuronal cell death. The effects of a stroke impact many aspects of a person's ability to function including speech, movement, sensation, gait, balance, and hand eye coordination. The mortality and morbidity associated with strokes are a major concern for public health[1].

Once a patient has survived the acute phase of a stroke the focus shifts to rehabilitation. During this point in a patient's care, return of function is the main priority. It is difficult to determine how close an individual will return to their baseline due to the many factors that can impact the severity and length of a stroke. One general principle is that the longer a stroke takes to resolve, the worse the brain damage will be and the more difficult the recovery will be. Stroke rehab is not a simple process either. Rehab can often be lifelong and require continuous work by the patient to regain normal life functions[4].

Virtual reality has grown to become a potential influence tool for the regain of function in the care of patients. Virtual reality has been around since the late 20th century but major advancements have not been made until recently[5]. Modern virtual reality is a much simpler technology in that the entire apparatus can be worn on one's head and simulate a completely virtual world. It can also provide real time feedback to the individual that can be used to monitor progress and change over time. The possibilities of

using this technology in rehabilitation show promise by being able to control the environment of a patient and allow for the creation of simulated activities that mimic everyday tasks. Additionally, the more compact nature of virtual reality units may allow patients to take their care home with them and continue treatment outside of the clinic for longer periods of rehabilitation exposure, which has been shown to lead to better overall outcomes.

Statement of the Problem

The cost to the healthcare system for stroke care is a huge financial expenditure. The burden of stroke care is not one that can be easily mended. Current physical therapy is effective but time consuming and costly. Therefore, the utilization of new and innovative technology in stroke care must be further explored. Virtual reality is one such technology that allows for simulations to help train patients in skills they lost due to their stroke and also a reduced need for providers to be hands on with patients, as they can complete activities on their own through virtual reality.

Several studies have evaluated the usage of virtual reality in stroke rehab and have found evidence to support its use in clinical care. However, many of these studies have utilized small sample sizes of patients and outdated technology to test their hypothesis. As this technology continues to advance and the cost of virtual reality drops it is more enticing to revisit its inclusion in healthcare.

Given the immense cost of stroke care in the United States the evaluation of virtual reality in stroke care is necessary to determine if this growing technology can help to create better outcomes for patients.

Hypothesis

The inclusion of virtual reality within the standard protocol for stroke neurorehabilitation will increase the return of motor function in patients who experienced physical deficits post-stroke at 6 months when comparing FMA scores of motor function, sensory function, balance, joint range of motion, and joint pain between those with and without VR therapy.

Objectives and specific aims

The objective of this study is to determine the efficacy of virtual reality in addition to current standard of care in bettering patient outcomes regarding their motor recovery. This study, conducted within the Boston Medical Center system, will compare the outcomes of patients with virtual reality incorporation into their care with those who have not utilized virtual reality and only received standard post stroke rehabilitation. This analysis will help to provide evidence for or against the utilization of new generation virtual reality in the rehabilitation of patients who have undergone a stroke. Specifically this study aims to:

- Explore the utility of virtual reality in the rehabilitation of patients who have experienced a stroke

- Evaluate the effectiveness of virtual reality to improve patient's outcomes after stroke rehabilitation

REVIEW OF THE LITERATURE

Overview

Strokes affect over 800,000 people in the United States per year and leave many with long term preventable disability[6]. As such, prevention of strokes is always the most important task but there must also be focus on returning individuals back into society once a stroke has occurred. The focus of neurorehabilitation is to return an individual to social and working activities as soon as possible[7].

Epidemiology and Pathophysiology of stroke

The burden of stroke on the healthcare system is immense. It is predicted that a new stroke occurs every 40 seconds and every 4 minutes someone will die from a stroke[4]. Additionally, stroke is the leading cause of long-term disability in patients in the United States[8]. The risk of stroke varies depending on race and ethnicity, as well as lifestyle. High blood pressure, high cholesterol, smoking, obesity, and diabetes are all factors that increase the risk of stroke. Most of these risk factors are modifiable so it is important to target lifestyle management in decreasing the incidence of stroke.

There are primarily three types of strokes that can occur -- ischemic, hemorrhagic, and transient ischemic attacks (TIA)[9]. An ischemic stroke occurs when a blood vessel leading to the brain becomes blocked by a clot or a plaque, preventing blood flow to an area of the brain. Ischemic strokes account for 87% of all strokes[6]. In a hemorrhagic stroke a weakened blood vessel ruptures into the cranial cavity due to increased pressure in the vessel or a weakness in the wall. A TIA is caused by a clot that is quickly dissolved

by the body's own mechanisms. These strokes are short lasting but are often a sign of an impending full ischemic stroke.

All strokes have the ability to impact one's ability to function at almost any level. By decreasing the supply of oxygen to the brain, a stroke causes nerve cell damage which in turn interrupts the brain's ability to use nerve pathways as it had prior to the stroke. Because the death of neurons can occur anywhere in the brain, patients present with a huge variation of symptoms in movement, speech, vision, cognition, and sensation (Table 1), however, they are not limited to these symptoms[10]. Due to this, patients often require long term intensive therapy to help them restore the function they once had. For the purposes of this thesis the acute care of stroke will not be discussed. Rather, it will focus on post-acute phase stroke care.

Table 1. Distribution of Stroke Symptoms Vurumadla et al.

Symptom	Percentage of individuals reporting symptom
Change in speech	58%
Deviation of mouth	32%
Slurred speech	66.66%
Right sided weakness	64.66%
Left sided weakness	38.66%
Headache	58.66%

To evaluate the damage a stroke has inflicted, the National Institute of Health (NIH) created the NIH stroke scale which scores a person on a variety of possible symptoms like motor control, eye movement, speech, and level of consciousness[11]. The scale scores individuals up to a maximum of 31, which indicates a stroke that has impeded almost all brain function (Appendix 1)[11]. Another predictor of stroke severity is the 6S score which uses six common signs and symptoms of stroke to predict the severity of the stroke, as well as the in-hospital mortality of a patient[12]. Though both of these methods work at the onset of a stroke, it is necessary to have completely different scales to monitor recovery from the stroke. Scales such as the Fugyl-Meyer Assessment have been developed to determine motor recovery after a stroke[13]. Along with this, scales of cognition such as the Montreal Cognitive Assessment (MOCA) can be used to assess changes in behaviors and memory after the damage of a stroke has ended[14].

The current treatment for neurorehabilitation, physical therapy, aims to return individuals back to social and working activities so that they may function with as little assistance in society. It is also important in helping teach individuals ways to compensate for disabilities that may remain after they have regained some of their functional status[4]. Much of the care of post-stroke patients is multidisciplinary in nature and includes care from physicians, nurses, physical therapists, occupational therapists, speech language pathologists, social workers, and psychologists[4]. The care that is rendered to these patients requires a wholistic approach as the symptoms they may endure can impact a variety of aspects of their lives. Rehab typically begins for patients while they are still in the acute care setting following the initial stroke once they have been stabilized. This is

often accomplished by repeated sessions with a physical and occupational therapist to promote movement, strengthening, and range of movement[15]. This is generally achieved by having the patient perform tasks in a repetitive and intensive manner with continuous modifications to ensure progress and engagement[16,17]. These treatment regimens usually last anywhere from 6 months to 1 year after the patient is initially discharged from the hospital[4]. Recent studies regarding neuroplasticity found that repetitive and task specific activities may cause changes in the brain allowing for remapping of motor pathways for these tasks[18]. As such, this is a mainstay of current physical therapy regiments in helping patients to regain their lost function. Though outpatient physical therapy rehabilitation has been shown to help stroke recovery, only 30.7% of stroke patients continue into outpatient therapy after their acute rehabilitation post stroke[19]. There is a need to motivate patients to attend their rehabilitation sessions so they may attain the highest levels of function possible. To initiate more research into this, the NIH has continued increasing their spending in stroke rehab to help find new and innovative technologies that can help keep the patient involved with their care[20]. Some of these technologies as of now include home tele-rehab without the required onsite visits to normal physical therapy sites and transcranial direct current stimulation to help improve motor recovery in patients[21]. Along with this virtual reality has been a large area of interest as it allows for the potential of home rehab that can be scaled to a patient's ability level and modified to keep a patient engaged and active in their rehabilitation[22,23]. Thus, there is a need to find a method that is both fun and effective in allowing patients to practice normal activities so that they are both willing and able to perform participate in the rehabilitation process.

The History of Virtual Reality

The history of virtual reality originates in ancient times where paintings were used to elicit the feeling that we are present in a place we are not. Though this is a humble beginning, it is from where the idea of projecting a new environment around an individual stemmed. From there, the creation of photography took on this role by being able to capture places and recreate them in another medium. In the 1950's Morton Heilig created a "Sensorama," a video cabinet that was able to simulate all of the senses and allowed individuals to become fully immersed in a movie experience[5]. Following, Morton developed the first head mounted virtual reality machine, which was able to project stereo sound and wide stereoscopic vision[5]. It wasn't until 1987 that the term virtual reality was coined by Jaron Lenier who founded the company Visual Programming Labs[24]. This company was key to the development of much of today's modern virtual reality and helped create devices which were capable of integrating haptic feedback into the user experience. From here many gaming companies have created their own virtual reality systems, including the SEGA Virtual Glasses in 1993 and the Nintendo Virtual Boy in 1995[5]. As technology has continued to advance, the processing power computers has vastly increased, while the size of devices has shrunk. Computers that would originally fill entire rooms now have their processing power matched by a device that fits in a pocket. Television screens that at the time of the "Sensorama" were only black and white can now show images in high definition and full color that closely mimic the real world. As such, virtual reality has taken these advances and has become more lightweight and practical than it has ever been. Along with this, modern virtual

reality is capable of incorporating user inputs, as much of the advancement in the field has come from its usage in video gaming[16]. These new generation lightweight and advanced models of virtual reality reflect the huge strides the field has taken since its inception. As these products continue to become available to consumers and the technological capabilities of the devices become more advanced, their applications in fields besides video gaming become more apparent. With the development of software that allows the simulation of everyday tasks, such as grocery shopping, eating food, or even opening doors, virtual reality could be utilized to train stroke survivors the better their rehabilitation process. As the power of virtual reality continues to grow its applications in medicine cannot be overlooked.

Existing research

As virtual reality has become more cost effective, simple to use, and technologically capable, there is increased potential for its integration into healthcare. There have been numerous studies that have attempted to determine the effects of virtual reality in stroke rehabilitation and virtual reality integration into rehabilitation has been found to be beneficial in most cases[25–29]. However, most studies have been conducted with small sample sizes and using virtual reality methods that are becoming outdated. This then suggests a need for further research into the how best virtual reality can be integrated into stroke rehabilitation as a whole.

In a study completed by Minyoung Lee et al. comparing the use of virtual reality with group-based rehabilitation, it was found that, when using an individualized virtual

reality program in stroke rehabilitation, there was a greater increase in Fugyl-Meyer assessment upper extremity (FMA-UE) and Manual Function Tests (MFT) compared with patients who underwent group based therapy[25]. These tests are used to quantify upper limb motor function recovery by assessing a variety of parameters, such as range of motion, motor function, pain, and sensory function. This study analyzed a group of 26 patients all over the age of 50 who had a unilateral stroke lasting longer than one year with mild to moderate stroke related deficits. All eligible participants were randomly assigned to either the VR therapy or control groups. The virtual reality group and control group both underwent three thirty-minute sessions a week for eight weeks with measurements taken at baseline prior to rehab and at the conclusion of the trial period. The VR intervention group utilized a Kinect motion capture device to analyze 20 different joint locations and project an avatar that could be visualized by the patient and would interact with a virtual activity. The patients then used this avatar to follow commands given through a virtual instructor designed for the study to create a diverse workout regimen with a variety of activities to increase motor recovery. The control group had their rehabilitation provided through group instruction with an in-person therapist to provide a similar workout regimen as the VR group. Following conclusion of the study, there was significant increase in upper extremity function in the virtual reality group adjusted between group mean difference in both FMA 7.00(2.47-11.52)(P=0.004) and MFT 2.16(0.63-3.70)(P=0.008), whereas the control group did not show a significant increase. The calculated effect size for this study was 80% based on the standard deviation of total FMA and MFT scores at the conclusion of the study. It was found that

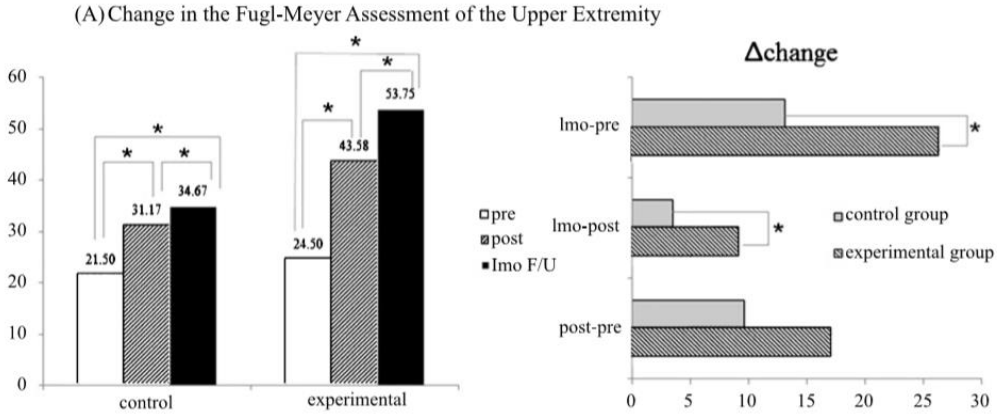
the VR group showed a 7-point increase in UE-FMA compared to control, which indicated a clinically meaningful increase in upper extremity function when compared to group-based therapy. Overall, this study favors the implementation of virtual reality systems when working with stroke patients with upper extremity deficits. In addition, this the study measured attendance rates between the two groups and found that the virtual reality treatment group had a 95.14% attendance rate compared to the standard treatment which was 88.54%, though this was thought to be due to the novelty of the virtual reality in treatment as well as greater ease in scheduling time for virtual reality sessions. When analyzed with an independent-T test though there was no significant difference between the two groups showing that both VR and group-based therapy were highly acceptable in this study population. This study does, however, demonstrate the potential positive impacts of virtual reality in rehabilitation of upper limb motor function through FMA-UE testing. The study lacked a large population size due to its pilot status, though, as they only recruited 26 patients to evaluate effectiveness of virtual reality. The patients they accepted into the trial were randomized but, due to the differences between stroke severity, the baseline measures of FMA scores in the study were skewed such that even with randomization the groups baseline scores were not shown to be equally distributed to the two arms. This was, however, minimized by using an analysis of covariance and setting the baseline values as covariates. The slightly older population utilized in this study is also a limitation as advanced technology may serve as a detriment to treatment in the elderly populous due to a decreased acceptance for new technology

being integrated into their care. Overall, though this study was able to find an increased level of motor function return when utilizing virtual reality-based rehabilitation.[14]

Another study completed by Yoon-Hee Choi et al. focused on mobile game related virtual reality in the setting of ischemic stroke rehabilitation[26]. This double-blind randomized controlled clinical trial aimed to assess the feasibility and effectiveness of a mobile phone based virtual reality experience in stroke rehab. Patients (N=24) underwent 10 sessions of daily therapy 5 days per week over a 2-week period. One group received the virtual reality therapy and conventional therapy in a one-hour session and the other received only conventional physical therapy for the full hour block. Patients were evaluated at the beginning and end of treatment using manual muscle testing (MMT), as well as by the FMA-UE and the Beck Depression inventory. Both groups of the study showed improvement in symptoms at the end of the study compared to the beginning (Figure 2). FMA-UE scores in the experimental group were significantly different than those in the control group. Significantly higher scores were found during the post treatment analysis for those in the experimental arm. On top of this the study found that at one month follow up patients in the experimental group continued to have increased FMA-UE compared to those in the control group. Though this study was able to show that virtual reality-based rehab does impact stroke care, the small sample size that was analyzed may not prove to be generalizable to a broader scale. On top of this the study only evaluated patients at one-month post treatment and scores may become more similar at further points post treatment. This study did, however, demonstrate that virtual reality-based rehabilitation has a positive impact on FMA-UE scores post stroke rehabilitation

compared to control both directly post treatment and at 1 month follow up. This supports the idea that some parts of normal stroke rehabilitation may be able to be replaced with virtual reality components and have positive outcomes for patients.

Figure 1. Change in FMA-UE scores Yoon-Hee Choi et al.



Another study completed by Young-Bin Oh et al. attempted to demonstrate the efficacy of real instrument training in virtual reality environments to help improve upper extremity function after a stroke[27]. Patients (N=31) in this randomized controlled trial underwent 6 weeks of training, 3 days per week for 30 minutes. The experimental arm underwent virtual reality training along with real musical instrument training, while the control arm performed only traditional occupational therapy. Patients were assessed prior to beginning therapy, after the treatment, as well as 6 weeks after the completion of the therapy utilizing the FMA-UE and MMT, as well as the MOCA. Pre, post, and follow up scores where then compared using a paired t test and Wilcoxon sign-rank tests and the

differences between groups were analyzed using an independent t test and Mann-Whitney U tests. FMA-UE scores were 36.5±17.8, 38.6±18.5, and 38.8±18.5 for the control group and 37.6±14.4, 39.5±15.1, and 41.5±14.8 for the experimental group in pre, post, and follow up, respectively ($p<0.001$). Along with this MMT wrist scores where 2.6±1.3, 2.8±1.1, and 2.8±1.1 ($P=0.135$) for the control group and 2.8±0.9, 3±0.8, and 3.1±0.8 ($P=0.039$) in the experimental arm for pre, post, and follow up scores. The experimental arm of this study demonstrated a significant improvement in MMT wrist compared to the control arm ($P=0.039$). Results of FMA-UE were significantly improved in both arms ($P=0.001$) in both arms of the study. This study was limited due to the relatively small sample size of its study population, as well as a more heterogeneous population in regard to stroke characteristics amongst the participants, such as motor function and lesion characteristics. This may limit the generalizability of the findings as the study population does not represent a large enough population of people and may not represent the symptoms of strokes at all their varying severities. However, this study demonstrated that VR therapy combined with real instrument training, as well as conventional therapy, improved the upper extremity function in patients in the chronic phase of stroke rehabilitation. However, the experimental arm was more effective in fine motor skill recovery when compared to the conventional rehabilitation group. As such, this study suggests that virtual reality as an adjunct to or combined with standard physical therapy may provide an innovative intervention for comprehensive stroke care.

Dae-Sung Park et al. conducted yet another study of the effects of virtual reality by utilizing Xbox Kinect systems in the care of stroke patients[28]. This trial

recruited 25 patients from an inpatient rehabilitation center with a diagnosis of hemiplegic stroke. The experimental group received 30 minutes of VR training with the xbox connect followed by a 30-minute session of conventional therapy for 6 weeks. These sessions consisted of a variety of sports related games that could be scaled to a patient's physical capabilities and strength. In contrast, the control group received physical therapy for 30 minutes daily for the same duration. Each session for the control group instead focused on the standard protocol of rehabilitation including range of motion, strengthening, balance, and gait training. Patients were assessed at the beginning and end of their therapy session utilizing the FMA-LE score, as well as by the Berg Balance Scale (BBS). The change in FMA-LE in the intervention group from pre to post therapy was 9.80± 4.85 and was 6.20± 5.22 in the control group ($p<0.05$). Additionally, the BBS score change was 14.20±4.26 for the intervention group and 7.4± 5.78 for the control group when comparing pre to post therapy ($p<0.05$). From these results it was found that in both groups there was a significant improvement in BBS and FMA-LE. The FMA-LE scores were not significantly greater in the experimental group when compared to control but BBS scores proved to be significantly higher in the experimental arm compared to control. One of the issues that arose from this study and its analysis of VR is that each group received a differing amount of therapy during their six-week sessions. This could cause a more favorable improvement in the experimental arm as they were able to receive more therapy than the control participants. On top of this the technology that was utilized during this study is now outdated compared to current

available models. The video game console that was utilized during this study is no longer in production, thus making the software and hardware difficult to obtain. Despite the limitations within this study the findings still support the utilization of VR in the rehabilitation of patients and, when added as a complement to current therapy, it can lead to improved outcomes in returning motor function for patients.

Cognitive Assessment Utilizing Virtual Reality

In a study by Youn Joo Kang et al., patients were able to utilize a virtual reality shopping experience integrated into their rehabilitation[29]. This study aimed to test the effectiveness of virtual reality as a tool to evaluate cognitive deficits in individuals after a stroke, as well as to measure patient satisfaction with virtual reality devices. Twenty participants per arm were selected for this preliminary trial, which utilized a virtual reality grocery store to evaluate behaviors and cognitive function in stroke patients compared with healthy individuals. They sought to determine whether the virtual environment could measure cognitive dysfunction, such as deficits in attention, memory, perception, and problem solving. This was determined by taking a measure of the variables and indices (Figure 2). Stage 1 performance index between the two groups showed a significant difference between the stroke group at 88.3± 13.3 and the control group at 105.3±8 ($p<0.001$). At the conclusion of the study, it was found that the virtual reality program was effective in providing a scale of cognitive dysfunction in the study population compared to control. However, during the study they found that, due to the screens they utilized in their head mounted systems, many of the patients in the study experienced simulation sickness syndrome (SSS). They found that this was equal

amongst both arms of the study, 36.3±25.2 points for the stroke group and 35.8±31.4 in the control on the simulation sickness questionnaire ($p<0.001$). There was no association between experiencing SSS with age, education level, or previous computer usage but gender was not evaluated. One of the weaknesses of this study was that they found that due to the quality of their virtual reality simulation tools many participants had difficulty becoming immersed in the virtual reality experience. This was mainly contributed to the quality of the screens included in the virtual reality devices. This study does lack generalizability though as the differences seen where compared between stroke patients and non-stroke patients. Thus, this would need to be further supported with randomized controlled trials to show a true benefit. As such, the data provided here is a steppingstone for future randomized controlled trials where such software could be tested and evaluated between groups that included stroke patients in both arms. Along with this the study does not analyze the effect of gender on its analysis of SSS which was shown in study by Stanney et al. to be an important factor when analyzing the effectiveness of virtual reality and the rates of experienced SSS[30]. This study showed that due to differences in interpupillary distance females may experience SSS at a higher rate than males unless this is accounted for during the VR fitting process, As such, this study may have benefitted from further elaboration into the effects of gender on SSS. Overall though, this study supports the integration of virtual reality into clinical practice. The development of a cognitive screening tool using virtual reality can help to lessen provider load by allowing for automated stroke evaluation. On top of this it allows for the development of an assessment tool that can simulate a variety of situations and tasks with scalable

difficulty allowing for an in-depth analysis of a patient's cognition and mental state. The virtual reality assessment program has the potential to be a safe, easy to use, and relatively cheap alternative to current cognitive screening tools in stroke patients.

Figure 2. Variables and Indices of Virtual Shopping Simulation Kang et al.

	Stage 1	*Stage 2*	*Stage 3*
Cognitive factors	Computer navigation and interaction	Memory and attention	Executive function
Variables and indices	Total time	Immediate recognition memory score	Total time
	Total distance	Delayed recognition memory score	Total distance
	Total collision	Visual memory score	Judgment score
	Number of selected items	Auditory memory score	Calculation score
	Interaction error[a]	Attention reaction time	Executive index[b]
	Performance index[b]	Responsiveness on attention task	
		Selected items of attention task	
		Attention index[b]	

Much of the research that has been completed investigating virtual reality and its applications in rehabilitation have shown positive outcomes with the inclusion of virtual reality in rehabilitation of patients who have undergone a stroke. This has been shown by increased motor recovery rates on patients rated by FMA, BBS, and MMS scores compared to control groups without VR therapy. Unfortunately, many studies that have been performed to this point have only been able to enlist a small sample size of patients and some have used technology that is outdated and no longer obtainable on a large scale. As such, to complement the existing research into the efficacy of virtual reality, we aim to create a large scale randomized controlled trial utilizing the most up to date virtual reality available. This will help solidify the research into the positive effect VR therapy has and push for the implementation of virtual reality into the care of more stroke victims.

METHODS

Study design

This study will be a randomized controlled trial to assess the efficacy of virtual reality in stroke rehabilitation to allow individuals to better perform activities of daily living. The control arm of the study will receive no virtual reality intervention in their rehabilitation, while the experimental arm will have a virtual reality component added to their rehabilitation. Both arms will still receive standard of care rehabilitation with sessions planned three times per week for the length of the trial. Outcomes from the trial will be assessed using the Fugl-Meyer Assessment of Motor recovery after stroke (FMA) scale, which is widely used and internationally accepted. This evaluation will be completed by a blinded professional therapist at the conclusion of therapy once every month. They will also be tested at baseline and at the conclusion of the study to determine any changes in their rehabilitation progress.

Recruitment, Study Population and Sampling

Patients will be recruited from the Boston Medical Center Neurology Department, as well as Braintree Rehabilitation for entrance into the study. Patients will be identified via their inpatient care team or upon transfer to Braintree rehab for screening and potential entrance into the study. Patients who are interested in the trial will be contacted and screened for inclusion criteria by the study's clinical coordinator. At this time, if the patient meets the inclusion criteria consent will be obtained and the patient will proceed with study enrollment.

For the study, the inclusion criteria will be as follows: 1) patients aged 18-65 years old 2) with a confirmed first diagnosis of ischemic or hemorrhagic stroke within the last year 3) and a physical motor deficit post stroke with 6-month duration and without complete loss of motor function of the effected extremity. Exclusion criteria from the study are: 1) the physical inability to complete rehabilitation exercises; 2) changes in mental status post stroke causing inability to follow commands; 3) changes to vision or hearing; 4) a history of epilepsy, or adverse reactions to screen exposure; 5) a history of headaches, migraines, or dementia; and 6) existing medical condition causing motor dysfunction

Sample size for this study will require the recruitment of 64 participants split equally between the two arms assuming an alpha value of 0.05, beta of 0.2 and a Cohen's d of 0.715. This will be the statistical measure with which we use to compare changes in FMA scores between our experimental and control arms. This Cohen's d was determined from the 2017 RCT in the Journal of Stroke and Cerebrovascular Diseases by Dae-Sung Park et al. which found virtual reality inclusion into standard rehabilitation post stroke increased FMA scores by 3.6±2.25 compared to non-virtual reality based therapies. The results from this paper, showed a small benefit to the incorporation of virtual reality into standard rehabilitation of stroke patients but lacked a large sample size. As such, this study supports the further examination of VRBR in stroke victims but requires further testing into its usage with a large randomized controlled trial to further evaluate its efficacy using other measures of motor recovery. We will plan to recruit 250 participants to account for an approximately 20% drop out rate from the study.

Planned Intervention

Participants who have met the inclusion criteria will be first evaluated using a baseline FMA then randomized to the two treatment arms of the trial. The control arm will receive no virtual reality in their rehabilitation process and only receive standard of care stroke rehabilitation. The experimental arm will incorporate virtual reality into half of their two-hour sessions during their 3 sessions per week throughout the 6-month period. The initial FMA performed by a physical therapist will help to establish a baseline for each patient before starting their treatment arm.

Each session will be conducted by a licensed physical therapist who will follow patients throughout their rehabilitation. Each session will provide a guided set of exercises that target the individual's physical disability and challenge their ability to utilize the weakened extremity. For those in the virtual reality arm the specific virtual reality activity will be catered to the affected area of motor weakness. All virtual reality sessions will utilize wireless standalone virtual reality kits to allow participants to move as freely as possible during their sessions without the constraints of cords or wires that may be potential hazards. A series of basic task exercises will be created for the virtual reality arm to help facilitate their therapy and these activities will attempt to mimic activities of daily living such as cooking, lifting objects, or other fine motor skills. All activities will focus on repetitive utilization and strengthening exercises to comply with current standards of care and the theory of neuroplasticity post stroke. Participants will be expected to attend all physical therapy sessions each week so, during initial screening and

throughout the experiment, ride assistance will be provided as needed to ensure maximal attendance.

Study variables and measures

Due to the variety of symptoms strokes may cause it is difficult to cover every system that may be impacted. In this study we will focus on motor recovery via measurement utilizing the Fugyl-Meyer assessment of motor recovery after stroke. This will provide data regarding the stages of motor recovery in this study population. It includes data on motor function, sensation, balance, and joint function throughout recovery course.

Fugyl-Meyer Assessment

The FMA is considered one of the gold standard evaluations of patient's recovery from stroke. The assessment, which takes approximately 30 minutes to administer, utilizes a 3-point ordinal scale with 0 (cannot perform) to 2 (performs fully). A maximum score of 226 can be achieved from the five categories of motor function (100 points), sensation (24 points), balance (14 points), range of motion (44 points), and joint pain (44 points). (Appendix 2,3)[31] The cumulative score is then used to evaluate for the severity of impairment and improvement over time. The results collected will be interpreted by following cumulative score over time to determine the effects of virtual reality on recovery.

Demographics

Upon initial screening and acceptance into the study baseline demographics will be obtained through a survey administered by the study's clinical coordinator. These will include age, gender, ethnicity, race, medications, comorbidities (hypertension, hyperlipidemia, diabetes, etc.), medications, and stroke risk factors.

Data collection

Study participants will be assessed using the FMA by a licensed physical therapist who will be blinded to the allocation of treatment within the study. This will help to reduce bias and ensure the most accurate data possible. All completed FMA data will be collected from the clinical sites on a weekly basis by a research coordinator who will ensure its safekeeping and storage through the trial period. Once completed the data will be transferred to the research assistant who will oversee data entry and analysis. The research assistant will then work to determine the effect that the intervention had on outcomes in the experimental arm. These will specifically address the recovery of motor functions at the end of the trial compared to baseline.

The clinical coordinator will head the recruitment process, which will include screening of eligible candidates for their initial entry and gathering of demographic data. If an eligible participant opts to be a part of the study, they will be scheduled for all of their physical therapy appointments and follow ups at their time of admission. The clinical coordinator will also be responsible for follow up visits every other month with participants to ensure they have the resources they need to continue participation in the trial and have not encountered any new or worsening symptoms since the trial began. If

patients feel at any time that they do not want to continue in the trial or they are experiencing concerning symptoms, they may contact the clinical coordinator by telephone to withdraw.

Data analysis

All accumulated research data will be collected and combined by the research assistant of the study for the two separate arms. They will summarize the demographics data that has been collected. For any continuous variables a mean and standard deviation will be reported. Categorical variables will be summarized using frequencies and proportions. As for the cumulative FMA scores that will be gathered through the trial, means and standard deviations will be calculated for each month that the FMA was measured during the trial. This will give us a baseline value as well as 6 months of FMA scores gathered throughout the study separated by the two individual groups to allow for evaluation of changes through the study. We will plan to compare baseline values against the final FMA score using a Paired T test analysis to determine change between the treatment arms and values will be plotted in a table. We will then compare the mean change between the groups in mean FMA score utilizing the student's T test for analysis. This assumes the variable is parametric but if this assumption is not met we will utilize a Wilcoxon signed rank test and the Mann-Whitney U test.

Timeline and resources

Overall, this study will be conducted over approximately a two and a half period given appropriate patient recruitment. IRB approval for this study will likely take 4-5

months for final approval, recruitment will take at most 1 year, with a six month intervention period following adequate recruitment, and the statistical analysis of the resulting data should take no more than 4 months. The team for this study will include 2-3 physical therapists, one clinical coordinator, one research assistant, and one IT coordinator/ programmer. Cost incurred during this study will include virtual reality equipment at $399 per system, as well as the cost for development of software to utilize the hardware. Three systems will be purchased to ensure there is adequate equipment for simultaneous sessions to be possible. We will budget $5,000 for the creation of necessary software through an outside contracted service.

Institutional Review Board

This study does not qualify for any of the exempt or expedited categories for IRB approval. Though the study is within normal limits of rehabilitation some patients may experience adverse reactions to virtual reality and thus some risk is possible for discomfort during the study. As such, we will submit this study to the IRB with a level 3 application for full board review. Recruitment will not begin prior to the attainment of IRB approval.

CONCLUSION

Discussion

Further research into the use uses of virtual reality will provide potential information about the incorporation of such technology into the care of patients with strokes. Current rehabilitation methods are effective by utilizing repeated physical actions to stimulate neuroplasticity in the brain and allow for new pathways to become established to take over for areas damaged by stroke. Though this method of rehabilitation is effective in almost all cases, it has drawbacks in that it is costly and time consuming. As such, virtual reality and its inclusion in this study offer the potential to change how we perform stroke rehabilitation as a whole, improving it for the better.

This study aims to gather data on a diverse group of patients who have experienced a variety of different strokes symptoms and severities. This will also include patients from a variety of demographics and backgrounds for generalizability. We will also ensure that an adequate sample size is used so as to provide sufficient statistical power. Additionally, we will be utilizing current generation virtual reality hardware that is stand alone and doesn't require additional equipment to operate which may pave the way for future testing into the usage of virtual reality for at home treatment. During this study though, all participants will continue to receive standard of care physical therapy alongside the virtual reality intervention but at a lower duration.

The potential for bias in our study cannot be excluded. Without the hiring of a larger number of physical therapists, it may be difficult to avoid confounding, as we must distribute therapists to each arm as to not allow them to unblind the study. On top of this,

we may need additional therapists to assess patients on top of those providing care to ensure there is not overlap in who is able to see which therapy a patient is receiving. Though the therapists themselves may skew the data we will attempt to minimize by keeping the evaluator blinded to which arm of the study the participants belong. One additional issue with the current state of VR is that during the time of the study there may become more advanced and simpler to use technology that is released. Though this is always an issue as technology continues to advance at a breakneck pace, we can only evaluate the current generation and attempt to prove that VR can continue to be utilized even as the hardware and software available advances. It is possible that future studies may be able to use the software created during this study with future devices and that by proving the effectiveness of current VR models we will only help to advance stroke rehab along with future technological advancements.

Research into stroke rehabilitation is difficult due to the wide variety of possible symptoms that a patient may experience. This makes targeting rehabilitation difficult and determining the efficacy of treatments even harder. There is no specific way to determine how diffuse or minimal a patient's symptoms will be. Due to this it is necessary to fully assess patients throughout their recovery. Treatment for one patient may not be as effective in another due to the complexity and distribution of their stroke symptoms. This may make it difficult to generalize our study as no two strokes are exactly alike.

Summary

Up to this point research has found that virtual reality incorporation into stroke rehabilitation can have positive effects in improving rehabilitation outcomes for patients. These studies have shown promise for the use of virtual reality in returning patients to their baseline levels of function. Though these studies have all shown positive outcomes with virtual reality, most of them have used technology that is outdated and have only used small sample sizes for their research.

By taking the shortcomings of the past research on virtual reality into consideration, we will look to further the investigation into virtual reality in this medical application. By gathering FMA scores from a large and diverse sample size of patients with a variety of stroke severities, we hope to find a strongly positive effect in utilizing virtual reality for motor rehabilitation. This may allow for a change in the current methods for treating stroke patients and better aiding them in returning to their day to day lives in a shorter and more cost-effective time.

Clinical and/or public health significance

The burden of strokes in the United States and worldwide continues to impact healthcare at an immense level. The New England Journal of Medicine states that approximately 1 out of 4 individuals will experience a stroke in their lifetime[8]. Strokes are one of the leading causes of long-term disability, which increases the economic burden with every stroke that occurs. Prevention is ideal, as this avoids morbidity and mortality all together,

but when strokes occur the most efficient way to return people to their baseline must be used.

Though physical therapy and standard rehabilitation are effective means of helping those that have undergone strokes, the potential incorporation of new technology may assist with the process. Virtual reality is potentially a massive cost saving measure for the health care system, if found to be effective in this capacity. The average cost per patient for outpatient stroke rehabilitation in the first year following stroke is $17,000[32]. This cost continues to rise if the person experiences a more severe stroke and needs extended rehabilitation. The incorporation of virtual reality into this process could help to alleviate some of the cost associated with the rehabilitation process. By allowing therapists to rely on a rehabilitation activity with minimal supervision, they will be able to potentially work with more patients simultaneously and, thus, save cost. The initial cost of virtual reality may be expensive for set-up but one clinic may be able to run several simultaneously to have even more patients treated at the same time.

Though this study will continue to use supervised rehabilitation with a physical therapist, there is also the potential for a future in which at home rehabilitation can be performed. In this case, patients may no longer need to come to a clinic or can attend with much less frequency for their rehabilitation needs. This could mean that the only cost would be for initial set up of their virtual reality systems. This would, however, be a next step for a further study once the efficacy of virtual reality has become more well established.

The continued growth and advancement of virtual reality may also provide the ability to also provide telecare for patients. This may provide the gateway for future face to face encounters through VR and allow patients to receive care no matter where they are.

Though virtual reality has been around for some time now, advancements in its quality and usability make it a prime target for medical use. Through its usage in stroke rehabilitation it may help to better outcomes, lower costs for patients, and potentially allow for at home rehabilitation. Additionally, virtual reality may have applications throughout medicine and continued research into its incorporation should be considered.

APPENDIX

1) NIH Stroke Scale Grading Sheet [24]

Category	Score/Description		Date/Time Initials	Date/Time Initials	Date/Time Initials	Date/Time Initials	Date/Time Initials
1a. **Level of Consciousness** (Alert, drowsy, etc.)	0 = Alert 1 = Drowsy 2 = Stuporous 3 = Coma						
1b. **LOC Questions** (Month, age)	0 = Answers both correctly 1 = Answers one correctly 2 = Incorrect						
1c. **LOC Commands** (Open/close eyes, make fist/let go)	0 = Obeys both correctly 1 = Obeys one correctly 2 = Incorrect						
2. **Best Gaze** (Eyes open - patient follows examiner's finger or face)	0 = Normal 1 = Partial gaze palsy 2 = Forced deviation						
3. **Visual Fields** (Introduce visual stimulus/threat to pt's visual field quadrants)	0 = No visual loss 1 = Partial Hemianopia 2 = Complete Hemianopia 3 = Bilateral Hemianopia (Blind)						
4. **Facial Paresis** (Show teeth, raise eyebrows and squeeze eyes shut)	0 = Normal 1 = Minor 2 = Partial 3 = Complete						
5a. **Motor Arm - Left** 5b. **Motor Arm - Right** (Elevate arm to 90° if patient is sitting, 45° if supine)	0 = No drift 1 = Drift 2 = Can't resist gravity 3 = No effort against gravity 4 = No movement X = Untestable (Joint fusion or limb amp)	Left					
		Right					
6a. **Motor Leg - Left** 6b. **Motor Leg - Right** (Elevate leg 30° with patient supine)	0 = No drift 1 = Drift 2 = Can't resist gravity 3 = No effort against gravity 4 = No movement X = Untestable (Joint fusion or limb amp)	Left					
		Right					
7. **Limb Ataxia** (Finger-nose, heel down shin)	0 = No ataxia 1 = Present in one limb 2 = Present in two limbs						
8. **Sensory** (Pin prick to face, arm, trunk, and leg - compare side to side)	0 = Normal 1 = Partial loss 2 = Severe loss						
9. **Best Language** (Name item, describe a picture and read sentences)	0 = No aphasia 1 = Mild to moderate aphasia 2 = Severe aphasia 3 = Mute						
10. **Dysarthria** (Evaluate speech clarity by patient repeating listed words)	0 = Normal articulation 1 = Mild to moderate slurring of words 2 = Near to unintelligable or worse X = Intubated or other physical barrier						
11. **Extinction and Inattention** (Use information from prior testing to identify neglect or double simultaneous stimuli testing)	0 = No neglect 1 = Partial neglect 2 = Complete neglect						
TOTAL SCORE							

2) FMA UE Assessment Sheet[31]

FMA-UE PROTOCOL — Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT
UPPER EXTREMITY (FMA-UE)
Assessment of sensorimotor function

ID:
Date:
Examiner:

Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. A method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.

A. UPPER EXTREMITY, sitting position					
I. Reflex activity				**none**	**can be elicited**
Flexors: biceps and finger flexors (at least one) **Extensors**: triceps				0 0	2 2
			Subtotal I (max 4)		
II. Volitional movement within synergies, without gravitational help				**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination).	Shoulder	retraction		0	1	2
		elevation		0	1	2
		abduction (90°)		0	1	2
		external rotation		0	1	2
	Elbow	flexion		0	1	2
	Forearm	supination		0	1	2
Extensor synergy: Hand from ipsilateral ear to the contralateral knee	Shoulder	adduction/internal rotation		0	1	2
	Elbow	extension		0	1	2
	Forearm	pronation		0	1	2
			Subtotal II (max 18)			
III. Volitional movement mixing synergies, without compensation				**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)			0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion			0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position			0	1	2
			Subtotal III (max 6)			
IV. Volitional movement with little or no synergy				**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm neutral	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation			0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion			0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position			0	1	2
			Subtotal IV (max 6)			
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side				**hyper**	**lively**	**normal**
Biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive			0	1	2
			Subtotal V (max 2)			
			Total A (max 36)			

Approved by Fugl-Meyer AR 2010 — 1 — Updated 2019-03-03

B. WRIST support may be provided at the elbow to take or hold the starting position, no support at wrist, check the passive range of motion prior testing		none	partial	full
Stability at 15° dorsiflexion elbow at 90°, forearm pronated shoulder at 0°	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsiflexion / volar flexion elbow at 90°, forearm pronated shoulder at 0°, slight finger flexion	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Stability at 15° dorsiflexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsiflexion / volar flexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Circumduction elbow at 90°, forearm pronated shoulder at 0°	cannot perform volitionally jerky movement or incomplete complete and smooth circumduction	0	1	2
	Total B (max 10)			

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		none	partial	full
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
a. **Hook grasp** flexion in PIP and DIP (digits II-V), extension in MCP II-V	cannot be performed can hold position but weak maintains position against resistance	0	1	2
b. **Thumb adduction** 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
c. **Pincer grasp, opposition** pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
d. **Cylinder grasp** cylinder shaped object (small can) tug upward, opposition of thumb and fingers	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
e. **Spherical grasp** fingers in abduction/flexion, thumb opposed, tennis ball, tug away	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
	Total C (max 14)			

D. COORDINATION/SPEED, sitting, after one trial with both arms, eyes closed, tip of the index finger from knee to nose, 5 times as fast as possible		marked	slight	none
Tremor	at least 1 completed movement	0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		≥ 6s	2 - 5s	< 2s
Time start and end with the hand on the knee	6 or more seconds slower than unaffected side 2-5 seconds slower than unaffected side less than 2 seconds difference	0	1	2
	Total D (max 6)			

TOTAL A-D (max 66)	

H. SENSATION, upper extremity eyes closed, compared with the unaffected side		anesthesia	hypoesthesia or dysesthesia	normal
Light touch	upper arm, forearm palmary surface of the hand	0 0	1 1	2 2
		less than 3/4 correct or absence	3/4 correct or considerable difference	correct 100%, little or no difference
Position small alterations in the position	shoulder elbow wrist thumb (IP-joint)	0 0 0 0	1 1 1 1	2 2 2 2
			Total H (max12)	

I. PASSIVE JOINT MOTION, upper extremity, sitting position, compare with the unaffected side				**J. JOINT PAIN during passive motion**, upper extremity		
	only few degrees (less than 10° in shoulder)	decreased	normal	pronounced pain during movement or very marked pain at the end of the movement	some pain	no pain
Shoulder						
Flexion (0° - 180°)	0	1	2	0	1	2
Abduction (0°-90°)	0	1	2	0	1	2
External rotation	0	1	2	0	1	2
Internal rotation	0	1	2	0	1	2
Elbow						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Forearm						
Pronation	0	1	2	0	1	2
Supination	0	1	2	0	1	2
Wrist						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Fingers						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Total (max 34)				Total (max 24)		

A. UPPER EXTREMITY	/36
B. WRIST	/10
C. HAND	/14
D. COORDINATION / SPEED	/6
TOTAL A-D (motor function)	/66

H. SENSATION	/12
I. PASSIVE JOINT MOTION	/24
J. JOINT PAIN	/24

3) FMA LE Assessment Sheet[31]

FMA-LE PROTOCOL — Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT
LOWER EXTREMITY (FMA-LE)
Assessment of sensorimotor function

ID:
Date:
Examiner:

Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. 1. a method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.

E. LOWER EXTREMITY					
I. Reflex activity, supine position			**none**	**can be elicited**	
Flexors: knee flexors			0	2	
Extensors: patellar, achilles (at least one)			0	2	
Subtotal I (max 4)					
II. Volitional movement within synergies supine position			**none**	**partial**	**full**
Flexor synergy: Maximal hip flexion (abduction/external rotation), maximal flexion in knee and ankle joint (palpate distal tendons to ensure active knee flexion).	Hip	flexion	0	1	2
	Knee	flexion	0	1	2
	Ankle	dorsiflexion	0	1	2
Extensor synergy: From flexor synergy to the hip extension/adduction, knee extension and ankle plantar flexion. Resistance is applied to ensure active movement, evaluate both movement and strength (compare with the unaffected side)	Hip	extension	0	1	2
		adduction	0	1	2
	Knee	extension	0	1	2
	Ankle	plantar flexion	0	1	2
Subtotal II (max 14)					
III. Volitional movement mixing synergies sitting position, knee 10cm from the edge of the chair/bed			**none**	**partial**	**full**
Knee flexion from actively or passively extended knee	no active motion less than 90° active flexion, palpate tendons of hamstrings more than 90° active flexion		0	1	2
Ankle dorsiflexion compare with unaffected side	no active motion limited dorsiflexion complete dorsiflexion		0	1	2
Subtotal III (max 4)					
IV. Volitional movement with little or no synergy standing position, hip at 0°			**none**	**partial**	**full**
Knee flexion to 90° hip at 0°, balance support is allowed	no active motion or immediate, simultaneous hip flexion less than 90° knee flexion and/or hip flexion during movement at least 90° knee flexion without simultaneous hip flexion		0	1	2
Ankle dorsiflexion compare with unaffected side	no active motion limited dorsiflexion complete dorsiflexion		0	1	2
Subtotal IV (max 4)					
V. Normal reflex activity supine position, assessed only if full score of 4 points is achieved in part IV, compare with the unaffected side			**hyper**	**lively**	**normal**
Reflex activity knee flexors, Patellar, Achilles,	2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
Subtotal V (max 2)					
Total E (max 28)					

F. COORDINATION/SPEED, supine, after one trial with both legs, eyes closed, heel to knee cap of the opposite leg, 5 times as fast as possible		marked	slight	none
Tremor	at least 1 completed movement	0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		≥ 6s	2 - 5s	< 2s
Time start and end with the hand on the knee	6 or more seconds slower than unaffected side 2-5 seconds slower than unaffected side less than 2 seconds difference	0	1	2
		Total F (max 6)		

H. SENSATION, lower extremity eyes closed, compare with the unaffected side		anesthesia	hypoesthesia or dysesthesia	normal
Light touch	leg foot sole	0 0	1 1	2 2
		less than 3/4 correct or absence	3/4 correct or considerable difference	correct 100%, little or no difference
Position small alterations in the position	hip knee ankle great toe (IP-joint)	0 0 0 0	1 1 1 1	2 2 2 2
			Total H (max12)	

I. PASSIVE JOINT MOTION, lower extremity supine position, compare with the unaffected side		only few degrees (<10° hip)	decreased	normal
Hip	Flexion	0	1	2
	Abduction	0	1	2
	External rotation	0	1	2
	Internal rotation	0	1	2
Knee	Flexion	0	1	2
	Extension	0	1	2
Ankle	Dorsiflexion	0	1	2
	Plantar flexion	0	1	2
Foot	Pronation	0	1	2
	Supination	0	1	2
Total (max 20)				

J. JOINT PAIN during passive motion, lower extremity			
	pronounced pain during movement or very marked pain at the end of the movement	some pain	no pain
Hip	0	1	2
	0	1	2
	0	1	2
	0	1	2
Knee	0	1	2
	0	1	2
Ankle	0	1	2
	0	1	2
Foot	0	1	2
	0	1	2
Total (max 20)			

E. LOWER EXTREMITY	/28
F. COORDINATION / SPEED	/6
TOTAL E-F (motor function)	/34

H. SENSATION	/12
I. PASSIVE JOINT MOTION	/20
J. JOINT PAIN	/20

LIST OF JOURNAL ABBREVIATIONS

Arch Phys Med Rehabil	Archives of Physical Medicine and Rehabilitation
Cochrane Datanase Syst Rev	Cochrane Database of Systematic Reviews
Cyberpsychol Behav	Cyberpsychology & Behavior
Disabil Rehabil	Disability and Rehabilitation
Eur J Integr Med	European Journal of Integrative Medicine
Front Robot AI	Frontiers in Robotics and AI
IEEE Trans Neural Syst Rehabil	IEEE Transactions on Neural Systems and Rehabilitation Engineering
Int J Pharm Pharm Sci	International Journal of Pharmacy and Pharmaceutical Research
J Neuroengineering Rehabil	Journal of Neuroengineering and Rehabilitation
J Physiother	Journal of Physiotherapy
J Stroke	Journal of Stroke
J Stroke Cerebrovasc Dis	Journal of Stroke and Cerebrovascular Diseases
Med Biol Eng Comput	Medical & Biological Engineering & Computing
Med Sci MS	Médecine Sciences: M/S
MMWR Morb Mortal Wkly Rep	MMWR: Morbidity and Mortality Weekly Reports
N Engl J Med	New England Journal of Medicine
Restor Neurol Neurosci	Restorative Neurology and Neuroscience
Top Stroke Rehabil	Topics in Stroke Rehabilitation

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