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Implementation of Modified Constraint-induced Therapy in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital

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IMPLEMENTATION OF MODIFIED CONSTRAINT-INDUCED THERAPY IN UPPER LIMB STROKE REHABILITATION IN AN INPATIENT REHABILITATION HOSPITAL

Presented in Partial Fulfillment of the
Requirements for the Degree of
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DOCTOR OF OCCUPATIONAL THERAPY

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Certification

We hereby certify that this Capstone project, submitted by, Umana Udoeyop conforms to acceptable standards and is fully adequate in scope and quality to fulfill the project requirement for the Doctor of Occupational Therapy degree.

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Executive Summary

Background: Despite increasing and strong evidence of modified constraint-induced therapy (mCIT) as an effective intervention approach for patients with chronic and subacute stroke in outpatient settings, it is still not widely used for the rehabilitation of patients with acute stroke who are typically admitted to inpatient rehabilitation hospitals.
Purpose: The purpose of this study is to implement an evidence-based approach using mCIT in the upper extremity rehabilitation of patients with acute stroke in an inpatient rehabilitation hospital and to demonstrate its feasibility and efficacy in increasing the motor recovery, and the amount and quality of arm use when compared to traditional occupational therapy intervention.
Theoretical Framework. The theoretical framework is based on behaviorist theory, and the model of human occupational (MOHO).
Methods. The study is a quasi-experimental, multiple baseline, randomized, pretest-posttest control-group design study, using a dose-matched control intervention, traditional rehabilitation (TR) for comparison with mCIT. A total of six participants admitted to an inpatient rehabilitation within two weeks of their first stroke and who met the eligibility criteria were randomly assigned to the two groups. The participants were assessed on outcome measures namely the Canadian Occupational Performance Measure, the Fugl-Meyer Assessment, the Wolf Motor Function Test, and the Motor Activity Log before and after intervention.
Results. Four of the 6 participants completed the study according to the study protocol. This study demonstrated significant improvement in motor recovery, improved arm function, more frequent and effective use of the affected arm, and clinically significant improvement in the participants' perception of occupational performance and satisfaction with performance by both intervention approaches. It has also demonstrated greater improvement following intervention with mCIT compared with TR in all outcome measures studied except in the client's perception of satisfaction with performance, with significantly greater change in affected arm motor recovery and the frequency of affected arm use.
Conclusions: The findings of this study demonstrate the feasibility and efficacy of mCIT in upper limb rehabilitation of patients with acute stroke in an inpatient rehabilitation hospital. This strengthens the case for the routine implementation of this evidence-based intervention approach that has been strongly demonstrated in patients with subacute and chronic stroke.

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CERTIFICATE OF AUTHORSHIP

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Certification of Authorship: I hereby certify that I am the author of this document and that any assistance I received in its preparation is fully acknowledged and disclosed in the document. I have also cited all sources from which I obtained data, ideas, or words that are copied directly or paraphrased in the document. Sources are properly credited according to accepted standards for professional publications. I also certify that this paper was prepared by me for this purpose.

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Date of Submission: 4/25/17

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Section 1: Nature of Project and Identification of Problem

Introduction

Stroke is a leading cause of adult disability in the United States, with an estimated prevalence of 7 million stroke survivors (Wolf & Nilsen, 2015). With an annual incidence of approximately 795,000 new or recurrent strokes in the United States, this is one of the most significant causes of physical disabilities treated by occupational therapy practitioners (Go et al., 2013; Nilsen et al., 2015). Patients recovering from stroke face multiple challenges, such as weakness on one side of the body, decline in cognitive and emotional functioning, social disability, inability to walk and care for themselves, and a decrease in community participation (Wolf & Nilsen, 2015). Broeks, Lankhorst, Rumping, and Prevo (1999) state that about half of those recovering from stroke will be left with a non-functioning arm due to paralysis, with most of the motor recovery occurring within the first three months. Taub, Crago, and Uswatte (1998) have postulated that individuals with unilateral upper extremity weakness as a result of stroke may preferentially use the non-affected side while avoiding the use of the affected side, resulting in a "learned nonuse" phenomenon, first observed in animal experiments with monkeys (p. 55). Constraint-induced therapy (CIT) was proposed by Taub et al. (1998) to overcome learned nonuse by restraining the use of the unaffected arm, while engaging the patient in functional activities with the affected arm, thus inducing cortical reorganization based on a theory of brain plasticity (Miltner, Bauder, Sommer, Dettmers, & Taub, 1999; Shi, Tian, Yang, & Zhao, 2001; Page, Sisto, Levine, Johnston, & Hughes, 2001). CIT involves restraint of the unaffected limb for up to 90% of waking hours, forcing use of the affected limb during daily activities (Taub, Crago, & Uswatte, 1998; Wolf & Nilsen, 2015). CIT protocol also includes intensive and repetitive training in functional task activities by shaping or task practice using the affected limb

for 6 hours each day for 2 weeks (Morris, Taub, & Mark, 2006; Wolf & Nilsen, 2015). Modified constraint-induced movement therapy (mCIT) is a shortened version of the original CIT protocol described by Taub and colleagues (1998) in which the amount of time that restraint is applied to the less affected limb is decreased and / or distributed over a longer period (Page, Sisto, Levine, Johnston, & Hughes, 2001).

There are several reports of the efficacy of CIT in upper extremity stroke rehabilitation (Miltner et al., 1999; Taub, et al., 2006; Wolf et al., 2006). Several studies including that of Page, Sisto, Levine, and McGrath (2004) have shown that mCIT is an efficacious method of improving function and use of the affected arm of patients with hemiparesis following chronic stroke. The efficacy of mCIT in increasing affected arm use and function has been demonstrated mostly in the outpatient clinics on individuals with subacute and chronic stroke (Page, Sisto, Johnson, Levine, & Hughes, 2002; Shi, Tian, Yang, & Zhao, 2011; Page, Sisto, Levine, & McGrath, 2004). There are only reports of preliminary and pilot studies demonstrating the feasibility and efficacy of mCIT in the rehabilitation of patients with acute stroke (Dromerick, Edward, & Hahn, 2000; Page, Levine, & Leonard, 2005).

Problem Statement

In order to realize the goal of the centennial vision of the American Occupational Therapy Association (AOTA, 2007), there is need for occupational therapy practice in stroke rehabilitation to be based on the best available evidence (Gillen, 2015). Reviews have uncovered strong evidence of effective occupational therapy interventions for patients recovering from stroke especially those addressing motor deficits (Gillen, 2015; Nilsen et al., 2015). Despite the convergence of evidence, there is a disconnect between what has been learned from evidence and what occupational therapists do in practice in stroke rehabilitation, a gap that seems to be

widening as noted by Gillen (2015). Among the multiple factors contributing to this gap is the attachment of many occupational therapists to traditional approaches even with limited evidence of their effectiveness (Gillen, 2015). The review of research evidence by Nilsen et al. (2015) described common elements in effective interventions for motor rehabilitation following stroke to include emphasis on "training of the impaired arm and hand using goal-directed, individualized tasks that promote frequent repetitions of task-related or task-specific movements" (p. 4-5). These elements are central to CIT and mCIT and are consistent with occupational therapy philosophy of occupation-based practice (AOTA, 2014). However, Latham et al. (2006) noted in a study of rehabilitation techniques for clients with stroke in six inpatient rehabilitation hospitals that CIT was the approach or type of intervention used in only 2.7% of all interventions. The study included patients who had a recent stroke (within one year of admission) as the reason for the admission, with no interruption in rehabilitation services greater than 30 days. The findings by Latham et al. (2006) demonstrated that despite its proven efficacy, CIT is not a commonly used intervention approach by occupational therapists in the rehabilitation of patients with acute stroke in inpatient rehabilitation hospitals, thus confirming Gillen's (2015) observation about the gap between empirical evidence, and the real world of occupational therapy practice.

Based on the opinions of therapists in Southwestern Ohio, Daniel, Howard, Braun, and Page (2012) explained the low rate of application of CIT in clinical practice to include concern about payer reimbursement for these interventions, the potential difficulty the patients would face during the clinical therapy sessions, the prolonged duration of restrictive devise application, and the lack of awareness of the availability of modifications in CIT that addressed these challenges. Page, Sisto, Levine, Johnston, and Hughes (2001) described a modified constraint-

induced therapy (mCIT) protocol to address these limitations to the original CIT by distributing shorter treatment sessions to 30 minutes, limiting the restriction of the less affected upper extremity to 5 hours per day for 5 days per week, and extending the protocol to 10 weeks of outpatient treatment. These researchers demonstrated the feasibility and efficacy of mCIT with individuals with chronic stroke (Page, Sisto, Levine, & McGrath, 2004), subacute stroke (Page, Sisto, Johnston, Levine, & Hughes 2002), and acute stroke (Page, Levine, & Leonard, 2005). The feasibility and efficacy of mCIT protocols lasting from 2-4 weeks in subacute, and acute stroke have been demonstrated in studies from China, Europe, and India, and the United States (Dromerick et al., 2009; Dromerick, Edward, and Hahn, 2000; El-Helow et al., 2015; Page, Levine, and Leonard, 2005; Singh & Pradhan, 2013; Wang, Zhao, Zhu, Li, & Meng, 2011). Occupational therapists need to bridge the evidence-practice gap by implementing intervention strategies that are based on scientific evidence, and are proven to be effective in addressing occupational performance deficits in patients with stroke who have motor impairments. Since available evidence has clearly demonstrated the efficacy and feasibility of mCIT in chronic, subacute, and acute stroke, it makes sense to explore its implementation in routine stroke rehabilitation in an inpatient rehabilitation hospital. The rationale is because an inpatient rehabilitation hospital is the preferred setting for most patients with acute stroke with moderate or severe symptoms, who have significant functional deficits and medical and/or nursing needs, and have the ability to tolerate at least 3 hours of therapy per day for 5-7 days per week (Management of Stroke Rehabilitation Study Group, 2010; Miller, 2010; Wolf & Nilsen, 2015). Since mCIT has been demonstrated to reverse the effects of learned nonuse (Page et al., 2005), it does make more sense to apply mCIT early in the acute setting as a preemptive measure to prevent patients from learned nonuse.

Purpose of the Project

The purpose of this study was to implement an evidence-based approach using modified constraint-induced therapy (mCIT) in the upper extremity rehabilitation of patients with acute stroke admitted to an inpatient rehabilitation hospital. The aim was to close the evidence-practice gap in stroke rehabilitation with an intervention approach with strong evidence-basis of efficacy in chronic and subacute stroke, and great promise in acute stroke, in the setting where it really matters. This study would serve as a model for routine implementation of mCIT in upper limb stroke rehabilitation of patients with acute stroke in inpatient rehabilitation hospitals.

Project Objectives

This research proposal was a quasi-experimental study to test the hypothesis that the implementation of mCIT for upper extremity rehabilitation of patients with acute stroke in an inpatient rehabilitation hospital will lead to greater motor recovery of the affected extremity, and an increase in amount and quality of arm use, compared to traditional occupational therapy interventions.

Scientific Underpinnings

Developments in neuroscience and movement science provided evidence of an approach to rehabilitation called constraint-induced therapy (CIT) described by Taub, Crago, and Uswatte (1998) based on observations in animal experiments and successfully adapted to clinical use. Constraint-induced therapy is based on a principle in which operant-conditioning techniques are applied to change the behavior of subjects with stroke from developing learned nonuse, resulting in increased use of the affected upper limb in daily activities (Taub, Crago, & Uswatte, 1998; Page, Johnson, Levine, & McGrath, 2004). The important distinction with CIT is that rather than using compensatory strategies as in the traditional approaches to stroke rehabilitation, CIT

restricts the less affected upper extremity while applying intensive training of the affected upper extremity with "shaping" and task practice based on operant conditioning for 6 hours daily for 14 days (Taub, Crago, & Uswatte, 1998, p. 158). The restraint and shaping techniques in CIT changes behavior by overcoming a phenomenon termed "learned-nonuse" which develops in the affected limb following stroke (Taub, Crago, & Uswatte, 1998, p.155). The effect of CIT is the result of the induction of cortical reorganization based on a theory of brain plasticity (Miltner, Bauder, Sommer, Dettmers, & Taub, 1999; Taub et al., 1998). A more detailed description of the theoretical framework is provided in the literature review.

Significance of the study

The focus of occupational therapy is to help individuals achieve health, wellbeing, and participation in life through engagement in occupations, or activities (AOTA, 2014). In inpatient rehabilitation hospitals, occupational therapists achieve the goal of enabling people to engage in occupations through evaluation and assessment of clients striving to know the extent of their deficits after stroke, to determine the needs and goals of the clients (Wolf & Nilsen, 2015). In inpatient rehabilitation hospitals, upper extremity stroke rehabilitation provided by occupational therapists typically includes a combination of approaches. The approaches are broadly speaking in two categories namely, an impairment-focused or bottom-up approach, and an occupation-based or top-down approach (Coster, 1998; Gray, 1998; Trombly, 1993). The impairment-focused approach addresses the motor or sensory impairments or deficits as the primary focus of intervention with the ultimate goal of improving the client's occupational performance as a byproduct (Coster, 1998; Gray, 1998; Trombly, 1993). Such components include impairments in strength, range of motion, balance, coordination, visual perception, problem solving, and attention among others (Gray, 1998; Trombly, 1993). However, as noted by Trombly (1993) and

Gray (1998), simply addressing the deficits in these components may not automatically translate to improvement in occupational performance. According to Trombly (1993), Coster (1998), and Gray, (1998), occupation-based or top-down approach starts with an inquiry into the client's competency for their roles and their meaningfulness, identifies the important tasks that define the client's key roles, the tasks that enable the performance of such roles, and the critical tasks that the client is unable to perform in order to function in those roles. The main difference between the two approaches is the focus of an occupation-based or top-down approach on the primary objective of improving the client's occupational performance in activities of daily living (ADLs), including bathing, dressing activities, grooming, eating and toileting, instrumental activities of daily living (IADLs), bed mobility, leisure, home management, community integration, and wheelchair training, using occupations as the interventions, and following disability from disease or injury (Coster, 1998; Fisher, 1998; Gray, 1998; Trombly, 1993).

According to Smallfield and Karges (2009), occupational therapy interventions in inpatient rehabilitation hospitals include prefunctional (or preparatory) activities in 65.77% of the sessions. These are "impairment-focused-activities" aimed at improving the body function and structure of the client to prepare them for functional activities (Smallfield & Karges, 2009, p. 411). These include range of motion exercises, and those classified by Latham et al. (2006) as upper extremity control activities, defined as the training and facilitation of normal movement, strength, range of movement, or alignment in the upper extremity. In addition, traditional inpatient rehabilitation incorporating occupational therapy interventions on stroke programs also use occupation-based activities, predominantly ADLs, including bathing, dressing activities, grooming, eating and toileting, and less so on IADL, bed mobility, leisure, home management,

community integration, and wheelchair training as interventions, following disability from disease or injury (Smallfield & Karges, 2009; Latham et al., 2006).

Based on the conclusion of reviews by Ernst (1990), there was no convincing evidence at the time, of the effectiveness of rehabilitation of any kind on functional status of stroke survivors, thus making the case for well-designed trials to determine effective interventions. According to Taub, Crago, and Uswatte (1998), this gap in evidence from clinical research to support the efficacy of interventions used in stroke rehabilitation began to be filled by advances in neuroscience and behavioral psychology, leading to the subsequent emergence of CIT.

In a survey of 92 therapists in southwestern Ohio, Daniel, Braun and Page (2012) found that 83% of therapists working in outpatient and inpatient hospital and neuro-rehabilitation settings felt that most clinics would not have the resources to implement CIT, and 75% reported that it would be difficult or very difficult to administer CIT in their clinics. Other potential obstacles mentioned by a majority of the therapists included concern about payer reimbursement for CIT, and potential difficulty the patients would face during the clinical therapy sessions and the prolonged duration of restrictive devise applications. Page, Sisto, Levine, Johnston, and Hughes (2001) designed a form of modification of CIT to address these limitations of CIT by distributing shorter treatment sessions to 30 minutes, limiting the restraining of the less affected upper extremity to 5 days per week for 5 hours, and extending the protocol to 10 weeks of outpatient treatment (Page, Sisto, Levine, Johnston, & Hughes, 2001). Studies on mCIT demonstrated increased use and function of the affected upper extremity after mCIT participation by patients with chronic stroke (Page, Levine, & Leonard, 2005; Page, Levine, Leonard, Szaflarski, & Kissela, 2008; Page, Sisto, Levine, & McGrath, 2004), and the increase in upper extremity ability continued up to three months after intervention.

Modified constraint-induced therapy was initially described as an efficacious outpatient intervention for rehabilitation of patients with subacute and chronic stroke (Page, Sisto, Levine, Johnston, & Hughes, 2001; Page, Sisto, Johnston, Levine, & Hughes, 2002; Page, Sisto, Levine, & McGrath, 2004). Page, Levine and Leonard (2005) reported modest improvement in limb use and function in a randomized controlled pilot study to determine the feasibility of mCIT in individuals with acute stroke compared to traditional rehabilitation in individuals with acute stroke patients with upper limb hemiparesis. These results are suggestive of use-dependent cortical reorganization resulting in functional improvement, and offer great potentials for recovery since as noted by Page et al (2005), acute and subacute phases are "believed to be times of considerable potential recovery" (p. 31). However, this was an outpatient modified protocol combining the 30-minute 3 days per week of therapy on the affected upper extremity and the 5-hour 5 days per week restraining of the unaffected arm performed in the participant's home for a 10-week study duration. More studies have been published in recent years demonstrating the efficacy of mCIT for inpatient rehabilitation in individuals with acute and subacute stroke with protocols lasting from 2-4 weeks in studies in China, Europe, and India, and the United States (Dromerick et al., 2009; Dromerick, Edward, & Hahn, 2000; El-Helow et al., 2015; Page, Levine, & Leonard, 2005; Singh & Pradhan, 2013; Wang, Zhao, Zhu, Li, & Meng, 2011). Nijland et al. (2013) have described in detail a protocol for early mCIT in inpatient rehabilitation of patients with acute stroke.

Since the late 1900s, when researchers like Taub, Crago, and Uswatte (1998) noted the paucity in evidence of the effectiveness of credible interventions on outcomes following rehabilitation, the last 3 decades have witnessed "almost 1000 randomized control trials in stroke rehabilitation," with "very little translation of this evidence base into clinical practice" (Stinear,

Ackerley, & Byblow, 2013, p. 2039). Stinear et al. (2013) noted that the evidence base for new motor rehabilitation techniques like mCIT initiated early after stroke was relatively small as very few of the good quality studies were initiated during the time when most rehabilitation occurs. Thus a majority of the evidence base in CIT and mCIT were obtained in patients with chronic stroke, whereas stroke rehabilitation typically begins in the acute phase in inpatient rehabilitation hospitals, or skilled nursing facilities (Miller, 2010; Stinear et al., 2013; Wolf & Nilsen, 2015). This may likely explain the paucity in implementation of mCIT in routine clinical practice even when reasonably strong evidence of its efficacy has emerged. Latham and colleagues' (2006) study demonstrated that CIT was the approach or type of intervention used in 2.7% of all interventions on clients with stroke in six rehabilitation hospitals. The most frequently used activities included upper extremity control (22.9% of total treatment time), dressing activities (14.9 % of total treatment time), and pre-functional activities (9% of total treatment time), whereas CIT was the approach used in 1.8-4.1% of all treatment sessions in inpatient rehabilitation hospitals (Latham et al., 2006). In contrast, the more common neuromuscular interventions were balance training, (44.5%), postural awareness (44.7%), and motor learning (42.6%), musculo-skeletal interventions like strengthening (31.5%), and passive range of motion (19.4%), compared to the 2.7% of all interventions that were based on CIT.

Summary

The purpose of this study was to demonstrate the efficacy of mCIT in upper extremity rehabilitation of patients with acute stroke resulting in hemiplegia in an inpatient rehabilitation hospital as a way to demonstrate its feasibility and applicability in this setting for this subset of patients recovering from stroke. The study was expected to serve as a model for the implementation and application of mCIT in stroke rehabilitation in inpatient rehabilitation

hospitals as a pilot program for an evidence-based approach to rehabilitation of patients with acute stroke in inpatient rehabilitation hospitals. Stinear, Ackerley, and Byblow (2013) have argued that testing new treatment for stroke rehabilitation in the time and place of its intended use "paves the way for its translation to clinical practice" (p. 2041). Nijland et al (2013) referred to studies that suggest a critical time window of reactive neuroplasticity within the first 30 days after stroke as an opportunity for therapists to "successfully apply evidence-based therapies such as mCIT for acute stroke survivors" (p. 6). The aim of the study was to translate research evidence to clinical practice in the quest to realize the Centennial Vision of occupational therapy as a "powerful, widely recognized, science-driven, and evidence-based profession" (American Occupational Therapy Association, 2007, p. 614).

Section 2: Review of the Literature

Introduction

Strokes commonly result in motor impairments that may impair a person's ability to engage in meaningful occupations (Nilsen et al., 2015). Occupational therapists provide rehabilitation to assist stroke survivors to improve their occupational performance using a variety of approaches across all settings (Wolf & Nilsen, 2015). With an estimated 6.6 million Americans ≥20 years of age recovering from a stroke, an overall prevalence of 2.6%, and an annual incidence of approximately 795,000 new or recurrent strokes in the United States, this is one of the most significant causes of physical disabilities treated by occupational therapy practitioners (Go et al., 2013; Mozaffarian et al., 2016; Nilsen et al., 2015). A projected 20.5% increase in prevalence of stroke from 2012 data will result in additional 3.4 million adults who would have suffered a stroke by 2030 (Ovbiagele et al., 2013). The impact of stroke as a leading cause of physical disability will therefore continue to expand with this expected increase in prevalence of survivors (Center for Diseases Control, 2013). Among 108 patients recovering from stroke in the Framingham Heart Study of the National Heart, Lung, and Blood Institute, 50% had hemiparesis, 30% were unable to walk without assistance, and 25% were dependent in activities of daily living (Kelly-Hayes et al., 2003). Broeks, Lankhorst, Rumping and Prevo (1999) observed that about half of those recovering from stroke are left with functional impairment of the upper extremity as a result of paralysis, with most of the motor recovery occurring within the first three months. Immediately after the onset of stroke, patients usually receive care from a medical service in an acute care setting in a specialized stroke unit or neurological intensive care unit in a hospital (Wolf and Nilsen, 2015; Mozaffarian, 2016).

Following hospitalization for acute stroke, 24% of Medicare patients are discharged to inpatient rehabilitation facilities, 31% to skilled nursing facilities (SNFs), and 45% return

directly home, 32% of the latter using home healthcare services (Buntin, Colla, Deb, Sood, & Escarce, 2010). Those who have continued rehabilitation needs that are beyond the capacity of community-based programs are usually admitted to an inpatient rehabilitation hospital (Management of Stroke Rehabilitation Working Group, 2010; Wolf and Gillen, 2015). Occupational therapists are usually involved in addressing the limitations in occupational performance and participation in all phases of stroke care in acute care, rehabilitation, and community or outpatient settings (Wolf & Nilsen, 2015). Practice analysis data from the National Board for Certification in Occupational Therapy (2013a; 2013b) shows that approximately 60% of occupational therapy practitioners provide services for stroke survivors. In whichever setting they may be providing service, occupational therapy practitioners have an obligation to base their practice on the best available evidence of what is effective in restoring recently hospitalized stroke survivors to their prior level of occupational performance, with a focus on each client's desired goals. This obligation is in keeping with the practice framework of the American Occupational Therapy Association (AOTA, 2014) and its centennial vision of an evidence-based, science-driven profession (AOTA, 2007). In their evidence-based review of research on people with motor impairments after stroke, Nilsen and colleagues (2015) found evidence of a variety of interventions that can improve the occupational performance of survivors.

While concerns were raised by researchers like Ernst (1990) in the 1990s, of the paucity in convincing evidence of the effectiveness of rehabilitation of any kind on functional status of stroke survivors, there were significant developments in neuroscience and movement science providing evidence of a new approach to rehabilitation called constraint-induced therapy (CIT) described by Taub, Crago, and Uswatte (1998) for patients with stroke first demonstrated in

animal experiments and successfully adapted to clinical use. CIT uses a protocol aimed at increasing functional use of the more impaired upper extremity of stroke survivors with hemiparesis (Taub, Crago, Uswatte, 1998; Reiss, Wolf, Hammel, McLeod, & Williams, 2012).

Constraint-Induced Therapy in Stroke Rehabilitation

Taub, Crago, and Uswatte (1998) postulated that stroke survivors with unilateral upper extremity weakness may preferentially use the non-affected side while avoiding the use of the affected side, resulting in a "learned nonuse" phenomenon, first observed in animal experiments with monkeys (Knapp, Taub, & Berman; 1958, 1963**).** CIT was proposed by Taub and his colleagues (1998) to overcome learned nonuse by restraining the use of the non-affected arm, while engaging the patient in functional activities with the affected arm as will be further explained below. CIT is a method of treatment that involves restraint of the unaffected limb for up to 90% of waking hours, while forcing use of the affected limb for everyday activities, and engaging it in shaping and intensive and repetitive task training 6 hours per day for two weeks (Nilsen et al., 2015; Taub et al., 1998). Studies have demonstrated significant improvement in arm motor function following the use of CIT (Wolf et al, 2006, Nilsen et al., 2015). The therapeutic effect of CIT is attributed to its induction of use-dependent cortical reorganization based on a theory of brain plasticity (Morris, Taub, & Mark, 2006; Sterr & Saunders, 2006).

Theoretical Basis of Constraint-induced Movement Therapy

Various theories, models of practice and frames of references are used by occupational therapy practitioners to provide guidance in their practice and a rationale for designing interventions for their clients (Law & McColl, 1989; Krefting, 1985). Stroke rehabilitation using CIT may be explained based on the behaviorist theory (Skinner, 1953; Sterr & Saunders, 2006; Taub, Crago, & Uswatte, 1998) and the model of human occupation (Kielhofner & Burke, 1980).

These theoretical underpinnings may be used to explain the working of the two main components of CIT which involve techniques to change the behavior of the client by discouraging the use of the less affected upper limb by means of a mitt worn as a restraint, and intensive training of the paretic upper limb using repetitive functional activities (Morris, Taub, & Mark, 2006; Taub, et al., 1998).

Behaviorist theory. The behaviorist theory refers to the process of learning or "conditioning" observable, tangible behaviors "in response to some environmental stimulation" (Stern, 2009, p. 377). CIT is based on advances in neuroscience and behavioral psychology research to change the arm-use behavior of monkeys from whose forelimbs somatic sensation had been surgically abolished (Knapp, Taub, & Berman; 1958, 1963). The monkeys stopped using the deafferented arm in the experiments, but could be trained to use the arm by immobilizing the intact arm for several days, or training the affected arm (Taub, Crago, & Uswatte, 1998; Miltner et al., 1999). Taub and colleagues (1998) explained the loss of motor function of the deafferented arm as a result of a learned behavior they aptly termed "learned nonuse" as a result of loss of sensory feedback, resulting in a decrease in functional use of the affected arm and developed a hypothesis that the same principles would apply in human beings with unilateral deafferentation following a stroke with hemiparesis (p. 155). Taub and his colleagues (1998) postulated that stoke survivors with unilateral upper extremity weakness may preferentially use the non-affected side while avoiding the use of the affected side, resulting in a "learned nonuse" phenomenon, first observed in animal experiments with monkeys (p. 155). CIT was therefore proposed by Taub and his colleagues (1998) to overcome learned nonuse by restraining the use of the non-affected arm, while engaging the patient in functional activities with the affected arm, thus inducing cortical reorganization based on a theory of brain plasticity

(Miltner, Bauder, Sommer, Dettmers, & Taub, 1998; Shi, Tian, Yang, & Zhao, 2001; Page, Sisto, Levine, Johnston, & Hughes, 2001).

Training protocols for the affected limb have been based on repetitive adaptive task practice or shaping performed under the clinical supervision of the therapist. Shaping is performed using blocks of a specific functional task, broken down into successive manageable components addressing components of the task that the patient is unable to complete using the affected arm (Reiss et al., 2012; Taub, Crago, & Uswatte, 1998). Shaping is conducted using a behaviorist theory principle called operant conditioning in which the therapist provides feedback to the patient, motivating the patient to use the affected limb in repetitive practice of meaningful tasks (Sterr & Saunders, 2006; Taub et al., 1998). The training exercise, together with the forced use of the affected arm for long periods results in restoration based on the theory of brain neuroplasticity induced by "use-dependent increase in cortical reorganization" of the areas of the brain that control movement in the more affected limb (Reiss et al., 2012, p. 2). Liepert and colleagues (2000) have provided strong evidence in support of this phenomenon in their study using Transcranial Magnetic Stimulation to demonstrate a significant increase in the cortical hand representation in the affected hemisphere following CIT, an indication that the intervention produced a trend toward normalization of cortical representation. The study used a 12-day period of CIT resulting in significantly increased area of cortical representation in the area of the affected cerebral hemisphere innervating the affected hand muscle, and corresponded to a greatly improved motor performance of the paretic limb (Liepert et al., 2000).

The term operant conditioning was first described by Skinner (1953, p. 65) and implies that a change in behavior or response to a stimulus that was followed by reinforcement was likely to be strengthened (Stern, 2009). During shaping sessions, the therapist provides positive

verbal reinforcement whenever improvement was recorded, and avoids any negative or discouraging comment when attempts are unsuccessful (Morris, Taub, & Mark, 2006; Page & Levine, 2007). Shaping as used in CIT and mCIT follows closely the three important conditions for operant conditioning described by Stern (2009) namely, that the reinforcement must follow, not precede the response, that the reinforcement should immediately follow the behavior, and thirdly that the reinforcement must be contingent on the response. Sterr and Saunders (2006) have emphasized the importance of task learning that is meaningful using the affected upper extremity while the less affected hand is restrained for effective skill re-learning. This occurs as the affected upper extremity is used during all everyday activities, in addition to its being used during shaping for repetitive practice of functional tasks that are important to the patient (Sterr & Saunders, 2006).

Model of Human Occupation. Stroke rehabilitation using mCIT also aligns with the model of human occupation (MOHO) described by Kielhofner and Burke (1980), an occupation-focused, client-centered and evidence-based approach to occupational therapy practice (Shinohara, Yamada, Kobayashi & Forsyth, 2012). According to the MOHO concept, occupational performance is a product of the interplay of three subsystems namely the volition, the habituation, and the performance capacity subsystems (Kielhofner & Burke, 1980; Kielhofner, 2008; Shinohara, Yamada, Kobayashi & Forsyth, 2012). The subsystems are organized in hierarchies, with the volition system the highest, governing the others, and refers to the client's valued goals, interests and personal causation, or self-image of competence as an actor (Kielhofner & Burke, 1980).

The volition subsystem determines what the individual choses to do on the basis of what actions the client will find pleasing and satisfying to do, and what actions are likely to achieve

the desired results or allow mastery of the world (Kielhofner & Burke, 1980; Kielhofner, Burke, & Igi, 1980). In designing the mCIT protocol for this study, the focus of the individualized therapy session is on activities chosen by the client, during which the patient engages in intensive and repetitive training of the affected upper extremity using shaping or task practice. With assistance from the therapist, the client choses the activities for the individualized sessions using a client-centered, occupation-based assessment tool, like the Canadian Occupational Performance Measure (COPM, 2015). The intervention is therefore guided by the volition subsystem based on the individual's motivation, valued goals and interests The importance of the volition component in mCIT is well illustrated in the observation by Bayona, Bitensky, Salter, and Teasell (2005) that training in repetitive activity alone, "without usefulness or meaning in terms of function" has less efficacy than even "less intense but task-specific training regimens with the more affected limb" in producing "cortical reorganization and associated, meaningful functional improvements" (p. 58).

The habituation subsystem consists of habits, internalized roles, and routines, and guides the individual to output of action that are enacted automatically out of consciousness in order for the client to meet the demands of the environment (Kielhofner, Burke, & Igi, 1980). In the mCIT protocol, task re-learning using the affected upper extremity for all everyday activities while the less affected hand is restrained is an effective preparation for habituation, which refers to routine patterning, or the habits and roles that are critical for the client's sense of self (Schultz-Krohn & Pendleton, 2006; Kielhofner, 2008).

The performance subsystem produces skilled action composed of physiological (neurological and kinesiological) and symbolic functions, and consists of component actions that lead to accomplishment of the task (Kielhofner & Burke, 1980). According to Kielhofner and

Burke (1980), skills consist of the component actions that are needed to accomplish a purpose or goal in order to perform required tasks. Skills include movements, perception, decision-making and problem solving. According to Kielhofner, Burke, and Igi (1980), the rules that govern skill development in the performance subsystem contain information on how the individual reacts with the environment. While performance capacity (skilled action) is developed early in life, Kielhofner and Burke (1980) have stated that individuals can generate new skills throughout life "by engaging the environment in exploratory play" and practice toward mastery (p. 579). Both principles are at play in mCIT. During the individualized therapy session, the occupational therapist breaks the skills required to perform functional activities chosen by the client into small steps. By observing the client's attempt to perform the activity, the therapist identifies the components in which the client is deficient, and trains the client to practice the deficient components repeatedly. Feedback is an important element that guides the skill development in this model ((Kielhofner & Burke, 1980).). According to Kielhofner, Burke, and Igi (1980), feedback guides the learning of a skill, determines whether the particular activity is interesting and provides the system with the environment's response to its role performance. A key component of the shaping technique used by the occupational therapist during the individualized therapy session in the mCIT protocol is the constant feedback provided as soon as the client records improvement in mastering a particular skill component. The repetitive task-oriented training used in mCIT is a form of "serious mastery training," which is "energized by the volition subsystem's urge toward mastery" since it is based on functional activity chosen by the client (Kielhofner & Burke, 1980, p. 579). The second component of mCIT is based on having the participant wear a restraint for 5 hours per day on the less affected hand while the more affected upper extremity is used for everyday activities including activities of daily living

(ADLs) like bathing, dressing activities, grooming, eating and toileting, instrumental activities of daily living (IADLs) like meal preparation, housework, use of telephone, bed mobility, and wheelchair training, and leisure activities. In this manner, the mCIT protocol enables the development of new skills by actively engaging the client in the use of his or her more affected hand and the environment in exploratory play and problem solving under the rules governing the performance subsystem.

In its application to mCIT, the interrelationship of the different subsystems of MOHO to each other are clearly illustrated. According to Kielhofner, Burke, and Igi (1980), people disabled by injuries and illness experience "imbalance among volition, habituation and performance systems" (p. 788). In designing mCIT protocols for patients with stroke, the occupational therapist assists the patient to develop skills for carefully selected functional activities valued by the client (volitional subsystem) by training in repeated activities using shaping techniques while providing feedback (performance subsystem). Translating the output from the performance subsystem to the habitation subsystem is illustrated in the "adherence-enhancing behavioral methods" or "transfer package" developed in mCIT protocols to transfer gains in skills made in the clinical setting of individualized training into the client's routine daily life situation (Morris, Taub, & Mark, 2006, p. 261).

The MOHO concept can also be used to explain traditional occupational rehabilitation for patients with acute stroke in inpatient rehabilitation hospitals and the traditional rehabilitation protocol used in this study. Findings from Latham et al. (2006) and Smallfield and Karges (2009) show that approximately two-thirds of occupational therapy intervention sessions used for patients with stroke in inpatient rehabilitations hospitals include prefunctional activities, meaning impairment-focused activities including upper extremity control activities, strength, range of

motion, or alignment in the upper extremity. These are preparatory activities that aim to improve the structure and function of the body in preparation for functional activity. These interventions correspond to the performance subsystem in MOHO. Occupational therapy interventions for stroke rehabilitation in inpatient rehabilitations are also based on occupation-based activities, predominantly ADLs, IADLs, leisure, home management, community integration, and wheelchair training (Coster, 1998; Gray, 1998; Smallfield & Karges, 2009; Latham et al., 2006). Coster (1998), Gray (1998) and Trombly (1993) have described occupation-based practice as a top-down approach that begins with an inquiry into the client's role competency and meaningfulness, identifying the important tasks that define the key roles, the tasks that enable the clients to perform the key roles, and those critical tasks the client is unable to perform in order to function in their key roles. Using the client's key roles as a basis for assessment and designing interventions to enable the client fulfill their desired roles, routines and habits corresponds to the habituation subsystem of MOHO. The traditional rehabilitation intervention protocol in this study also used such an occupation-based approach corresponding to MOHO, with occupation-based activities chosen by the client with the help of the therapist using a client centered assessment tool, the Canadian Occupational Performance Measure (COPM, 2015), the intervention using a compensatory approach. This corresponds to the volition subsystem of MOHO.

Elements of Constraint-Induced Therapy

Although the CIT protocol has undergone many modifications over the three decades of its use, the most commonly used protocols maintain three main elements that were present in the original protocol as described by Taub, Crago, and Uswatte (1998). These include repetitive

task-oriented training of the affected upper extremity, constraining use of the more affected upper extremity, and adherence-enhancing behavioral strategies.

Repetitive task-oriented activities. In the original or signature CIT protocol, participants received 6 hours a day on weekdays of individualized training using functional task activities under the supervision of a therapist for a total of 2 weeks (Morris, Taub, & Mark, 2006). The training may consist of shaping using the principles of structured behavioral training as already described, or less structured task practice consisting of functionally based activities (Morris et al. 2006; Taub, Crago, & Uswatte, 1998). The duration of each supervised practice session have been reduced in mCIT protocols with a wide variation observed in a systematic review and meta-analysis involving randomized controlled trials (RCTs) comparing mCIT with traditional rehabilitation (TR) by Shi, Tian, Yang, and Zhao (2011). The duration of the practice sessions ranged from 30 minutes/day for 3 days/week in 4 RCTs, 1 hour/day for 3 days/week in 2 RCTs, 2 hours/day for 5 days/week in 5 RCTs, and 3 hours/day for 5 days/week in 2 RCTs (Shi et al., 2011). The total treatment time of mCIT treatment protocols also varied widely, ranging from 2 weeks in 3 RCTs to 3 weeks in 4 RCTs, and 10 weeks in 6 RCTs (Shi et al., 2011). This systematic review provided evidence of the effectiveness of mCIT in reducing the level of disability, and improving the ability to use the paretic arm compared to traditional rehabilitation. (Shi et al., 2011).

Constraining use of the more affected upper extremity. The original CIT protocol incorporated the use of a restraint on the less affected upper extremity in the form of a sling, while the participant relies on the more affected upper extremity for everyday activities (Morris, Taub, & Mark, 2006; Taub, Crago, & Uswatte, 1998). The form of restraint has since evolved to the use of a protective safety mitt which as explained by Morris and colleagues (2006) prevents

the use of the less affected upper extremity for functional tasks while allowing its extension for protection in case of a fall. The protective safety mitt appears to be the preferred method of restraint in most mCIT research studies (Page, Sisto, Levine, Johnson, and Hughes, 2001; Nijland, Wegen, Krogt, Bakker, Buma, Klomp, Kordelaar, and Kwakkei, 2013). Participants wear the constraint on the less affected hand for 90% of the hours spent awake for 14 consecutive days in the original CIT protocol (Taub, Uswatte, King, Morris, Crago, & Chatterjee, 2006). In mCIT, participants spend less time with the restraint applied to the affected upper extremity (Page, Levine, & Leonard, 2005). Based on the systematic review and meta-analysis of randomized controlled trials (RCTs) on the effectiveness of mCIT by Shi, Tian, Yang, and Zhao (2011), the restraint time for the less affected hand varied from 5 hours a day in 7 RCTs to 6 hours a day in 7 RCTs.

Adherence-enhancing behavioral strategies. The third component of the original CIT protocol is the so-called "transfer package" which refers to techniques the authors developed to enhance patient engagement, participation, and accountability adhering to the requirements of the intervention protocol (Morris, Taub, & Mark, 2006). These were especially important in the context of the outpatient setting in which almost all these studies were conducted, and required patients to wear restraints on their less affected extremity for up to 90% of waking hours, while using their affected upper extremity for daily activities. The discipline and commitment in meeting their needs using a functionally impaired upper extremity, away from the supervision of a therapist must have been very demanding on patients. Such measures include monitoring, problem-solving, and behavioral contracting (Morris et al., 2006). Participants were required to maintain a record of their activities and the duration of each activity to be reviewed by the therapist to encourage consistency and compliance. Problem solving may be addressed by

teaching participants how to identify obstacles that may hinder their adherence to the treatment program, and how to overcome those obstacles through practical solutions. In addition, participants may be required to sign a formal contract to document their commitment to perform activities they have mutually agreed to with the therapist, during their hours wearing the restraint (Taub, Crago, & Uswatte, 1998; Morris et al., 2006).

Outcome Measures in Modified Constraint-Induced Therapy Research

The development of CIT and mCIT created a need to develop new outcome measures so as to adequately measure "functional activity in the life situation" as the most important outcome measure for the new intervention (Taub, Crago, & Uswatte, 1998, p. 160). These included the Motor Activity Log (MAL; Taub et al., 1998) and the Actual Amount of Use Test (AAUT; Taub et al., 1998), the Wolf Motor Function Test (WFMT; Taub et al., 1998; Wolf, Lecraw, Barton, & Jann, 1989), the Action Research Arm Test (ARA; Page, Levine, Leonard, 2005), the Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA; Fugl-Meyer, Jaasko, Leyman, Olsson, & Steglind, 1975; Page, Levine, Leonard, 2005). Studies demonstrating the reliability and validity of these instruments have resulted in their near universal adoption as the standard outcome measures in CIT research and practice (Uswatte, Taub, Morris, Light, & Thompson, 2006; Wolf, Catlin, Ellis, Morgan, & Piacentino, 2001; Morris, Uswatte, Crago, Cook III, & Taub, 2001; Duncan, Propst, & Nelson, 1983; Hsieh et al., 2009).

Development of Modified Constraint-Induced Therapy

Physical deconditioning due to stroke and co-morbid conditions typically associated with the stroke patient population including impaired cardiovascular fitness, gait deficit, and the impact of aging have been mentioned as some of the reasons why these patients may be unable to participate in a traditional CIT stroke rehabilitation program (Page, Sisto, Levine, & McGrath,

2004). Concern about compliance with long duration of restraining of the less affected upper extremity for 90% of waking hours, and the intensity of the shaping therapy lasting up to six hours daily for two weeks led Page, Sisto, Levine, Johnston, and Hughes (2001), working with others in their lab to describe the mCIT approach. This mCIT protocol proposed by Page et al. (2001) addresses these concerns in order to improve the feasibility and the likelihood of compliance in the clinic. The amount of time in which the non-affected limb is restrained, and the duration of the training sessions for the affected limb are substantially decreased and /or distributed over a longer period of time (Page et al., 2001). In a description of their mCIT protocol, Page, Levine, and Leonard (2005) combined ½ hour therapy sessions three days a week for 10 weeks of functional practice sessions, with restraining of the unaffected limb for five hours each day for five days each week for 10 weeks.

Effectiveness of Modified Constraint-Induced Therapy and Role in Stroke Rehabilitation

Several studies including those of Page, Sisto, Levine, Johnston, and Hughes (2001) and Siebers, Oberg, and Skargren (2010) have shown that modified constraint induced therapy (mCIT) is an efficacious method of improving function and use of the affected arm of patients with hemiparesis following chronic stroke. The efficacy of mCIT in increasing affected arm use and function has been demonstrated mostly in the outpatient clinics on patients with subacute (Page, Sisto, Johnson, Levine, & Hughes 2002) and chronic stroke (Page, Sisto, Levine & McGrath, 2004; Page, Levine, Leonard, Szaflarski, & Kissela, 2008). Preliminary and pilot studies demonstrating the feasibility and efficacy of mCIT in acute stroke rehabilitation have been reported by Dromerick, Edward, and Hahn (2000) and Page, Levine, and Leonard (2005).

However, CIT and mCIT are still not widely used in inpatient rehabilitation hospitals, which is the setting most patients with acute stroke are discharged to. A study by Latham et al.

(2006) noted that that CIT was the approach or type of occupational therapy intervention used in only 2.7% of all interventions in a study of rehabilitation techniques for patients with stroke in six rehabilitation hospitals. The study included 954 patients who had had a recent stroke (within 1 year of admission) as a reason for admission, and had no interruption in rehabilitation services of greater than 30 days (Latham et al., 2006).

In order to demonstrate the feasibility and efficacy of mCIT in patients with acute stroke in inpatient rehabilitation hospitals, studies have been published in recent years demonstrating the efficacy of mCIT for inpatient rehabilitation of patients with acute and subacute stroke with protocols lasting from 2-4 weeks in studies in China, Europe, and India, and the United States (Dromerick et al., 2009; Dromerick, Edward, & Hahn, 2000; El-Helow et al., 2015; Page, Levine, & Leonard, 2005, Singh & Pradhan, 2013; Wang, Zhao, Zhu, Li, & Meng, 2011). Nijland et al. (2013) have described in detail a protocol for early mCIT in patients with acute stroke. This study provided the most detailed description of mCIT protocol utilized in evidence-based research. In their protocol, repetitive task training is applied for one hour per working day, and the patient wears a mitt on the less affected hand for a minimum of 3 hours per day for 3 consecutive weeks (Nijland et al., 2013). The key feature of this protocol is the provision of homework to patients at the end of each training session with the aim of encouraging them to exercise the more affected limb during the 3 hours in which the restraint is worn (Nijland, 2013). This descriptive study is an important resource for researchers developing mCIT protocols, and practicing therapists seeking to implement mCIT evidence in real world clinical practice (Nijland et al., 2013).

Settings for Stroke Rehabilitation

Care of patients with stroke in the United States starts in acute care hospitals where those admitted with acute stroke receive an evaluation and diagnostic tests for the first few days (Krakauer, Carmichael, Dale, Corbett, & Wittenberg, 2012). Once medically stable, the patients are discharged to a variety of settings ranging from home with no therapy, home therapy program, skilled nursing facilities, and inpatient hospitals (Krakauer et al., 2012; Wolf & Nilsen, 2015; Mozaffarian et al., 2016). Buntin, Colla and Escarce (2009) found that the majority of Medicare beneficiaries who are discharged with acute stroke receive rehabilitation services in skilled nursing facilities after discharge (32%), followed by inpatient rehabilitation hospitals (22%), and then home health care (15%). For those in need of rehabilitation, an inpatient rehabilitation hospital is the recommended setting for patients with acute stroke who are medically stable and possess the ability to tolerate at least 3 hours of multidisciplinary rehabilitation program including formal physical, occupational, and speech therapy per day for 5-7 days per week (Miller et al., 2010; Krakauer et al., 2012; Management of Stroke Rehabilitation Working Group, 2010; Wolf & Nilsen, 2015). In addition, stroke survivors admitted to inpatient rehabilitation hospitals must have medical comorbidities that require 24-hour availability and close supervision of a physician and a registered nurse with specialized training or experience in rehabilitation (Miller et al., 2010). Also, the rehabilitation team is required to determine that significant functional improvement can be expected from prospective patients within a reasonable time, and that the patient can return to a community setting rather than another residential setting or inpatient setting like SNF or long-term care facility (Miller et al., 2010).

Stroke survivors who are unable to tolerate the intensity of the program in an inpatient rehabilitation hospital, or require 24-hour care or skilled medical care are usually referred to a

subacute rehabilitation facility. Upon discharge from inpatient rehabilitation hospitals and, subacute rehabilitation facilities, clients may receive further service in community settings as outpatient programs or in-home services (Krakauer et al., 2012; Management of Stroke Rehabilitation Working Group, 2010; Wolf & Nilsen, 2015). As recommended in the Practice Guidelines of the American Occupational Therapy Association, occupational therapy services at the rehabilitation phase of recovery which occur in inpatient rehabilitation hospitals should focus on restoration of and compensation for performance deficits affecting occupational performance, and maximizing independence in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) in preparation for the patient's return to community living (Wolf & Nilsen, 2015).

Conclusion

Although demonstrating great promise, with reasonably strong evidence of feasibility and efficacy, published research on CIT and mCIT have been hampered by methodological limitations, mostly due to small sample sizes. Other limitations include the use of subjective outcome measures, including self-report measures, like the MAL, and observer-initiated measures like the FMA, and the ARA test as clearly stated by Page et al (2005). Some of the studies do not include long-term follow up to assess the long-term effects of this approach in many of the studies (El-Helow et al., 2005; Dromerick et al., 2009). In spite of the limitations, the available evidence has clearly demonstrated the efficacy and feasibility of mCIT in the rehabilitation of patients with chronic, subacute, and acute stroke. The proposed study will focus on the implementation of mCIT in the upper extremity rehabilitation of patients with acute stroke in an inpatient rehabilitation hospital. It makes sense to explore its implementation in routine stroke rehabilitation in an inpatient rehabilitation hospital, which is the usual disposition setting

for patients recovering from acute stroke who are able to tolerate at least 3 hours of therapy per day for no fewer than 5 days per week in whom functional recovery can be expected within a reasonable time period (Miller et al., 2010). Since mCIT has been demonstrated to reverse the effects of learned nonuse (Page et al, 2005), doesn't it make more sense to apply it early in the acute stage of stroke in an inpatient rehabilitation hospital in the first instance to prevent patients from learning nonuse? The weight of the present evidence is a strong endorsement of such an approach.

Section 3: Methods

Project Design

This research study was designed to demonstrate the feasibility and efficacy of the implementation of an evidence-based approach in routine upper extremity stroke rehabilitation of patients with acute stroke in an inpatient rehabilitation hospital, by comparing the impact of modified constraint-induced therapy (mCIT) to traditional rehabilitation (TR) in that setting. This was achieved through an experimental study design to test the hypothesis that mCIT will lead to greater motor recovery of the affected arm, an increase in amount and quality of arm use, and improvement in occupational performance compared to TR on patients with acute stroke in an inpatient rehabilitation hospital, controlling for the dose of intervention used. The study was a true experiment with a multiple baseline, randomized, pretest-posttest control-group design, using a dose-matched control intervention (TR) for comparison with mCIT (Creswell, 2014)). The design involved random assignment of the participants to two groups to receive either mCIT, or TR. A pretest occupational profile (American Occupational Therapy Association, 2014) and outcomes, namely the Canadian Occupational Performance Measure (COPM, 2015), the Fugl-Meyer Assessment (FMA), the Wolf Motor Function Test (WMFT), and the Motor Activity Log (MAL), were administered to each of the two groups. The study was a between-subject design using the two treatment approaches (mCIT and TR) as independent variables, to compare the simultaneous effects of these treatment variables on outcomes (dependent variables). A single occupational therapist, the principal investigator who was trained to acquire proficiency in the administration of the outcome measures, conducted the pretest and posttest assessments for all study participants using these instruments including the COPM, FMA,

WFMT, and the MAL. The study received approval from both the hospital and university Institutional Review Boards.

Description of Project Setting

The study was conducted in a 50-bed freestanding rehabilitation hospital that provides comprehensive rehabilitation for patients with diagnoses such as orthopedic, neurological, cardiac, and pulmonary conditions, and specialized inpatient programs for stroke, brain injury and trauma. It is part of a network of rehabilitation hospitals owned by a national corporation, and is one of the nation's largest providers of post-acute care healthcare services. The key community partners of the rehabilitation hospital include nearby acute care hospitals, and a large number of community nursing homes operating skilled nursing facilities, outpatient rehabilitation centers, and home health organizations. Their mission statement is to be the healthcare company of choice for patients, employees, physicians and shareholders by providing high quality care in the communities. The hospital is located in south central United States serving three counties with combined population of population 340, 000 approximately 94% of whom are non-Hispanic Whites, 2.3% are African Americans, and 1.6% Hispanics (County Health Rankings & Roadmaps, 2016).

The leadership team in the hospital has six directors working under a chief executive officer. The director of therapy services is a physical therapist and oversees the four therapy departments including physical therapy, occupational therapy, speech therapy, and respiratory therapy, each with a supervisor. The major programs and services provided include specialized rehabilitation services including amputee, arthritis, balance and vestibular rehabilitation, bowel and bladder training, brain injury, hip fracture, joint replacement, neurological disorders, Parkinson's disease, strokes, spasticity management, spinal injury, multiple trauma and others.

Early rehabilitation of individuals after acute stroke who are able to tolerate at least 3 hours of therapy per day for not less than 5 days per week occurs in inpatient rehabilitation hospitals (Miller, 2010; Management of Stroke Rehabilitation Working Group, 2010; Wolf & Nilsen, 2015). Based on data from the National Board for Certification in Occupational Therapy (2013a, 2013b), approximately 60% of occupational therapy practitioners provide rehabilitation services to people who are recovering from stroke. In order to realize the vision of a science-driven, and evidence-based profession, occupational therapy practitioners need to apply the best available evidence, in their practice, and implement occupation-based practice consistent with their professional practice framework (American Occupational Therapy Association, 2007; 2014). Occupational therapists providing services to patients with stroke therefore need to implement an evidence-based approach for upper extremities rehabilitation using interventions that target the clients' preferred outcomes in order to make stroke rehabilitation more occupation-based, evidence-based, client-centered and therefore increase the likelihood of client engagement, participation and satisfaction with therapy (Baum & Law, 1997; American Occupational Therapy Association, 2014). Conducting this study on patients with acute stroke in an inpatient rehabilitation hospital will also enable research and clinical practice to target stroke rehabilitation to the early period (first 30 days) after stroke which has been identified as a period of "heightened plasticity" of the brain, and a critical time period for initiation of treatment (Krakauer, Carmichael, Corbett, & Wittenberg, 2012, p. 923). This setting was chosen in order to align the evidence of effectiveness of the intervention to the timing of stroke rehabilitation in routine occupational therapy practice. Much of the evidence of feasibility and effectiveness of CIT and mCIT has been obtained from research on patients with chronic, and subacute stroke in outpatient settings. However, in routine clinical practice, stroke rehabilitation typically begins in

inpatient rehabilitation hospitals with acute stroke (Management of Stroke Rehabilitation Working Group, 2010; Wolf & Nilsen, 2015). As stated by Stinear, Ackerley, and Byblow (2013), such misalignment between timing of interventions in research studies and what obtains in everyday practice may account for a significant limitation in the translation of research evidence to clinical practice.

Identification of Participants

The participants in this study were a convenience sample of all patients with acute stroke who were admitted to the inpatient rehabilitation hospital during the study period. To be included in the study, patients must have had their first ischemic stroke within two weeks prior to enrollment into the study. Other inclusion criteria were the ability to actively extend at least 5 degrees at the metacarpophalangeal and interphalangeal joints and 10 degrees at the wrist, a score of ≥ 70 on the Modified Mini-Mental State Exam (Teng & Chui, 1987), age $\geq 18 \leq 95$, no excessive spasticity, as defined by a score ≤ 3 on the Modified Ashworth Spasticity Scale (Bohanon & Smith, 1987), and no excessive pain in the affected upper limb, measured by ≤ 4 on a 10-point visual analog scale (Wewers & Lowe, 1990), affected upper limb nonuse defined as an amount of use score of < 2.5 on the Motor Activity Log (MAL), and not participating in any other experimental rehabilitation or drug study (Page, Sisto, & Levine, 2002; Page, Sisto, Johnston, Levine, & Hughes, 2002; Page, Levine, & Leonard, 2005). The exclusion criteria included those with stroke longer than 14 days prior to study enrollment, excessive spasticity as defined by a score > 3 on the Modified Ashworth Spasticity Scale, excessive pain in the affected upper limb measured by a score of > 4 on a 10-point visual analog scale, and participants aged $<$ 18, or pregnant. A total of six participants were enrolled for the study, and these were randomized to the two intervention groups.

The principal investigator was notified by the admissions liaison when a patient with a first acute stroke was accepted for admission to the inpatient rehabilitation hospital and would conduct a preliminary screening based on demographic and clinical data provided. Those who met the inclusion criteria were informed about the research study using a verbal recruitment script (see appendix), and were invited to participate in the study. Those interested in participating received more detailed information on the study during which signed informed consent was obtained by the principal investigator according to the mandate of the Institutional Review Boards of the university and healthcare system. Prior to obtaining informed consent, the principal investigator performed targeted screening assessment for competency following the consent discussion by asking the potential subject specific questions on, or to describe risks, anticipated benefits, research purpose and the voluntary nature of their participation (National Institutes of Health, 2009; Appelbaum, 2007)). If the subject had adequate consent capacity based on this initial screening, it was documented by the principal investigator that the subject understood the key issues. Subjects still considered to have impaired consent capacity after initial assessment underwent formal capacity evaluation using a standardized questionnaire, the aid-to-capacity evaluation (ACE) which was administered by the principal investigator (Feng et al., 2007; Etchells et al., 1999). Those who met the criteria for inclusion, and were willing to participate, and had capacity to consent, signed the consent form to participate in the study. Participants who were determined to have impaired decision making capacity had their designated Durable Power of Attorney, or a legally authorized representative (LAR) or a surrogate decision-maker appointed by the attending physician in accordance with state law, participate in the consent discussion and sign the consent form on their (participant's) behalf.

Project Methods

A total of 14 patients with acute stroke were admitted to the inpatient rehabilitation during the period for data collection from October 28, 2016 to December 15, 2016 and were screened using the inclusion and exclusion criteria. Using these criteria 6 patients (mean age=72.5, SD=7.31, range=61-84) who were found to be eligible and agreed to participate were enrolled in the study following informed consent. The mean time from stroke onset to enrollment was 4.3 days (SD=1.2, range=3-6). Those enrolled included 3 male subjects (mean age=72.7, SD=1.15) and 3 female subjects (mean age=72.4, SD=11.50). Three patients had a stroke with left hemiparesis, while 3 patients had right hemiparesis. After screening and informed consent were obtained, the enrollment data of the participants accepted for the study were placed in a designated folder in a locked cabinet. Random allocation of participants was performed through computer software generated random sequence from Research Randomizer (Urbaniak & Plous, 2013) using blocked design in which potential participants were divided into blocks of 2 participants, and each participant within a block was randomly assigned to one of the two study groups; mCIT, or TR. The allocation was revealed to the treating therapist by the enrolling staff after administration of pretest measures.

Instruments

A designated occupational therapist, the principal investigator administered the outcome measures on all study participants prior to intervention and at the end of the intervention (pre- and post-test) to prevent potential variation in the assessments. The assessments included the Canadian Occupational Performance Measure (COPM), the Fugl-Meyer Assessment (FMA), the Wolf Motor Function Test (WMFT), the Motor Activity Log (MAL) and field notes with investigator's observations. The principal investigator has 5 years of experience as an

occupational therapist with broad experience including stroke rehabilitation in an inpatient rehabilitation hospital and acquired competence in the administration of the measures. This was acquired through comprehensive online courses for the COPM (2017) and the FMA (Occupation Therapy.com, 2016), training videos and manuals for the WMFT and MAL provided by the University of Alabama at Birmingham Constraint-Induced Movement Therapy Research Group (2011), and practical training with the occupational therapy supervisor in the inpatient rehabilitation hospital.

The Canadian Occupational Performance Measure. The Canadian Occupational Performance Measure (COPM, 2015) is an individualized, client-centered outcome measure for identification and evaluation of self-perceived occupational performance problems, establishment of treatment goals and assessing changes in perceived performance and satisfaction with occupational performance over time (Law et al., 1990; Cup, Scholte op Reimer, Thijsen, & van Kuy-Minis, 2003; Eyssen et al., 2011). The method of administration involved asking participants to identify occupational performance problems in the areas of self-care, productivity and leisure, then rating the importance of each activity and rating their performance and satisfaction with each activity. Several studies on patients with stroke have demonstrated high test-retest reliability for performance scores (0.89, $p<0.001$) and satisfaction score (0.88, $p<0.001$) and acceptable inter-rater reliability and discriminant validity of the COPM, and its usefulness as a measure of change in occupational performance and satisfaction from the initial evaluation and identification of the specific needs of the client and setting of treatment goals, thus enabling meaningful goal directed interventions (Cup et al. 2003; Eyssen et al., 2011; Phipps & Richardson, 2007).

The Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA). The FMA is a quantitative measure of motor recovery, balance, sensation, coordination, and speed following a stroke (Fugl-Meyer, Jaasko, Leyman, Olsson, & Steglind, 1975). The upper extremity section of the FMA that was used for this study is a 66-point assessment of several impairments using a 3-point ordinal scale ranging from 0 (cannot perform, and 1 (can perform partially), to 2 (can perform fully). Each participant was tested on each item by giving a verbal instruction, and carried out the movement with the less affected upper extremity, and then attempted the same movement with the affected extremity. Movements were tested from proximal to distal with the more difficult movements performed in the latter stage of the test. Studies have shown that the FMA has high test-retest and inter-rater reliability (Duncan, Propst, & Nelson, 1983; Hsieh et al., 2009). The FMA also demonstrated a large degree of responsiveness, and good construct and predictive validity properties and is a relatively sound outcome measure of motor function after stroke compared to the Action Research Arm Test and the Wolf Motor Function Test (Hsieh et al., 2009).

The Wolf Motor Function Test (WMFT). The WMFT was originally conceptualized to examine the effects of forced use or CIT on motor function of survivors of strokes and traumatic brain injury (Wolf, Lecraw, Barton, & Jann, 1989). It has since been modified to serve as a reliable outcome measure in CIT research on stroke with all degrees of functioning, demonstrating high inter-rater reliability, internal consistency, test-retest reliability, construct validity, criterion validity, and adequate stability (Wolf, Catlin, Ellis, Morgan, & Piacentino, 2001; Morris, Uswatte, Crago, Cook III, & Taub, 2001). Wolf, McJunkin, Swanson, and Weiss (2006) provided a pilot normative database to serve as reference points to describe patients, set goals, and evaluate treatments. The revised protocol as described by Page, Sisto, Levine,

Johnston, and Hughes (2002) was used for this study. The designated therapist (the principal investigator) obtained a measure of the patient's ability to perform 19 simple limb movements and tasks with the affected upper extremity. Two of the items measured strength, and 17 items were timed and scored.

Motor Activity Log (MAL) and Daily Dairy. The MAL is a semi-structured interview measuring how stroke patients use their affected limb for 30 important activities of daily living (ADLs) during the period under review was used for this study (Taub, Crago, & Uswatte, 1998; Morris, Taub, & Mark, 2006). During the MAL interview, the participants were asked to independently rate how much and how well they have used the affected arm in the designated activities during the past week. The participants rated how much they were using their affected arm for each item on a 6-point scale for Amount of Use (AOU), and how well they were using their affected arm on a 6-point scale for Quality of Movement (QOM). Tasks included classic ADLs, such as brushing teeth, buttoning a shirt/blouse, and eating with a fork or spoon. Data analysis from a multisite, randomized, controlled trial of early and delayed constraint-induced therapy showed that the MAL exhibited reliability and good convergent validity (Uswatte, Taub, Morris, Light, & Thompson, 2006). In addition to the MAL interview of the activities for the week preceding the beginning of the study, and the MAL interview of activities during the week at the end of the interventions, the participants listed their activities outside the lab during the period in which they were wearing the restraint, and reported if they were using their more affected upper extremities particularly on those activities listed in the behavioral contract (Morris, Taub, & Mark, 2006). The treating therapist conducted a daily review of the diary in order to "heighten participants' awareness of their use of the more affected upper extremity and

emphasize adherence to the behavioral contract and the patients' accountability for their own improvement" (Morris, Taub, & Mark, 2006, p. 262).

Interventions

Each participant was provided individualized 1 hour occupational therapy sessions, 5 times per week for 10 days using either the mCIT protocol, or the traditional rehabilitation (TR) protocol designed for this study based on his or her randomized group assignment. The same therapist provided each participant's entire treatment. All the interventions for the study were provided by two designated occupational therapists with an average of 10 years of experience in neuro-recovery. All mCIT interventions were performed by an occupational therapist with bachelor's degree in occupational therapy and prior experience in a CIT pilot project and working as the occupational therapy supervisor in the hospital. All TR interventions were performed by an occupational therapist with master's degree in occupational therapy, currently in charge of the stroke program in the hospital.

Modified Constraint-Induced Therapy (mCIT). Each participant assigned to mCIT participated in individualized 1-hour occupational therapy sessions, 5 times/week for 10 days, administered to the affected upper extremity by the same therapist. The therapy session was spent on shaping techniques and included challenging activities targeting deficient components of 2-3 activities chosen by the participant with help from their therapist, e.g. writing, using a fork and spoon, brushing teeth, combing hair (Page & Levine, 2007). "Shaping" is defined as an operant conditioning training method in which a desired behavioral or motor objective is "approached in small steps by successive approximations" (Morris, Taub, & Mark, 2006, p. 259). The approach requires training in the desired behavior in small incremental steps of increasing difficulty, while rewarding the participant with enthusiastic approval for

improvement, but never blaming him/her for failure (Taub et al, 1998; Page, Sisto, Johnston, Levine, & Hughes, 2002; Morris, Taub, & Mark, 2006). The movements responsible for the functional tasks selected as most important by the participant were broken into the smallest measurable elements by the therapist (Page & Levine, 2007). The therapist identified the deficient component for each participant during initial evaluation and directed and encouraged the participant to practice that component repeatedly during the treatment session. For example, eating with a spoon may be broken down into reaching for the item, grasping it, scooping the food item, bringing it to the mouth, and withdrawing the spoon from the mouth. The individual components were progressively mastered, then combined until the entire movement could be performed. During the training process, each element was timed to document the smallest improvement in performance. An important component of shaping was for the interventionist to provide verbal reinforcement promptly when performance improvement was made. Also, when 3 or more negative unsuccessful attempts were made, the therapist provided reinforcement in the form of encouraging comments but never negative or discouraging (Page & Levine, 2007). Other elements included the use of modeling or coaching by means of cues or prompts (Morris, Taub, & Mark, 2006; Page & Levine, 2007). As stated by Morris, Taub, and Mark (2006), tasks that were used emphasized movements in need of improvement, and at the upper range that could be accomplished by the participant, yet avoiding excessive effort that could demotivate the participant. Participants received 1 hour of individualized training of the affected extremity daily for 5 days a week for 10 days. Each session was divided into two 30-minute sessions or three 20-minute sessions depending on the subject's ability to sustain training. All participants assigned to mCIT were required to wear a restraint on the less affected upper extremity 5 hours each weekday at a time of frequent use using a polystyrene-filled mitt, while they performed

daily activities using the affected upper extremity, keeping a detailed log of all activities and restraint use time. The log was completed at the end of each day by the patient in collaboration with his or her nurse, who assisted in the documentation of the entry if the patient had impairment in writing skills. The treating therapist reviewed this record daily and documented the individual participant's training activities and progress. Prior to commencing the study, each participant signed a behavioral contract detailing the agreed upon activities they would carry out when wearing the restraint (See Appendix B).

Traditional Rehabilitation (TR). Each participant assigned to TR participated in individualized 1-hour occupational therapy sessions, 5 times/week for 10 days, administered by the same therapist similar to the traditional occupational therapy offered to patients with acute stroke in the inpatient rehabilitation hospital where the study was conducted. Each session was divided into two 30-minute sessions or three 20-minute sessions depending on the subject's ability to sustain the therapy. The individualized occupational therapy sessions consisted of a combination of compensatory techniques for ADLs, and exercises in range of motion, strengthening, traditional positioning for the affected upper extremity, weight bearing, guarding functional reach, and electrical stimulation. The compensatory techniques involved the use of the less affected upper extremity to perform functional tasks like ADLs such as dressing, bathing, feeding, grooming, and toileting, and to assist the more affected arm during reaching tasks. Range of motion, weight bearing, guarding functional reach, strengthening and electrical stimulation focused on the more affected arm with assistance from the less affected arm. The exact treatment prescription for each patient was tailored to his or her clinical and functional assessment. No restraint was used and participants were allowed to use either upper extremity for their daily activities without any need for activity log.

Data Analysis

Data analysis was performed using SAS/STAT software (SAS Institute Inc., Cary, NC). Descriptive statistics was used to summarize the demographic information of the participants and the outcome measures at baseline and after 2 weeks of therapy for the two groups, mCIT and TR. These included a measure of the participants' occupational performance using the COPM, the motor recovery using the FMA, motor function using the WMFT, and amount and quality of arm use according to the MAL. A comparison between treatment groups with respect to demographics, and the clinical measures of outcome was evaluated using the Student's t-test. Paired t-test statistics was used to analyze the difference within each group in motor recovery, motor function, frequency and quality of arm use, occupational performance and satisfaction before and after intervention as measured by pretest and posttest FMA, WMFT, MAL, and COPM scores. Analysis of covariance (ANCOVA) statistics was conducted to determine if the two treatment groups differed significantly in their degree of change from pretest to posttest scores in FMA, WMFT, MAL, and COPM, controlling for pretest score as the covariate, group as independent variable, and posttest score as dependent variable. The significance level was set at $\alpha = .05$ for all analysis.

Ethical Considerations

The research proposal received the approval of the Institutional Review Board for the university and hospital. Informed consent was obtained from all participants before enrolment. All participants benefited from stroke rehabilitation in the process of their participation. Fidelity to confidentiality of patient interviews, medical records and all research documents were maintained. All research related records were kept in a secure locked filing cabinet in a locked office under the custody of the principal investigator. Data was identified by a unique study ID

assigned to each participant at enrolment, and all data forms were de-identified. The master contact list that matched the participants' names with their unique Study ID was only accessible to the principal investigator and faculty advisor. All data were entered into an Excel file format and were transferred to the statistical analysis software. All data stored in computers were password protected to ensure the privacy of participants. No identifiable data will be retained beyond the duration of the study. All de-identified data will be stored for a minimum of three years after conclusion of the study. However, use of data beyond three years will only occur following additional IRB approval. The random allocation sequence generated from the computerized program was kept in a secure computer file that was password protected and known only to the enrolling staff, and in a physical file under lock and key kept by the enrolling staff. Treatment data for each participant were documented in data sheet kept by each treating therapist and entered into password-protected electronic data file.

Timeline of Project

The need assessment study for this project was completed in the fall of 2015. Project proposal and institutional review board application were prepared and submitted to the hospital in the spring of 2016. University institutional review board approval was granted in the summer of 2016. A Principal Investigator’s Disclosure Agreement was submitted to the hospital in the summer of 2016. The project was approved by the hospital and implemented in the fall of 2016. The project report was prepared and presented in the spring term of 2017.

Section 4: Results and Discussion

Introduction

The purpose of this study was to implement an evidence-based approach using mCIT in the upper limb rehabilitation of patients with acute stroke admitted to an inpatient rehabilitation hospital and to demonstrate its feasibility and efficacy in increasing the motor recovery, and the amount and quality of arm use when compared to the traditional occupational therapy intervention. This will serve as a model for its routine application in the rehabilitation of patients with upper limb hemiplegia following acute stroke in the inpatient rehabilitation hospital.

Results

Of the 6 participants enrolled for the study, 4 completed their treatment in accordance with the study protocol and were determined to have met their treatment goals by a multidisciplinary meeting of occupational therapists, physical therapists, speech therapists, nurses, case managers, and a rehabilitation physician. One participant assigned to receive mCIT refused to wear the polystyrene mitt used as constraint after the first day of intervention. Although he proceeded to complete the study wearing a bracelet labelled with "mCIT", he was excluded from the analysis for non-adherence to study protocol. One other participant completed only one week of intervention before seeking discharge for family reasons and her data was excluded from the analysis. The results presented represents the 4 patients who completed the study and their demographics are included in Table 1. The subjects (1 male and 3 female) had a mean age of 75.8 years (SD=6.24, range =72-85) and a mean time from stroke to randomization of 4.3 days (SD=1.2, range 3-6). Two of these were randomized to receive mCIT, and two to receive TR.

Table 1: Demographics of Study Participants

Patient	Gender	Age (years)	Days Since Stroke	Side Affected	Group
Pt. 2	F	72	5	L	mCIT
Pt. 4	M	85	3	L	mCIT
Pt. 1	F	72	5	R	TR
Pt. 5	F	74	6	L	TR
Note. Pt.=patient	F=female M=male	M=75.8 SD=6.24	M=4.3 SD=1.2	L=left R=right	

mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

Table 2: Subject Characteristics by Study Group

Characteristic	mCIT (n=2) M (SD)	TR (n=2) M (SD)	t value	p value
Age	78.5 (9.19)	73.0 (1.41)	0.84	0.491
Days since stroke	4.0 (1.41)	5.5 (0.70)	1.34	0.311
MMMSE	78.5 (4.95)	86.0 (11.31)	0.86	0.481
Pretest FMA	36.5 (4.95)	42.5 (0.71)	1.70	0.232

Note. MMMSE= Modified Mini Mental State Examination, FMA=Fugl-Mayer Assessment, mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

Table 2 presents a comparison of the characteristics of the participants in each group. The mean age of the modified mCIT group was 78.5 years (SD=9.2, range 72-85) compared to 73 years (SD=1.41, range=72-74) for the traditional TR group. There was no statistically

significant difference between the two groups in age (t= 0.84; p>0.49). Mean time from stroke onset to randomization was 5.5 (SD=0.7) in the TR group, compared to 4 (SD=1.4) days in the mCIT group, with no significant difference between the two groups (t=1.34; p=0.31).

Table 3: Fugl-Meyer Assessment Scores before and after Intervention by Group

Patient	**Pretest**	**Posttest**	**Change**	**Difference**
		mCIT		
Pt. #2	40	60	+20	
Pt. #4	33	54	+21	
Mean	36.5	57	+20.5	**t=41.7, p=0.02**
		TR		
Pt. #1	42	61	+19	
Pt. #5	43	59	+16	
Mean	42.5	60	+17.5	t=11.67, p=0.054

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

A summary of the FMA data is presented in Table 3 and includes the pretest and the posttest FMA scores for the two groups. After 2 weeks of intervention using mCIT the mean FMA posttreatment score was significantly higher than the mean pretreatment score (t=41.0, p=0.02). The mean posttest FMA score was also higher than the mean pretreatment score in the TR group but just short of statistical significance (t=11.67, p=0.054). Following intervention, the mean change in FMA score in the mCIT group was 20.5 points compared to 17.5 in the TR group, but this difference was not statistically significant (t=1.9, P=0.2).

Table 4: Wolf Motor Function Test Scores before and after Intervention by Group

Patient	Pretest	Posttest	Change	Difference
		mCIT		
Pt. #2	84 secs	42 secs	-42 secs	
Pt. #4	110	60	-50	
Mean	97	51	-46	t=11.5, p=0.055
		TR		
Pt. #1	70	42	-28	
Pt. #5	76	53	-23	
Mean	73	47.5	-25.5	t=3.95, p=0.16

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

The pretest and the posttest WMFT scores for the two groups are presented in Table 4. The mean posttest WMFT score was lower than the mean pretest score for the group treated with mCIT at just below the level of statistical significance (t=11.50, p=0.055). The mean posttest WFMT score was also lower than mean pretest score for the TR group but the decrease was not statistically significant (t=3.95, p=0.16). Therefore, following intervention with mCIT and TR there was improvement on the mean WMFT scores as shown in improved ability to perform tasks, and a reduction in time taken to complete the task, with a significantly greater change in WMFT score following mCIT (46±4.82 seconds) compared to change of 24±5.66 seconds in the TR group (T=4.35, p=0.049).

Table 5: Motor Activity Log Amount of Use Scores before and After Intervention

Patient	Pretest	Posttest	Change	Difference
		mCIT		
Pt. #2	31	86	+55	
Pt#4	54	117	+63	
Mean	42.5	101.5	+59	t**=14.75, 0.04**
		TR		
Pt. #1	110	140	+30	
Pt. #5	78	113	+35	
Mean	94	126.5	+32.5	t**=13.0, p<0.05**

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

Table 6: Motor Activity Log Quality of Movement Scores before and after Intervention

Patient	Pretest	Posttest	Change	Difference
		mCIT		
Pt. #2	54	86	+32	
Pt. #4	66	117	+51	
Mean	60	101.5	+41.5	t=4.37, p=0.14
		TR		
Pt. #1	112	143	+31	
Pt. #5	80	114	+34	
Mean	96	128.5	+32.5	t=9.33, p=0.068

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

Table 5 and 6 present the results of the amount of use (AOU) and quality of use (QOM) subscales of the MAL respectively. In the group treated with mCIT, mean posttest AOU scores of the MAL had a significant increase over mean pretest scores ($t=14.75$, $p=0.04$). A similar observation was found in the group receiving TR ($t=13.0$, $p<0.05$). Improvement in AOU scores were significantly more marked following intervention with mCIT than in the group who received TR ($t=0.5.62$, $p=0.03$). The performance of patients in the two groups on the AOU was further evaluated using ANCOVA controlling for differences in pretest scores by using the mean pretest scores as covariate, and the mean posttest scores as dependent variable. The patients in the mCIT group exhibited significantly greater increases in AOU than patients who received TR ($F=2089.69$, $p=0.0160$). There was a 41.5-point increase in mean score on the QOM subscale of the MAL following intervention with mCIT compared to 32.5 increase in the group treated with TR, but the difference was not statistically significant ($t=4.37$, $p=0.14$). When comparing the two groups using ANCOVA, and controlling for the difference in pretest QOM, there was no statistical significance in the observed increments in QOM scores in the mCIT group compared to the TR group ($F=4.09$, $p=0.33$)

Table 7: Canadian Occupational Performance Measure Performance Scores before and after Intervention

Patient	Pretest	Posttest	Change in Performance	Difference
		mCIT		
Pt. 2	5	8.4	+3.4	
Pt 4	1.4	6	+4.6	
Mean	3.2	7.2	+4	t=6.67, p=0.95
		TR		
Pt. #1	2	8.2	+6.2	
Pt. #5	3	8	+5	
Mean	2.5	8.1	+5.6	t=9.33, p=0.068

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

Table 7 and 8 present a summary of the performance and satisfaction scores of the COPM respectively in the two intervention groups. The data indicates that patients treated with both mCIT and TR perceived improvement in occupational performance and satisfaction mean change in performance score on the COPM of 4 and 5.6 respectively for patients treated with mCIT and TR. The group treated with TR reported a greater change in mean occupational performance score compared to the group treated with mCIT, although this was not statistically significant (t=6.67, p=0.95; F=4.82, P=0.31). The mean change in satisfaction score on the COPM was an identical score of 30 in both groups with no significant difference (F=0.19, p=0.85).

Table 8: Canadian Occupational Performance Measure Satisfaction Scores before and after Intervention

Patient	Pretest	Posttest	Change in Satisfaction	Difference
		mCIT		
Pt. 2	1	8.2	+7.2	
Pt 4	1.4	6.2	+4.8	
Mean	1.2	7.2	+6	t=5.0, p=0.1257
		TR		
Pt. #1	1	8	+7	
Pt. #5	3	8	+5	
Mean	2	8	+6	t=6.0, p=0.1051

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2)

Table 9: Comparison of Mean Scores on Outcome Measures by Group

Outcome variable	mCIT Mean (SD)	TR Mean (SD)	Value	p
FMA			F=16.09	0.1736
Pretest	36.5 (4.95)	42.5 (0.71)		
Posttest	57.0 (4.24)	60.0 (1.41)		
Change	20.5 (0.71)	17.5 (2.12)	t=1.90	0.1982
WMFT			F=2.58	0.2496
Pretest	97.0 (18.38)	73.0 (4.24)		
Posttest	51.0 (12.73)	47.5 (7.78)		
Change	46.0 (4.82)	24.0 (5.66)	**t=4.35**	**0.049**
MAL: AOU			**F=2089.69**	**0.0155**
Pretest	42.5 (16.26)	94.0 (22.63)		
Posttest	101.5 (21.92)	126.5 (19.09)		
Change	59.0 (5.85)	32.5 (3.54)	**t=5.62**	**0.03**

MAL: QOM			F=4.09	0.33
Pretest	60.0 (8.49)	96.0 (22.63)		
Posttest	101.5 (21.92)	128.5 (20.51)		
Change	41.5 (13.44)	32.5 (2.12)	4.37	0.14
COPM Performance			F=4.82	0.3066
Pretest	3.2 (2.55)	2.5 (0.71)		
Posttest	7.2 (1.70)	8.1 (0.14)		
Change	4.0 (0.85)	5.6 (0.85)	t=6.67	0.95
COPM Satisfaction			F=0.19	p=0.8535
Pretest	1.2 (0.28)	2.0 (1.41)		
Posttest	7.2 (1.41)	8.0 (0)		
Change	6.0 (1.70)	6.0 (7.07)	0.0	1.0

Table 9 (contd)

Comparison of Mean Pretest and Posttest Scores on Outcome Measures by Group

Note. mCIT=Modified constraint-induced therapy (n=2), TR=Traditional therapy (n=2), FMA=Fugl-Mayer Assessment, WFMT=Wolf Motor Function Test, MAL:AOU= Motor Activity LOf, Amount of Use subscale, MAL:"QOM=Motor Activity Log Quality of Movement subscale, COPM Performance = Canadian Occupational Performance Measure-Performance subscale, COPM Satisfaction= Canadian Occupational Performance Measure-Satisfaction Subscale

A comparison of the efficacy of mCIT with TR in improving motor recovery, motor function, frequency and quality of affected arm use, and occupational performance and satisfaction based on paired t-test and ANCOVA statistics of pretest and posttest scores on FMA, WMFT, MAL, and COPM, is summarized in Table 9. The mean change in WFMT score in the

mCIT group was significantly greater than the mean change in the TR group (t=4.35, p=0.049). Intervention using mCIT also resulted in a significantly greater mean change in AOU score compared to the TR group (t=5.62, p=0.03). Intervention with mCIT produced greater mean change in QOM (t=4.37, p=0.14), and FMA (t=1.9, p=0.19) compared to TR, but these were not statistically significant. The mean change in COPM performance score in the mCIT group was not significantly different from the mean change in the TR group (t=6.67, p=0.95). The mean change in COPM satisfaction score in the mCIT group was also not significantly different from the mean change in the TR group (F=0.19, p=0.854). In both intervention groups, the mean change in COPM performance and satisfaction scores were significantly above the threshold of ≥2 and were clinically significant (Law et al., 2014).

Discussion

The findings of this study have demonstrated the implementation of mCIT in the upper limb rehabilitation of patients with acute stroke admitted to an inpatient rehabilitation. In our study, participants were randomly assigned to receive either mCIT or TR with treatment for a period of 10 days. The duration of treatment was within the period approved by payers, and the participants in each case were deemed to have attained their treatment goals by a multidisciplinary team of occupational therapists, physical therapists, speech and language therapists, nurses, and a physician who was a physiatrist, with the clients meeting their desired goals as demonstrated on the COPM.

Our study demonstrated that it was feasible to implement mCIT protocols within the confines of existing process as approved by payers, and inpatient rehabilitation hospitals. Approaching the implementation within the confines of existing reimbursement schedules is important based on the need to make mCIT a reimbursable procedure as discussed by Wolf

(2008). Using a two-week protocol enables mCIT interventions to fit into the typical length of stay (LOS) for stroke patients in inpatient rehabilitation hospitals in the United States which ranged from 8.9 days for mild stroke, to 13.9 days for moderate, and 22.2 days for severe stroke in a nationwide study between 2009 to 2011 by Camicia, Wang, DiVia, Mix, and Niewczyk (2016). Protocols like that of Page, Sisto, Levine, Johnson, and Hughes (2001) distribute shorter treatment sessions of 30 minutes, while limiting the period of constraining of the less affected upper limb to 5 hours daily for 5 days per week, while extending the protocol to 10 weeks. Such protocols are most suited to outpatient settings for use mainly for the rehabilitation of patients with chronic and subacute stroke (Page, Sisto, Levine, Johnston, & Hughes, 2001; Page, Sisto, Johnston, Levine, & Hughes, 2002; Page, Sisto, Levine, & McGrath, 2004). Treatment duration up to 10 weeks would not be suitable for the typical length of stay in inpatient rehabilitation hospitals noted in that nationwide study by Camicia et al (2016). The pilot study on patients with acute stroke using this protocol, although conducted in an inpatient rehabilitation hospital, was actually on outpatients who reported to the laboratory for pretest and posttest assessment, attended daily individualized therapy sessions in the hospital, but returned home each day to wear mitts as constraint on their less affected hand, while using the more affected upper extremity for performance of everyday activities (Page, Levine, & Leonard, 2005). Much shorter mCIT protocols lasting 2-4 weeks have been demonstrated to be effective in the rehabilitation of patients with chronic and subacute strokes, in outpatient settings, and in pilot studies in patients with acute stroke in inpatient rehabilitation hospitals. Our study has demonstrated the feasibility of a shorter mCIT protocol that fits into the schedule and process in inpatient rehabilitation hospitals, and its efficacy in improving the motor recovery, arm function, and the frequency and effectiveness of affected arm use in patients with hemiparesis from acute

stroke in inpatient rehabilitation hospital setting. This was shown in the significant changes in FMA, WMFT, and the AOU and QOU subscales of the MAL from pretest scores indicating significant improvement in affected upper extremity motor recovery, arm function, and amount and quality of hand use following mCIT intervention. These changes were accompanied by significant improvement in occupational performance and satisfaction in performance based on COPM change of ≥2 on each of the participant's chosen occupation, reflecting clinically relevant change (Law et al., 2014). Implementation of mCIT in the study demonstrated greater improvements in motor recovery, amount and quality of hand use than TR, with statistical significant improvement recorded in the WMFT, AOU subscale of the MAL.

Strengths and Limitations

Limitations of the study included the small sample size and lack of blinding in the pretest and posttest assessments which may limit the generalizability of the study findings, thus making the case for future studies with larger sample sizes, and blinding of the assessor to group assignment to avoid potential bias. Within the time constraint for our study, it was a challenge to find sufficient number of patients with acute stroke with adequate wrist extension to meet our inclusion criteria, and who had had no previous stroke prior to the index episode. Although Drommerick et al. (2000, 2009) had much larger sample sizes in their CIT studies on patients with acute stroke, other researchers like Page, Levine, and Leonard (2005), have noted the difficulty of finding stroke patients exhibiting adequate distal extension in the acute phase suitable for inclusion in mCIT research, and consequently used small sample size for their study on patients with acute stroke. The difficulty in recruitment for this study exemplifies the challenge envisaged by Page et al (2005) for future researchers on mCIT in patients with acute stroke. This study is therefore an attempt to "follow the trail to the next best external evidence

and work from there" by using the sample size available, to validate our treatment, if we cannot get the "goal standard" in sample size (Sackett, Rosenberg, Gray, Haynes & Richardson, 1996, p. 72).

Lack of blinding the patient group assignment to the assessor may constitute a potential risk of bias. While the pretest allocation was performed before the randomized group assignment in each case, it was not possible to blind the assessor to the group assignment for the posttest assignment because the principal investigator who performed all the assessments was responsible for monitoring the implementation of interventions for adherence to study protocol. A systematic review by Hrobjartsson et al. (2013) demonstrated evidence of observer bias in randomized clinical trials with subjective outcomes because of failure to blind assessors. Their study included outcomes using subjective measurement with no naturally distinct categories, and subcategories with vague or minor differences, thus rendering them susceptible to observer bias. In this study, the principal investigator who performed all the pretest and posttest assessments adhered to strict objective measurement criteria to mitigate the potential for bias in observer-reported measures including the FMA and WFMT, which use objective measurements. Other researchers have used a similar approach with strictly prepared measuring criteria in assessment tests administered by non-blinded assessors to mitigate the risk of observer bias in exploratory or pilot studies (Winstead et al., 2004; Siebers, Oberg, & Skargren, 2010). Although a systematic review by Hrobjartsson, Emanuelsson, Thomsen, Hilden and Brorson (2014) has demonstrated evidence of bias due to lack of patient blinding in randomized clinical trials with patient-reported outcomes, it is generally not possible to blind patients in mCIT studies like ours since the patients knew which treatment they received. While the subjectivity of patient-report measures like COPM and MAL has been noted as a limitation by researchers like Page, Levine, and

Leonard (2005), this does not necessarily lead to bias as there appears to be no incentive for the patient to rate one treatment over the other treatment without prior experience of the other. We do not feel that the lack of observer or patient blinding in this study resulted in significant bias in the pretest and posttest assessments based on these observations and safeguards. Future studies should further minimize the risk of bias by using blinded independent assessors, and consider adding objective arm use measures like accelerometers to measure arm use (Taub, Crago, & Uswatte, 1998).

Other potential limitations include the short length of stay in inpatient rehabilitation hospitals, which means that some of the subjects may complete their rehabilitation in less than the two weeks proposed for the study. Length of stay (LOS) for stroke patients in inpatient rehabilitation hospitals are pre-approved by the payers (insurance companies) based on the assessment of when treatment goals are expected to be met. Average LOS for stroke patients has been on the decline in recent years, with a 3-day reduction reported by Granger, Cotter, Hamilton, Deutsch, and Ottenbacher (2009) during the period from 2000 and 2007. Camicia, Wang, DiVia, Mix, and Niewczyk (2016) found a negative association between longer LOS and functional gains among the mildly impaired stroke patients, who are the typical patients selected in the inclusion criteria of mCIT research. These variations in LOS in patients with stroke in inpatient rehabilitation hospitals, and their association with stroke impairment severity, and stroke patient outcomes, therefore constitute limitations to mCIT research in inpatient rehabilitation hospitals that need to be addressed in future research on patients whose LOS are largely determined by payers.

Dromerick, Edwards, and Hahn (2000) have raised a concern that the emphasis on motor restoration in early CIT might compromise compensatory techniques and lead to excess

disability. In the study by Wu, Chen, Tsai, Lin, and Chou (2007), the authors used the Functional Independence Measure (FIM) instrument to objectively measure changes in activity performance through observation of activities including self-care or activities of daily living (ADLs), sphincter control, transfers, locomotion, communication, and social cognition ability of stroke patients. The authors demonstrated greater improvement in both FMA and FIM in the mCIT group than in the traditional group, and explained the improvement in ADLs as being due to reduced motor impairments rather than the development of new compensatory strategies. This study as well as that of Dromerick et al. (2000) did not find evidence that participants receiving mCIT had more ADL deficits than those receiving TR, although we did not include the FIM as one of our measures. There was clinically significant improvement in occupational performance and satisfaction with performance as measured using the COPM in both groups with no statistically significant difference between intervention groups.

Compliance with restraint use may still pose a problem in mCIT despite significant reduction in individualized therapy from 6 hours to one hour, and reduction in restraint use time from 90% of waking hours in the original CIT to 5 hours daily. One participant refused to wear restraints during the study and was excluded from the analysis.

Finally, although both groups received equal time of individualized occupational therapy it can be argued that the five hours per day in which the mCIT participants wore restraints on the less affected hand constitutes additional treatment which patients in the TR group did not have. This argument is strengthened by the behavioral contract which required these patients to carry out a list of activities and complete an activity log. However, these activities were self-directed and were neither supervised, nor directed by the therapist. The patients in the TR had a different therapy focus and were at liberty to perform equivalent activities throughout the day using a

compensatory approach in keeping with the guiding principle of this approach, and were not at a significant disadvantage. Nevertheless, future studies may consider adding a control group that receives all the interventions offered in TR and require the participants to maintain an activity log like the mCIT participants but not to wear restraint.

Implications for Practice, Healthcare Outcomes, Healthcare Delivery, Healthcare Policy

The evidence from this study demonstrates the feasibility and efficacy of mCIT in upper limb rehabilitation of patients with acute stroke admitted to inpatient rehabilitation hospitals, the preferred setting for the rehabilitation of these patients. While there is strong evidence of the effectiveness of CIT and mCIT in upper limb rehabilitation of patients with stroke, most of the evidence have been on patients with chronic and subacute stroke, mostly in outpatient settings. Providing this evidence in the setting that is relevant to stroke rehabilitation, and in the patient population in which stroke rehabilitation typically occurs, improves the chances for the application of the huge body of evidence in mCIT research into clinical practice. This study also contributes to closing the gap between evidence and occupational therapy practice in stroke rehabilitation defined by Gillen (2015) by demonstrating the feasibility and efficacy of an intervention approach with strong evidence of efficacy in patients with chronic stroke in the setting in which stroke rehabilitation typically occurs. Of great importance is the demonstration of its feasibility and efficacy as a reimbursable practice within the constraint of payer-driven length of stay, and adapting the protocol to the operations in an inpatient rehabilitation hospital.

The mCIT protocol used for the study places a focus on activities chosen by the participant with help of their therapist during the individualized occupational therapy sessions and is guided by the volitional subsystem of the model of human occupation (MOHO, Kielhofner, Burke, & Igi, 1980). The performance and habituation subsystems of MOHO also

explain the process of skill development by shaping, and the adherence-enhancing behavioral methods used to transfer the skills learnt during the individualized training into the patient's routine daily life situation (Kielhofner, Burke, & Igi, 1980; Morris, Taub, & Mark, 2006). The mCIT protocol as conceived enhances occupation-based practice. It is instructive to note. that the protocol for TR in this study also utilizes the same principle of using activities chosen by the participant with the help of their therapist during their individualized therapy sessions, which may help to explain the improvement in treatment outcomes including significant reduction in impairments, improved arm function, more frequent and effective use of the affected arm, and the participants' perception of occupational performance and satisfaction with performance by both intervention approaches. The choice of the Canadian Occupational Measure (COPM) as outcome measure enables the patient to identify and prioritize occupations that are most relevant to their key roles, which form the focus of intervention. The resulting emphasis on patient relevance may enhance the motivation and participation of the patients in the rehabilitation process, and result in improved treatment outcomes and satisfaction (Bodiam, 1999, Law et al., 2014). This should strengthen the case for its routine application in acute stroke rehabilitation in inpatient rehabilitation hospitals.

Future Research

The findings of this study are promising enough to justify larger scale studies using larger sample sizes to implement mCIT to improve the validity of the result and its generalizability to the rehabilitation of patients with acute stroke in inpatient rehabilitation. As discussed, assessor blinding will reduce the potential for bias in outcome measures. Follow-up studies are also indicated to determine if the gains from mCIT rehabilitation in patients with acute stroke are retained in the long term. In addition, the Functional Instrument Measure (FIM) may be a useful

instrument to complement the other outcome measures in future studies, to provide an objective measure of the impacts of mCIT on the patients' performance in ADLs, sphincter control, transfers, locomotion, communication, and social cognition ability of stroke patients. For mCIT to become a routine intervention method in inpatient rehabilitation of patients with acute stroke, future studies need to integrate the most widely used standardized measure for stroke rehabilitation by hospitals, and payers (Management of Stroke Rehabilitation Working Group, 2010). Finally, developing mCIT protocols for lower functioning stroke patients may enable research into the applicability of this effective intervention approach to the significant number of patients who did not meet the criteria for inclusion in our study. Page and Levine (2007) reported reduced impairment, increased use of affected arm, improved function and ability to perform valued activities following the use of an outpatient mCIT protocol on 4 patients with chronic stroke exhibiting minimal movement ability in the affected arm. Expanding the eligibility for mCIT application in acute stroke in future studies will assess its feasibility for a larger population of patients with acute stroke than is the case with current criteria.

Summary

Occupational therapy seeks to be a "science-driven, and evidence-based" profession that meets the needs of our society (American Occupational Therapy Association, 2007, p. 614). Despite strong evidence of effectiveness of interventions to improve occupational performance for those with motor deficits after stroke, a gap has existed in the application of this evidence to routine clinical practice in the rehabilitation of patients with acute stroke admitted to inpatient rehabilitation hospitals. In this study an evidence-based approach to the rehabilitation of patients with hemiplegia following acute stroke has been implemented in an inpatient rehabilitation hospital, and its feasibility and effectiveness demonstrated by a quasi-experimental, multiple

baseline, randomized, pretest-posttest control-group design study, using a dose-matched control intervention (TR) for comparison with modified constraint-induced therapy (mCIT). This study has demonstrated significant improvement in motor recovery, improved arm function, more frequent and effective use of the affected arm, and improvement in the participants' perception of occupational performance and satisfaction with performance by both intervention approaches. It has also demonstrated greater improvement following intervention with mCIT compared with TR in all outcome measures studied except in the client's perception of satisfaction with performance. The difference was statistically significant in the WMFT, and the AOU subscale of the MAL. This strengthens the case for the routine implementation of this evidence based intervention approach that has been strongly demonstrated in patients with subacute and chronic stroke, in patients with acute stroke admitted to inpatient rehabilitation hospitals. Larger scale studies are needed to further strengthen this evidence.

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Appendix A

Verbal Recruitment Script for Research Study

Implementation of Modified Constraint-Induced Therapy in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital

"We will be conducting a study on the use of Modified Constraint-Induced Therapy (mCIT) in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital by comparing it to the traditional approach to upper limb stroke rehabilitation. You are being invited to participate in this research study because of the effects of a stroke you recently suffered and may be assigned to have your stroke rehabilitation either by using mCIT or the traditional rehabilitation approach. A stroke occurs when an area of the brain is damaged by lack of blood flow. If you are interested in participating, you will be randomly assigned to one of two groups using a pre-determined computerized strict allocation method that will assign all new enrolled participants to either of the two groups. One group will receive occupational therapy in the traditional stroke rehabilitation method offered in Health South Rehabilitation Hospital Kingsport. The other group will receive occupational therapy using mCIT approach. You will participate in 3-4 hours of pretest assessments before, and 3-4 hours of posttest assessments at the end of your treatment program to measure your motor recovery and arm use, in order to assess the impact of the treatment. You will be taking part in individualized occupational therapy intervention sessions during your inpatient rehabilitation admission at HealthSouth Rehabilitation Hospital in Kingsport 5 times per week as part of the study. Each of those sessions will take about 1 hour. If you are assigned to the group to receive mCIT, you will spend an extra 5 hours each day for 5 days each week wearing a polystyrene mitt on your less affected hand as a restraint to keep you from using your less affected arm, while you perform your

everyday activities using your affected upper limb. Do you have any questions about the treatment and the assessments? Would you be interested in participating in this study?"

Script for Follow-Up of Interested Potential Participants

"Thank you for your interest in participating in the study. We will now explain the study in some detail, and have you sign some paper work to give your consent for the study. If you decide to take part in the study, it should be because you really want to volunteer. You can withhold your consent, or stop at any time during the study and still keep the benefits and rights you had before volunteering. In the event that you do not wish to give consent, or wish to withdraw your consent, you will be provided with occupational therapy for stroke rehabilitation using the traditional methods currently offered in HealthSouth Rehabilitation Hospital, Kingsport. An occupational therapist will be assigned to you to commence your therapy program.

If you are assigned to receive mCIT, you will participate in 1- hour therapy sessions 5 times a week for 2 weeks, with your unaffected arm restrained using a polystyrene mitt. Your 1-hour therapy sessions will be concentrated on the use of your affected limb with highly repetitive activities chosen by you and your treating therapist. Your therapy sessions will target functional tasks that are important to you, such as writing, eating, or grooming, using your affected upper extremity. During the 2 weeks of therapy, your unaffected hand and wrist will be restrained every weekday for 5 hours using a polystyrene-filled mitt as you perform your everyday activities using your affected hand.

If you are assigned to the traditional stroke rehabilitation (TR) group, you will receive regular 1-hour daily treatment sessions on weekdays for a total of 2 weeks. Your treatment will consist of upper extremity rehabilitation using different approaches and activities, the different activities chosen by you and your treating therapist to address deficits such as weakness and loss of function. Your therapy sessions will include your everyday activities, range of motion, strengthening, guarding functional reach, and electrical stimulation. Your unaffected extremity will not be restrained at any time if you are assigned to the traditional treatment group. You will have the freedom to use either upper extremity during your individualized therapy sessions and in your daily activities.

Please take your time to review the consent form. Feel free to ask me any questions, and sign the consent form if you would like to participate in the study".

Appendix B

Modified Constraint-Induced Therapy Participation Contract

1, _____ having given a signed informed consent to participate in the research study titled **The Role of Modified Constraint-Induced Therapy (mCIT) in the Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital**, and having been randomly assigned to undergo mCIT, do commit as follows:

1. I will faithfully participate in mCIT training sessions with my therapist lasting one (1) hour each weekday for two (2) weeks

2. I will faithfully wear a polystyrene-filled mitt as restraint on my affected hand for five (5) hours each day for the two (2) week duration of the study.

3. While wearing the mitt, I will faithfully engage in the following activities that have been chosen by me with the assistance of my therapist, using my more affected upper extremity, including but not limited to:

_____

_____

_____

_____

_____

4. I will complete a daily log of activities completed during the period of restraint use, and the duration of restraint use.

Signed on _____ (Date)

_____ _____

Patient Study #: _____ Therapist:_____

_____

Witness: _____

Appendix C

Consent to Participate in a Research Study

IMPLEMENTATION OF MODIFIED CONSTRAINT-INDUCED THERAPY IN UPPER LIMB STROKE REHABILITATION IN AN INPATIENT REHABILITATION HOSPITAL

Why am I being asked to participate in this research?
You are being invited to take part in a research study about the use of Modified Constraint-Induced Therapy (mCIT) in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital by comparing it to the traditional approach to upper limb stroke rehabilitation. You are being invited to participate in this research study because of the effects of a stroke you recently suffered and may be assigned to have your stroke rehabilitation either by using mCIT or the traditional rehabilitation approach. A stroke occurs when an area of the brain is damaged by lack of blood flow. If you take part in this study, you will be one of about 12 people to do so.

Who is doing the study?
The person in charge of this study is xxxxxxxxxxxxxxx, MSOT, OTR/L at Eastern Kentucky University. She is being guided in this research by xxxxxxxxxxxxxxx, PhD, OTR/L [Advisor]. There may be other people on the research team assisting at different times during the study.

What is the purpose of the study?
We are carrying out this study to determine if the use of Modified Constraint-induced Therapy for upper extremity stroke rehabilitation in an inpatient rehabilitation hospital will lead to greater motor recovery of the affected extremity and an increase in number and quality of arm use compared to traditional stroke rehabilitation.

Where is the study going to take place and how long will it last?
The research procedures will be conducted at xxxxxxx Rehabilitation Hospital. You will be taking part in individualized occupational therapy intervention sessions as part of the study during your inpatient rehabilitation admission at xxxxxxxxxx Rehabilitation Hospital in xxxxxxxxx 5 times per week during the study. Each of those sessions will take about 1 hour. If you are assigned to the group to receive modified constraint-induced therapy (mCIT), you will spend an extra 5 hours each day for 5 days each week wearing a polystyrene mitt on your less affected hand as a restraint to keep you from using your less affected arm, while you perform your everyday activities using your affected upper limb. The total amount of time you will be asked to volunteer for this study is 60 hours over the next 2 weeks if you are assigned to receive MCIT, or 10 hours over the next two weeks if you are assigned to receive traditional rehabilitation (TR). In addition, you will be required to participate in 3-4 hours of assessments before, and 3-4 hours of assessments at the end of your treatment program to measure your motor recovery and arm use.

What will I be asked to do?
You are referred for enrolment in this study because your clinicians believe you have met the criteria of people who could potentially benefit from modified-constraint-induced therapy (mCIT) for your upper limb stroke rehabilitation. Before you are enrolled, your research

therapist will conduct a detailed evaluation to determine your rehabilitation needs, and whether you will be eligible to participate in the study.

You will be assigned to one of two treatment groups by strictly following a random sequence that has been developed using the computer, for every new participant enrolled. One group will receive occupational therapy in the traditional stroke rehabilitation method offered in Health South Rehabilitation Hospital Kingsport. The other group will receive occupational therapy using modified constraint-induced therapy (mCIT) approach. You will be assigned to either of these two groups using a pre-determined computerized strict allocation method that will assign all new enrolled participants to the two groups. Using this method, every other enrollee will be assigned to one of the two treatment groups. Thus you have an equal chance of being assigned to either of the two groups.

If you are assigned to receive mCIT, you will participate in 1- hour therapy sessions 5 times a week for 2 weeks, with your unaffected arm restrained using a polystyrene mitt. Your 1-hour therapy sessions will be concentrated on the use of your affected limb with highly repetitive activities chosen by you and your treating therapist. Your therapy sessions will target functional tasks that are important to you, such as writing, eating, or grooming, using your affected upper extremity. During the 2 weeks of therapy, your unaffected hand and wrist will be restrained every weekday for 5 hours using a polystyrene-filled mitt as you perform your everyday activities using your affected hand.

If you are assigned to the traditional stroke rehabilitation (TR) group, you will receive regular 1-hour daily treatment sessions on weekdays for a total of 2 weeks. Your treatment will consist of upper extremity rehabilitation using different approaches and activities, the different activities chosen by you and your treating therapist to address deficits such as weakness and loss of function. Your therapy sessions will include your everyday activities, range of motion, strengthening, guarding functional reach, and electrical stimulation. Your unaffected extremity will not be restrained at any time if you are assigned to the traditional treatment group. You will have the freedom to use either upper extremity during your individualized therapy sessions and in your daily activities.

Are there reasons why I should not take part in this study?

You could be included in the study if you meet the following criteria:

1. If you experienced an ischemic stroke fewer than 14 days prior to study enrollment.
2. If you demonstrate ability to actively extend (straighten) your fingers at least 5 degrees at the metacarpophalangeal and interphalangeal joints.
3. If you demonstrate ability to actively extend (straighten) your wrist at least 10 degrees.
4. If you score 70 or more on the Modified Mini-Mental State Exam
5. If your age is between 18 and 95

You could be excluded from the study in any of the following circumstances:

1. If you experienced an ischemic stroke over 14 days prior to study enrollment
2. If you have excessive spasticity based on the evaluation.
3. If you have excessive pain in the affected upper limb.
4. If you do not wish to participate in any experimental rehabilitation or drug studies

5. If the affected limb nonuse is considered by the researcher more than the limit included in the study
6. If you are under the age of 18, or being pregnant.

If you are not included in the study, you will still be provided with occupational therapy for stroke rehabilitation using the traditional methods currently offered in HealthSouth Rehabilitation Hospital, Kingsport.

What are the possible risks and discomforts?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. You should however be aware of some potential risks and should discuss them with the study staff. The potential risks may include the following:

- You may experience pain or fatigue from repeated use of the affected arm during therapy session or for daily activities. However, this has not been found to be a significant problem and will go away with time. You are selected for this study partly because you are not suffering from excessive pain that may interfere with your partipation. You should discuss any excessive pain with your study therapist.

- You may experience anxiety or frustration as a result of focussing your activities on a weak and clumsy upper extremity while restraining the more dextrous extremity. This is uncommon but not serious. You should discuss such feelings promptly with your study therapist.

- You should be aware that a few people have raised potential concerns about safety during falls that might occur during the period the less affected arm is restrained. Such fears have not been realized in practice. In response to such fears, the type of restraint chosen for this study is limited to a mitt to allow participants the ability to use their forearms and upper arms to guard themselves from serious injury in case of falls. In addition, the duration of wearing restraint has been reduced to 5 hours. You should discuss any fear or apprehension you may have of falling promptly with your study therapist.

Will I benefit from taking part in this study?

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced an increased use and function of the affected arm after completing occupational therapy with mCIT Your willingness to take part, however, may, in the future, help occupational therapists to apply the positive research findings about mCIT in real world rehabilitation of patients with acute stroke in inpatient rehabilitation hospitals and help others who may have your condition.

Do I have to take part in this study?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

If I don't take part in this study, are there other choices?
If you do not want to take part in the study, there are other choices such as receiving traditional upper limb stroke rehabilitation as offered in HealthSouth Rehabilitation Hospital. The occupational therapist performing your evaluation will refer you to another hospital-based therapist who will be assigned to provide you traditional stroke rehabilitation. No additional step is required from you to secure alternative services.

What will it cost me to participate?
There are no costs associated with taking part in this study.

Will I receive any payment or rewards for taking part in the study?

You will not receive any payment or reward for taking part in this study.

Will I authorize the release of my protected health information and personal health information?
To take part in this study you will need to give your permission to the research team to obtain and use your protected health information (PHI). This health information will be used to do the research named above.
By signing this form, you are giving permission for the research team to obtain and use your PHI for the purpose of this research. This permission ends on October 31, 2016.
By signing this form you are also giving permission to HealthSouth Rehabilitation Hospital, Kingsport to disclose your individual health information for this research from the time of your last stroke until the end of this research study.
The specific information that will be released and used for this research is described below:
• All records
• Hospital discharge summary
• Radiology records
• Medical history / treatment
• Consultation
• Diagnostic imaging report

The researcher will use your individual health information only in the ways that are described in this research consent form that you will sign. This research consent form describes who will have access to your information. It also describes how your information will be protected. State and federal privacy laws protect your health information. These laws say that, in most cases, your health care provider can release your identifiable health information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not, you will not be allowed to join the research study. Also, you may change your mind at any time, and can take back your permission.

To take back your permission, you must send your written request to: xxxxxx xxxxxx, MSOT, OTR/L at xxxxxxxxxxxx, xxxxxxxx xxxxx, xxxxxxx, or call xxxxxx xxxxx at xxx-xxx-xxxx.

If you take back your permission, the research team may still keep and use any individual health information about you that they already have. But they can't obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research. If you take back your permission, you will need to leave the research study. This means that you would not have any more research involvement or tests. Your decision to not sign this permission, or to take back your permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

Who will see the information I give?
Your information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about this combined information. You will not be identified in these written materials.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key.

However, there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court if we believe you have abused a child or are a danger to yourself or someone else). Also, we may be required to show information that identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as Eastern Kentucky University or HealthSouth Rehabilitation Hospital

Can my taking part in the study end early?
If you decide to take part in the study, you still have the right to decide at any time that you no longer want to participate. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to end your participation in the study. They may do this if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

What happens if I get hurt or sick during the study?
If you believe you are hurt or if you get sick because of something that is done during the study, you should call xxxxxx xxxxxx at xxx-xxx-xxxx immediately. You may also call your nurse immediately, or use the call alert for immediate attention. It is important for you to understand that Eastern Kentucky University will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. That cost will be your responsibility. Also, Eastern Kentucky University will not pay for any wages you may lose if you are harmed by this study. However, care has been taken to select only participants who can meet

the physical demands of the study. In addition, your medical treatment will not be adversely affected by your participation in this study.

Usually, medical costs that result from research-related harm cannot be included as regular medical costs. Therefore, the costs related to your child's care and treatment because of something that is done during the study will be your responsibility. You should ask your insurer or your hospital-based social worker or case manager if you have any questions about your insurer's willingness to pay under these circumstances.

What if I have questions?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, xxxxxx xxxxxxxx at xxx-xxx-xxxx. If you have any questions about your rights as a research volunteer, contact the staff in the Division of Sponsored Programs at Eastern Kentucky University at 859-622-3636. We will give you a copy of this consent form to take with you.

What else do I need to know?
You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

I have thoroughly read this document, understand its contents, have been given an opportunity to have my questions answered, and agree to participate in this research project.

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person taking part in the study

_____

Name of person providing information to subject

Appendix D

Institutional Review Board

Form I: Research Involving Decisionally Impaired Individuals

This form is a required attachment to applications for projects involving individuals with impaired decision-making capacity.

1. Investigator Name: Umana Udoeyop

2. Research Project Title: Implementation of Modified Constraint-Induced Therapy in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital

3. Risk Level: Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests. **Classify the proposed research into one of the following categories and respond to the applicable questions.**

☒ **A.** The proposed research **does not involve greater than minimal risk** to the subjects.

- What procedures are in place to allow a subject advocate to assist subjects in navigating the research process?

An occupational therapist who is unaffiliated with the study will be appointed by the principal investigator to serve as subject advocate and independent assessor during assessment of a potential participant's capacity to consent.

The subject advocate's responsibility is to mitigate potential for coercion or conflict of interest. In the informed consent process.

The subject advocate must have no affiliation with the study or the sponsors of the study.

The principal investigator must document use of an independent assessor within the study files.

The subject advocate will provide a report outlining the outcome of each potential participant's initial assessment of capacity to consent.

The principal investigator is responsible for submitting this report of the assessor's findings to the IRB as part of the study's continuing review.

☐ **B.** The proposed research **presents greater than minimal risk and a prospect of direct benefit** to the subjects.

- What procedures are in place to allow a subject advocate to assist subjects in navigating the research process?

☐ **C.** The proposed research **presents greater than minimal risk and no prospect of direct benefit** to the subjects, but is **likely to yield generalizable knowledge about the subject's disorder or condition**.

- What procedures are in place to allow a subject advocate to assist subjects in navigating the research process?

- What procedures are in place for periodic reconsent and at what intervals will reconsent be documented?

- What procedures are in place to allow for additional time for potential participants to consult with family members about whether to participate?

4. Suitability of Subjects: Explain why individuals with impaired decision-making capacity are suitable subjects for this research.

Since stroke causes ischemic injury of the brain and can potentially affect cognition, mental acuity, awareness, and decision-making capacity of some survivors, there is need for clinical research to address the many consequences including impaired motor function and occupational performance. Excluding persons who may have impaired consent capacity as a result of stroke from participation in such research can significantly delay attempts to answer important scientific questions and develop new treatments and improved diagnostic, predictive, and preventive strategies. It is crucial to enroll subjects including those with impaired decision-making capacity as a result of stroke in a study of this nature in order to advance the development of new treatments to enhance the motor function and occupational performance of patients suffering from such disorders (National Institutes of Health, 2009).

5. Competency to Consent: Describe who will determine individuals' competency to consent and the criteria to be used in determining competency (i.e., use of standardized measurements, consultation with qualified professional, etc.)

Assessment of consent capacity will begin with initial screening of the patient by the principal investigator on admission to the inpatient rehabilitation hospital following acute stroke. The screening will determine if the subject meets the inclusion criteria for the study, which includes among other items, a score of ≥ 70 on the Modified Mini-Mental Status Examination. (3MSE). Further assessment will be conducted by the principal investigator and will begin at the start of the consent discussion with the prospective client by asking simple questions on consent-related issues to determine which prospective clients have problems understanding them. More targeted screening assessment will follow the consent discussion by asking the potential subject specific questions on, or to describe risks, anticipated benefits, research purpose and/or voluntariness issues (National Institutes of Health, 2009, Appelbaum, 2007)). If the subject has adequate consent capacity based on

this initial screening, it will be documented by the principal investigator that the subject understood the key issues. Subjects still considered to have impaired consent capacity after initial assessment will undergo formal capacity evaluation using a standardized questionnaire, the aid-to-capacity evaluation (ACE) which will be administered by the principal investigator (Feng et al., 2007, Etchells et al., 1999).

6. **Loss of Capacity to Consent:** Is it reasonable to expect that individuals may lose their capacity to consent or withdraw during the course of the research? ☒ Yes (answer A-B below) ☐ No

A. Describe the process for monitoring capacity, reconsent, and reassessment of willingness to continue participation.

Because of the relatively short duration of the study (two weeks), we do not expect significant fluctuations in individuals' consent capacity. However, since capacity can alter as a natural course of underlying illness, response to treatment, and effect of medications, we will maintain an ongoing process of periodical re-evaluating on a weekly basis, the individuals' understanding of all aspects of the research that are relevant to their decision to participate, and have the individuals voluntarily confirm their willingness to participate whenever a research staff, or subject's family member raises a concern about the subject's awareness or judgment and continued study participation.

B. Describe what provisions are in place to protect the subjects' rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research (i.e., power of attorney).

In the event the research subjects lose their capacity to consent or their capacity to withdraw during the course of the research, all research activity will be suspended and the principal investigator will be informed.

The principal investigator will promptly contact the subject's legally authorized representative (LAR), or an individual to inform them of the patient's incapacity, and proceed to obtain informed consent for the patient's continued participation.

In the event the subject had no designated LAR, the principal investigator will request the attending physician to appoint a surrogate decision maker in accordance with state law, in consultation with the hospital's ethics committee. Informed consent for continued participation should be obtained from the subject's LAR before resumption of any research activity.

7. **Consent for Individuals Incapable of Consenting on Their Own Behalf:** Explain how you will identify who is authorized to give legally valid consent on behalf of any individual(s) determined to be incapable of consenting on their own behalf.

A research subject determined to have impaired decision-making capacity will have a legally authorized representative (LAR) or a surrogate decision-maker appointed by the attending physician in accordance with Tennessee law and hospital policy.

The LAR or surrogate decision-maker will be involved during the recruitment interview and the informed consent process, review the informed consent form, and ask any questions for clarification.

The LAR or surrogate decision-maker will sign the consent form on behalf of the subject.

The names and contact information of the LARs or surrogate decision-makers authorized to give legally valid consent on behalf of those individuals determined to be incapable of consenting on their own behalf will be confirmed from their Advanced Directive documentation from their medical records in HealthSouth Rehabilitation Hospital.

The principal investigator will also confirm the names and contact information of individuals executing Durable Power of Attorney (DPA) on behalf of those subjects determined to be incapable of consenting on their own behalf will be confirmed from Advanced Directive documents presented by subjects or their care givers.

8. Assent: Explain the criteria you will use to determine when assent is required for subjects who are not competent.

- Some subjects who cannot provide legally effective consent on their own behalf may be able to provide some form of oral agreement or assent at the outset, and as appropriate throughout the course of the research.
- In such a circumstance, the subject's legally authorized representative or the individual executing Durable Power of Attorney would need to provide documented written consent on behalf of the subject.
- Assent will be required at the recruitment interview to indicate interest in participating.
- Assent will be required to give informed consent to participate in the research.
- Assent will be required to participate in individualized occupational therapy sessions and wearing of restraints.

9. Evaluating Dissent: Explain the methods to be used for evaluating dissent (i.e., description of behaviors that would indicate that an individual does not want to participate, such as moving away, certain facial expressions, or head movements).

Dissent will be suspected by any meaningful objection by the potential participant regarding study participation exhibited by behaviors such as:

- If the individual voices refusal to participate or follow instructions
- If the individual refuses to carry out instructions during therapy sessions, or refuses to wear the restraint on the affected hand outside therapy sessions.
- If the individual moves away, is combative towards research staff, or uses facial expressions such as a grimace that may indicate displeasure.

Such objection by the potential participant regarding study participation must be taken as a refusal or withdrawal and be honored, even if the LAR or the person obtaining consent disagrees with the decision.

10. Use of Institutionalized Individuals: Does the proposed research individuals who are institutionalized?

☐ Yes (answer A below and attach approval from an authorized representative at the institution) ☒ No

A. Provide a justification for the use of institutionalized individuals and explain why individuals who are not institutionalized cannot be substituted.

References

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Appendix E

Graduate Education and Research
Division of Sponsored Programs
Institutional Review Board

Jones 414, Coates CPO 20
521 Lancaster Avenue
Richmond, Kentucky 40475-3102
(859) 622-3636; Fax (859) 622-6610
http://www.sponsoredprograms.eku.edu

Notice Of IRB Approval
Protocol Number: 16-248
Institutional Review Board IRB00002836, DHHS FWA00003332

Review Type: ☐Full ☒Expedited

Approval Type: ☒New ☐ Extension of Time ☐Revision ☐Continuing Review

Principal Investigator: **Umana Udoeyop** Faculty Advisor: **Dr. Camille Skubik-Peplaski**

Project Title: **Implementation of Modified Constraint-Induced Therapy in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital**

Approval Date: **7/5/2016** Expiration Date: **11/1/16**

Approved by: **Dr. Jonathan Gore, IRB Member**

This document confirms that the Institutional Review Board (IRB) has approved the above referenced research project as outlined in the application submitted for IRB review with an immediate effective date.

Principal Investigator Responsibilities: It is the responsibility of the principal investigator to ensure that all investigators and staff associated with this study meet the training requirements for conducting research involving human subjects, follow the approved protocol, use only the approved forms, keep appropriate research records, and comply with applicable University policies and state and federal regulations.

Consent Forms: All subjects must receive a copy of the consent form as approved with the EKU IRB approval stamp. Copies of the signed consent forms must be kept on file unless a waiver has been granted by the IRB.

Adverse Events: Any adverse or unexpected events that occur in conjunction with this study must be reported to the IRB within ten calendar days of the occurrence.

Research Records: Accurate and detailed research records must be maintained for a minimum of three years following the completion of the research and are subject to audit.

Changes to Approved Research Protocol: If changes to the approved research protocol become necessary, a description of those changes must be submitted for IRB review and approval prior to implementation. Some changes may be approved by expedited review while others may require full IRB review. Changes include, but are not limited to, those involving study personnel, consent forms, subjects, and procedures.

Annual IRB Continuing Review: This approval is valid through the expiration date noted

above and is subject to continuing IRB review on an annual basis for as long as the study is active. It is the responsibility of the principal investigator to submit the annual continuing review request and receive approval prior to the anniversary date of the approval. Continuing reviews may be used to continue a project for up to three years from the original approval date, after which time a new application must be filed for IRB review and approval.

Final Report: Within 30 days from the expiration of the project, a final report must be filed with the IRB. A copy of the research results or an abstract from a resulting publication or presentation must be attached. If copies of significant new findings are provided to the research subjects, a copy must be also be provided to the IRB with the final report.

Other Provisions of Approval, if applicable: None

Please contact Sponsored Programs at 859-622-3636 or send email to tiffany.hamblin@eku.edu or lisa.royalty@eku.edu with questions about this approval or reporting requirements.