Effectiveness of a dynamic wrist-hand orthosis in early outpatient rehabilitation of the upper extremity post stroke: a multiple single subject design evaluation

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ABSTRACT

Background: Although early intensive therapy is important for those with upper extremity deficits after stroke, few therapeutic approaches allow those with moderate to severely impaired upper extremities to independently practice repetitive grasp-release activities. The SaeboFlex orthosis has shown promise in assisting with upper extremity recovery post stroke, however, the effects of continued use of the orthosis at home after discharge from inpatient rehabilitation have not been studied.

Purpose: The objectives of this study were to explore the effectiveness of the SaeboFlex orthosis in improving upper extremity function, strength, movement, spasticity and self-perceived occupational performance, with continued use immediately after discharge from inpatient stroke rehabilitation and while waiting for outpatient occupational therapy as well as to explore the relationship between the participants' level of self-efficacy and use of the SaeboFlex orthosis and the participants' experience of use of the SaeboFlex orthosis in the home environment.

Methods: A mixed method study combining a single subject ABA design and post intervention interviews was completed with two participants. Participants were seen in their homes soon after discharge from inpatient stroke rehabilitation, for one hour, three times a week for two weeks and then once a week for six weeks for progression of their SaeboFlex program and were encouraged to use the orthosis at least three times a week, for 50 minutes, for the duration of the 8-week intervention. Quantitative outcome measures were completed three times each at baseline, 4 and 8 weeks and evaluated the participants' upper extremity impairment as well as

their activity limitations and participation restrictions. The Canadian Occupational Performance Measure (COPM) was completed once at baseline, 4 and 8 weeks. Individual interviews were completed after the 8-week intervention and final assessments were complete.

Results: The two participants were both male, 58 and 49 years of age, with dominant and non-dominant paretic upper extremities. Significant improvements occurred in most of the quantitative outcome measures for both participants, including the COPM, with many of the improvements occurring during the first four weeks of the intervention. Four 'person' themes and one 'context' theme emerged from the qualitative data that supported and further explained the quantitative improvements. **Conclusions:** Early continued intervention using a SaeboFlex orthosis, after discharge from inpatient rehabilitation and while waiting for outpatient occupational therapy, resulted in improved upper extremity function, strength, movement, spasticity and occupational performance for both participants. Self-efficacy for self-management tasks improved for one participant. Further research is needed to determine whether functional gains are seen with a larger sample and are maintained over time.

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BACKGROUND

UPPER EXTREMITY RECOVERY POST STROKE

Stroke remains a leading cause of adult disability. Approximately 60,000 people with stroke and transient ischemic attack are treated in Canadian hospitals each year.[1] It is estimated that 405,000 Canadians were living with the effects of stroke in 2013 with that number projected to increase to between 654,000 and 726,000 Canadians living with the effects of stroke in 2038, due to the effects of aging, population growth and decreasing stroke mortality rates.[2]

Upper extremity hemiparesis is the most common and disabling of stroke sequelae and can be seriously debilitating.[3] Stroke causes upper extremity impairments in >80% of survivors[4] while over 50% of stroke survivors with upper extremity impairment do not regain functional use of their arm[5] and only 12% have complete functional upper extremity recovery.[6] Moderate to severe upper extremity hemiparesis post stroke may result in limited ability or the inability to produce functional arm and hand movements, making daily living tasks difficult or impossible.[7] The loss of upper extremity function post stroke can be categorized according to the International Classification of Functioning, Disability and Health framework.[8] *Impairments* post stroke may include upper extremity weakness, spasticity, pain and hand edema. *Activity limitations* post stroke may include difficulty using the upper extremity for daily activities such as eating, washing, dressing and writing. *Participation restrictions* post stroke may include difficulty pursuing former leisure interests such as golfing and biking, and difficulty returning to former vocational pursuits such as work or school. Upper extremity motor impairments can

have a considerable impact on stroke survivors' occupational performance and independence in meaningful daily activities.[9,10]

NEUROPLASTICITY AND UPPER EXTREMITY FUNCTION

Neuroplasticity, "the brain's ability to change throughout the lifespan" involves experience-driven changes of the neuronal synaptic structures.[11] This process of 'rewiring' the brain is important in stroke rehabilitation where damage to one or more areas of the brain can lead to substantial changes in physical, communicative, cognitive and visual-perceptual function. A meta-analysis of thirteen studies that examined changes in the brain following movement based therapy post stroke found that neural changes in the affected sensorimotor cortex of the brain followed the motor gains observed in the paretic upper extremity.[12] The magnitude of the structural grey matter change is directly proportional to the amount of clinical improvement[13] while skilled motor control reaching tasks can produce an expansion of wrist and finger representations within the motor cortex.[14] Theories of neuroplasticity specify that "intensive repetition with increasing levels of task difficulty are both required for enhancing motor recovery and increasing the cortical territory devoted to task performance".[15] Rehabilitation techniques, such as constraint induced movement therapy, show the greatest potential for improving functional outcomes by maximizing cortical reorganization[16] while early therapy is an important factor to induce neuroplasticity post stroke.[17] Therapists are in the ideal position to challenge those recovering from stroke by modifying the environment and the degree of difficulty of the chosen upper extremity tasks to create the 'just right challenge' that then creates an adaptive response originating at the cellular and molecular level.[11] Therapists

can also create 'enriched environments' in which to practice the desired tasks; environments that provide increased opportunity for learning and interaction and therefore promote cortical reorganization.[18] Greater intensity of stroke rehabilitation, including intensive use of the paretic upper extremity, is associated with improved outcomes and maintenance or expansion of cortical representation.[19] Motivation may also play an important role in neuroplasticity and motor recovery.[20] When individuals demonstrate greater motivation to perform daily activities, conditions occur in the nervous system that encourage the release of neurotransmitters and the subsequent development of stronger neural connections.[11]

TASK SPECIFIC TRAINING

Task specific training, defined as the "repeated, challenging practice of functional, goal-oriented activities"[21] has been shown to facilitate the recovery of upper extremity function[22-24] by affecting neuroplasticity and long term cortical reorganization post stroke.[25,26] Task specific training, which involves the repetitive and active practice of functional activities to learn or relearn a motor skill, can be used by itself or in combination with other treatments such as functional electrical stimulation or constraint induced movement therapy.[21] The Canadian Stroke Best Practice Recommendations: Stroke Rehabilitation Practice Guidelines, update 2015, section 5.1.A recommends that "patients should engage in training that is meaningful, engaging, repetitive, progressively adapted, task specific and goal-oriented in an effort to enhance motor control and restore sensorimotor function".[27] A recent evidence-based review highlighted the effectiveness of goal-directed, repetitive task specific movements on improving upper extremity function in clients with motor impairments post stroke,[28] with four studies

reporting that repetitive task specific training positively affected participants' activity as well as participation.[29-32] Although the optimal number of repetitions to affect neuroplasticity is unknown, studies suggest that 'hundreds of repetitions' of upper extremity task specific practice are required to optimize upper extremity function post stroke.[33] Unfortunately, interventions to maximize upper extremity recovery are often provided in low doses.[19,22] One recent study evaluated the number of upper extremity repetitions that occur in stroke rehabilitation,[19] where a single repetition is defined as "reaching to, grasping, moving or manipulating, and releasing an object".[33] This study of seven sites in Canada and the United States, found that task specific training occurs in only half of all inpatient and outpatient therapy sessions, with an average of only 32 functional repetitions per session, far below the number of repetitions thought to be required to facilitate the neural reorganization needed to improve upper extremity function post stroke.[19] Similarly, upper extremity rehabilitation in the early phases of stroke recovery has been found to comprise only 4-11 minutes of an approximately 47 minute occupational therapy session[34] despite the fact that high-repetition task specific training (>=300 repetitions) is possible in a one hour session without inducing pain or fatigue.[33] Higher repetitions of upper extremity use have been associated with better upper extremity outcomes post stroke[33,35] while time spent in therapy significantly predicts functional outcomes.[36]

CONSTRAINT INDUCED MOVEMENT THERAPY

Constraint induced movement therapy (CIMT) is one treatment intervention that has been studied extensively in recent years[37-39] and involves performing intense, repetitive task-specific

training with the paretic upper extremity. CIMT involves restraint of the nonparetic upper extremity for about 90 percent of waking hours, repetitive task training with the paretic upper extremity during daily activities for 6 hours per day for 2 weeks,[40] shaping of activities for optimal challenge, as well as techniques to facilitate transfer of therapeutic gains to daily life.[41] CIMT participants are required to have at least 10-20 degrees of active wrist extension of their paretic upper extremity combined with either 10 degrees of active finger extension of all joints in all digits or 10 degrees of active thumb extension/abduction plus 10 degrees of finger extension in at least two digits, with these movements ideally repeated three times in one minute.[42] In modified CIMT (mCIMT), which may reduce issues related to participant compliance when compared with the more time intensive traditional CIMT programs,[37] the amount of time spent in intensive training and/or the amount of time restraining the nonparetic upper extremity is shortened and spread out over a longer period of time. In mCIMT, training sessions can range from 30 minutes to 3 hours, 2-5 days per week for 2 to 10 weeks while the nonparetic upper extremity is restrained for generally less than 6 hours per day.[37] CIMT can induce practice-dependent neuroplasticity, which occurs when tasks are performed repeatedly to learn or re-learn a skill, by forcing neurons to fire together and therefore contributes to changing cortical maps of the brain.[43] Although CIMT has been shown to facilitate the recovery of upper extremity movement and function,[22,37,38] the number of stroke survivors that actually achieve the necessary wrist and finger extension to participate in CIMT programs is estimated to be approximately 5% - 30%.[44] Many stroke survivors have more severe impairment of the paretic upper extremity, lacking the active wrist and finger extension

necessary to participate in traditional or modified CIMT programs, and are therefore unable to independently achieve the repetitions required for optimal upper extremity recovery.[45-47] In addition to weakness of the paretic wrist and finger extensors, spasticity is very common, frequently developing within 1-2 weeks post stroke[48] with 83% of survivors at four years post stroke demonstrating some degree of abnormal tone.[49] Spasticity affects the return of movement post stroke by causing loss of joint range of motion, pain, muscle stiffness and loss of function in activities of daily living[50] and can therefore have a significant impact on both active and passive function of the paretic upper extremity.[51] Active and passive movement training are required to maintain range of motion and muscle strength[50] and to counteract the insufficient antagonist muscle recruitment and weakness that occurs post stroke.[52]

SAEBOFLEX ORTHOSIS

Few therapeutic approaches allow those with moderate to severely impaired upper extremities post stroke to independently practice highly repetitive grasp and release activities[53] and participate in task-oriented interventions.[45,54] Although receiving manual assistance from another person to assist with positioning the hand for grasping and releasing objects is possible, this is difficult for the stroke survivor to maintain independently at the number of repetitions required, particularly in the home setting where therapy appointments are less frequent and available assistance is less. Therapists need to consider alternate ways to increase therapy time outside of formal therapy sessions to maximize functional improvement[36] as well as promote increased active participation during therapy time and at home.[41] Actual daily use of the paretic upper extremity is limited both in the sub-acute rehabilitation phase[55] as well as one-

year post stroke.[56] According to the Canadian Stroke Best Practice Recommendations: Stroke Rehabilitation Practice Guidelines, update 2015, section 5.1.C, "Functional dynamic orthoses are an emerging therapy tool that may be offered to patients to facilitate repetitive task-specific training [Evidence Level B]".[27] One dynamic orthosis that is currently being used in upper extremity rehabilitation post stroke is the SaeboFlex orthosis (Saebo, Inc, Charlotte, NC). The SaeboFlex is an individually fit dynamic wrist-hand orthosis that positions the paretic hand at optimal biomechanical advantage so that grasp and release activities are possible.[53] The person with stroke volitionally uses his/her finger and thumb flexors to close the hand for grasping, followed by relaxation of the flexors to allow the extension spring system to reopen the hand, without assistance from the nonparetic hand, therapist or caregiver. The SaeboFlex program is a structured program that can be graded and progressed for each individual.[7] The adjustable nature of the SaeboFlex orthosis allows the therapist to increase the degree of challenge as the user progresses; the level of spring resistance depends on the degree of weakness, the amount of spasticity, the amount of voluntary control as well as the therapy goals.[7] Individuals with at least 15 degrees of active shoulder and elbow flexion and 1/2 of full active finger flexion as well as at least 15 degrees of passive wrist extension with the fingers straight (to be positioned in the orthosis) can be trained to use the SaeboFlex orthosis to assist with practicing repetitive grasp-release activities.[53] Active wrist and finger extension are not required for SaeboFlex use, as they are for CIMT and mCIMT programs. The SaeboFlex orthosis allows those with moderate to severe upper extremity hemiparesis post stroke to independently participate in repetitive grasp/release activities that they would otherwise be

unable to do.[7,47,57,58] The SaeboFlex orthosis may also be beneficial in that less individual therapy assistance is needed[45] which is not only cost effective,[46] but can also be useful for increasing the number of upper extremity grasp-release repetitions in the home environment. Self-administered home based upper extremity interventions for those with more impaired upper extremities post stroke are needed.[59]

SELF-EFFICACY AND STROKE RECOVERY

Self-efficacy originates from 'Social Learning Theory' and "refers to beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments".[60] Self-efficacy is based on life experience, including successes and failures, and influences the actions people choose to pursue, how much effort they put forth to attain their goals, how they respond to obstacles and failure, as well as the level of accomplishment they eventually realize.[60] People's beliefs that they can motivate themselves and have the power to produce results is important when pursuing rehabilitation activities.[60] Stroke survivors may call on this familiar pre-morbid self-concept when evaluating how they are coping with their altered abilities;[61] they may perform well on observed functional measures but not have the confidence in their own abilities and capabilities to persevere and cope with setbacks when they occur either during the inpatient phase or after being discharged from inpatient rehabilitation.[62] Self-efficacy is increasingly being studied for its relationship to rehabilitation outcomes post stroke[63] and its role in predicting recovery from a variety of chronic illnesses including stroke.[64] A variety of self-efficacy scales specific to the outcome being measured have been used.[63] Balance self-efficacy has been positively related to walking capacity[65] and

improved activity and participation post stroke,[66] while fall self-efficacy has been found to be a stronger predictor of balance, walking and ADL performance than assessments of physical function.[64] High self-efficacy has been associated with fewer depressive symptoms and improved quality of life post stroke,[67] improved performance with motor skill learning,[68] and increased ability to cope with stressful events such as stroke.[60] Lewin et al., found that high self-efficacy was a strong protective factor for depressive symptoms post stroke and suggested that considering self-efficacy, as well as social support, during inpatient rehabilitation may help prevent post stroke depression.[61] High self-efficacy has also been associated with successful self-management behaviours once stroke survivors are at home.[63, 69] Self-management programs to enhance self-efficacy post stroke are also being studied.[70-72] The role of self-efficacy in upper extremity recovery, including the continued use of upper extremity interventions such as the SaeboFlex orthosis, has not been studied; however with the high intensity of rehabilitation required to affect neuroplasticity and promote functional change, an individual's level of self-efficacy may prove to be an important factor in affecting his/her participation in rehabilitation as well as his/her upper extremity recovery. A self-efficacy measure for two dimensional arm reaching was recently developed and used to determine that reaching self-efficacy is correlated with both the location and target distance to be reached; however, the measure was designed on a two-dimensional plane specifically for use in laboratory based reaching movements.[73] Evaluating self-efficacy before and after rehabilitation interventions could allow therapists to monitor individual responses to the specific intervention as well as help therapists understand both successes and lack of progress in therapy.[62]

Measuring self-efficacy is important as it will provide information on whether the individual believes they can perform the activity which may be just as valuable to determine as whether the individual can actually perform the activity.[62] Self-efficacy beliefs are modifiable which may affect functional outcomes.[62,74,75] Albert Bandura identified four main ways through which self-efficacy can be acquired or improved: 'mastery experience' (mastering simple tasks encourages participation in more complex tasks), 'vicarious experience' (observing others with similar impairments successfully perform a task), 'verbal persuasion' (providing positive feedback about task performance) and 'physiological feedback' (reframing negative physiological symptoms as positive).[76] Stroke rehabilitation could be enhanced by providing a combination of these four sources of self-efficacy[63] as strategies to improve self-efficacy can increase the confidence needed to maintain positive rehabilitation goals.[67] Improvements in self-efficacy may in fact be required before improvements in stroke survivors' participation in their daily activities can occur.[71]

CURRENT STATE OF KNOWLEDGE OF SAEBOFLEX USE IN STROKE RECOVERY

Since the SaeboFlex orthosis is a relatively new therapy tool, evidence has only recently started to emerge. The number of studies completed to date is small, as is the total number of participants (n=124). A recent literature search identified eight studies completed with chronic stroke patients including: three small randomized controlled trials,[57,77,78] four case reports[47,53,79,80] and one retrospective study[81]; as well as two studies with acute stroke patients[46,58] and one study in the sub-acute phase of stroke rehabilitation.[45]

CHRONIC STROKE

In a pilot clinical trial by Jeon et al., involving participants with chronic stroke (mean time since stroke onset 28.6 months), the experimental group (n=5) improved significantly on measures of joint movement smoothness (as evaluated with a three-dimensional motion analysis system) and on the Box and Block Test, while the control group (n=5) did not improve on these measures.[77] Between group differences were not evaluated due to the small sample size. The intervention was completed 60 minutes per day, 5 times a week for 4 weeks in addition to regular therapy. The experimental group practiced nine specific grasp and release tasks per session while using a SaeboFlex orthosis while the control group wore a SaeboFlex orthosis but practiced only shoulder and elbow movements. A small randomized controlled trial by Barry et al., reported that there were no significant between-group differences between participants using the SaeboFlex orthosis (n=10, mean time since stroke onset 4.1 years) and those receiving manual-assisted therapy (n=9, mean time since stroke onset 5.1 years) when the participants were seen one hour per week for six weeks.[78] Although homework was assigned, limited information about therapy done at home between sessions was obtained, as homework logs were not consistently returned (8 out of 19 logs) and therefore could not be analyzed. Barry et al., noted that one of the primary outcome measures used, the Box and Block Test, might not have been sensitive enough to measure change since many participants scored zero; however, two participants (one from each group) achieved minimal clinical important difference on the Action Research Arm Test and the Box and Block Test. Barry et al., also noted that the relationship between the number of exercise repetitions completed and the functional improvement noted was moderate for two of the outcome measures used; higher numbers of

repetitions led to greater functional change. In a randomized controlled trial by McCombe Waller et al, participants received either 12 weeks of unilateral SaeboFlex training (n=13, mean time since stroke onset 3.1 years) or progressive bilateral arm training with rhythmic auditory cueing for 6 weeks followed by unilateral SaeboFlex training for 6 weeks (n=13, mean time since stroke onset 5.3 years).[57] All intervention sessions were one hour, three times a week with assessments completed pre- intervention, and at 6, 12 and 18 weeks. At the 18-week assessment, the twelve-week SaeboFlex group showed greater improvement in the Fugl Meyer Assessment and the Box and Block Test while the bilateral arm training plus SaeboFlex group improved on the Modified Wolf Motor Function Test and the University of Maryland Arm Questionnaire for Stroke, while neither group showed improvement on the Modified Ashworth Scale. Several brain regions showed significant changes in activation patterns with paretic hand movements in both study groups as evaluated with functional magnetic resonance imaging (fMRI) scans. Farrell et al., noted significant improvements in 5 out of 6 measurements of upper extremity active range of motion, as well as significant improvements in Fugl Meyer, summed Modified Ashworth Scale and Motor Status Assessment scores.[47] This study evaluated 13 participants (mean time since stroke onset 4.1 years) who used a SaeboFlex orthosis 6 hours per day for 5 days, combined with proximal strengthening and neuromuscular electrical stimulation. Woo et al., evaluated 5 chronic stroke patients (mean time since stroke onset 29.6 months) who participated in SaeboFlex training 1 hour per day, 5 times a week for 4 weeks and noted that Fugl Meyer upper extremity scores and Box and Block Test scores increased significantly.[80] Movement jerkiness scores decreased significantly in 7 out of 16 of the

movements measured with a three-dimensional motion analysis system. Although two of the chronic studies[53,79] were too small for meaningful statistical analysis, upper extremity improvements were documented. Pooyania and Semenko completed a retrospective study that looked at the upper extremity improvement of chronic stroke patients who used a SaeboFlex orthosis as part of their outpatient occupational therapy over a 3-year period, with and without concurrent botulinum toxin injections.[81] Although between group analysis was difficult given the small sample size (n=11 using SaeboFlex only, mean time since stroke onset 20.1 months; n=3 using SaeboFlex and botulinum toxin, mean time since stroke onset 43.7 months), both groups improved significantly on 13 out of 14 of the outcome measures documented. One additional study by Chang et al., evaluated a dynamic hand splint potentially similar to the SaeboFlex in that "three progressively stiffer elastic-spring strength levels" were used with ten chronic stroke participants (mean time since stroke onset 3.17 years).[82] The participants used the device to "practice finger extensions" at home, in addition to hospital based therapy, 30 minutes per session, 5 times a week for 3 months. Grip and finger strength showed a significant increase from the pre-test to after the 3-month intervention, as did the maximal voluntary contraction of wrist flexor and extensor muscles as evaluated with electromyography; however, the effect on the functional recovery of the hand was less clear. There was however, no information reported on the tasks completed by the participants while wearing the splint, the amount of therapist intervention provided or the amount of time the splint was actually used by the participants at home.

ACUTE STROKE

Two studies looked at SaeboFlex use as an adjunct to usual therapy in the acute phase of stroke recovery. Stuck et al., described a case series feasibility study (n=7) where participants used the SaeboFlex orthosis for a maximum of 45 minutes, 3 times a day for 12 weeks where intensity of use was monitored through participant completed training schedules.[46] The mean time since stroke onset was 21 days, while the range was 3-84 days post stroke. The study excluded those with 'mild' upper extremity weakness stating, "conventional rehabilitation alone may be sufficient"; participants had substantial weakness indicated by baseline Action Research Arm Test (ARAT) scores of less than or equal to 24 and a mean ARAT score of 10.[46] Although none of the participants trained at the maximum of 3 x 45 minutes a day, six of the seven participants achieved minimal clinical important differences on the ARAT and the Upper Limb Motricity Index. Clinically significant improvements were noted in secondary outcome measures as well. Participant experience was captured via an "end of study questionnaire" at the end of the 12-week intervention. The questionnaire revealed that all participants reportedly felt the SaeboFlex training had improved their upper extremity outcomes. The authors concluded that there is some initial indication that the SaeboFlex orthosis has the potential to "augment functional recovery" of the upper extremity in the early phase of rehabilitation post stroke.[46] A recent feasibility audit (n=19) looked at SaeboFlex use in the acute phase of stroke recovery in the United Kingdom (minimum of 45 minutes per day) and reported that mean Fugl Meyer scores improved significantly (mean improvement 25.4 points), with those participants using the SaeboFlex earlier in their rehabilitation program showing greater improvement and requiring the SaeboFlex for less time than those who started later.[58] The authors stated that 18

out of 19 participants were able to successfully incorporate their paretic upper extremities into their daily activities after SaeboFlex use and that participants "felt empowered" and improvements in self-management skills were noted.[58] Although improvements were noted in upper extremity function and goal-based tasks, activity and participation outcomes were not assessed and time post stroke data was not included. The possible effects of spontaneous recovery were discussed; three data sets were excluded due to significant improvements noted in one week and traditional therapy interventions were then utilized instead.

SUB-ACUTE STROKE

The study by Franck et al. (n=8) appears to be the first published study looking at the effectiveness of the SaeboFlex orthosis in the sub-acute phase of stroke recovery.[45] In this study, the mean time since stroke onset was 9.3 weeks, with a range of 4-19 weeks post stroke. The study was a multiple single case design where the authors conducted three baseline assessments (2 weeks apart), two intervention assessments and five follow-up assessments (2 weeks apart) on each of the participants. In the intervention phase, the SaeboFlex orthosis was used for 45 minutes a day, five days a week (3 days at the hospital and 2 days at home) for six weeks, as an adjunct to therapy as usual, with each intervention session preceded and immediately followed by upper extremity personal goal training. After removal of the baseline trends, Action Research Arm Test (ARAT) scores were significantly higher at the end of the intervention phase and in the follow-up phase for three of the participants and while improved in two other participants were not statistically significant. On the ABILHAND assessment, a measure of perceived everyday performance of the paretic upper extremity in real life tasks,

scores improved in four of the participants relative to their baseline performance. Those participants who showed little improvement at the baseline assessments benefited more from the additional training with the SaeboFlex orthosis than those who improved during the baseline assessment phase. The authors also investigated participants' motivation regarding use of the SaeboFlex orthosis by using the Intrinsic Motivation Inventory at the end of the follow-up phase with a resulting mean score of between 5.4 and 6.6 (Likert scale: 1-7) on 6 items and commented that all participants reported feeling highly motivated to use the orthosis for upper extremity training.

SUMMARY OF SAEBOFLEX USE IN STROKE RECOVERY

The SaeboFlex orthosis allowed those with moderate to severe upper extremity hemiparesis to independently participate in repetitive task specific training activities that they would otherwise be unable to do[7,47] therefore reducing the need for 1:1 therapy, which was potentially cost effective.[46] The effectiveness of the SaeboFlex orthosis varied depending on the type of study done, the outcome measures used, and the amount of time in supervised practice, which varied considerably in frequency and intensity. There was also great variability in the time since stroke onset of the participants between studies and within studies. Since improvement takes time, particularly in the chronic phase, studies with short intervention periods may not have been long enough in duration for significant improvements to be noted. It is also assumed that some of the chronic study participants had developed soft tissue changes of the paretic upper extremity as well as significant patterns of learned non-use,[56] with Davenport indicating that her one year post stroke subjects "had adapted to only using one arm".[79] In addition to

improvements in upper extremity function, postural control was also found to improve following arm training with the SaeboFlex orthosis.[83] The SaeboFlex orthosis may allow more opportunity for successful grasp and release practice at home,[78] thereby increasing the number of repetitions performed daily; however, not all of the studies discussed amount of use at home and for some home program compliance was identified as being a limitation.[46,53,78,79] Although three studies measured changes in spasticity and found improvements in pronator and wrist flexor spasticity,[53] as well as improvements in summed Modified Ashworth Scale scores of nine upper extremity muscle groups[47] and three upper extremity muscle groups[81] with chronic stroke participants, the effect of the SaeboFlex orthosis on spasticity in the earlier phases of stroke recovery, including the effect on both passive and active upper extremity goals, has not been studied. While goal setting was reported in four studies,[45,53,79,81] the effect of the use of the SaeboFlex orthosis on stroke survivors' self-perceived occupational performance issues involving the paretic upper extremity has not yet been studied. Several of the studies to date have looked at impairment based outcome measures before and after using the SaeboFlex orthosis[47,53,58,77,80]; the effect on activity and participation based outcomes has not been well studied.[58] Although limited, the literature at this point suggests that the SaeboFlex orthosis may assist some people in the acute, sub-acute and chronic phases of recovery post stroke attain further functional improvement of the paretic upper extremity; however further research is needed, especially in the early rehabilitation phases.

METHODOLOGY

RESEARCH PURPOSE AND OBJECTIVES

The **purpose** of this study was to explore the effectiveness of the SaeboFlex orthosis in improving upper extremity recovery for people in the early phases of rehabilitation post stroke.

The specific **objectives** of this study were:

1. To explore the effectiveness of the SaeboFlex orthosis in improving upper extremity function, strength, movement, spasticity and self-perceived occupational performance, with continued use immediately after discharge from inpatient stroke rehabilitation and while waiting for outpatient occupational therapy services.
2. To explore the relationship between the participants' level of self-efficacy and use of the SaeboFlex orthosis in the home environment.
3. To explore the participants' experience of use of the SaeboFlex orthosis in the home environment.

RATIONALE FOR THE STUDY

The Canadian Stroke Best Practice Recommendations: Stroke Rehabilitation Practice Guidelines, update 2015, states that "the earlier rehabilitation starts the better the outcome" (section 3.0) and that "outpatient and/or community based rehabilitation services should be available…when needed by patients…within 72 hours of discharge from inpatient rehabilitation (Evidence Level C)" (section 4.1.ii).[27] Rehabilitation interventions administered in the early phases of stroke recovery are associated with improved functional outcomes[84] and can potentially prevent secondary complications such as contractures and learned non-use.[45,46] It is

suggested that upper extremity movement, grip strength and dexterity should be practiced intensively during rehabilitation, both in the hospital and at home, as they facilitate the use of the hand in daily activities[56] and that guided home rehabilitation programs can improve the ability of stroke survivors to be more independent in their activities of daily living as well as prevent deterioration.[85] Since stroke survivors who are admitted to stroke rehabilitation units in Canada receive a median of 30 days of inpatient rehabilitation,[27] with slightly longer times of 6-8 weeks of inpatient rehabilitation reported at Riverview Health Centre in Winnipeg, Manitoba (Sepideh Pooyania, personal communication, April 7, 2016), ongoing therapy after discharge is important to optimize rehabilitation outcomes.[27] Outpatient programs are valuable and ensure that improvements made in the inpatient rehabilitation setting are maintained and improved upon;[86] however current waiting lists for outpatient occupational therapy services are long; potentially affecting upper extremity outcomes. This study explored the effectiveness of use of the SaeboFlex orthosis immediately after discharge from inpatient rehabilitation by following participants in their own homes while they were waiting for outpatient occupational therapy. The study explored several areas that have not yet been evaluated in the early rehabilitation stages post stroke such as the effect of the SaeboFlex orthosis on upper extremity spasticity, including its relationship to active and passive upper extremity movement goals, the effect of SaeboFlex use on participants' activity and participation outcomes including their self-perception of their upper extremity occupational performance issues, the potential relationship between self-efficacy and use of the SaeboFlex orthosis as well as the participants' experience using the SaeboFlex orthosis in the home environment.

CURRENT PRACTICE

Although the inpatient stroke rehabilitation unit was relocated from the Health Sciences Centre (HSC) to Riverview Health Centre in 2006, outpatient therapy services have remained at HSC. The waiting list for outpatient occupational therapy at HSC, for those discharged from Riverview Health Centre, has remained consistent at 2-3 months over the last 2 years, during which time patients discharged from inpatient rehabilitation are left waiting for outpatient occupational therapy services. Currently, therapists at Riverview Health Centre trial a SaeboFlex orthosis with suitable stroke inpatients during regular therapy sessions and may order a SaeboFlex orthosis (funded by Manitoba Health with a physician's prescription) for the patient to use during the remainder of their inpatient stay and at home after discharge. Once the orthosis is received by the stroke inpatient, he/she is taught how to don the orthosis and started on a program of grasp-release activities using the orthosis. A referral to outpatient occupational therapy at HSC or to occupational therapy at the Community Stroke Care Service is initiated at discharge from Riverview. Even though a home program is often provided, patients have been noted to demonstrate little follow through at home once they are finally seen for outpatient occupational therapy at HSC. The principal investigator recently led the development of a practical upper extremity Toolkit, which was updated in 2017, and based on the 2015 Canadian Best Practice Recommendations for Stroke Care, in an attempt to improve consistency of practice between rehabilitation settings locally; however, the 'gap' in service between inpatient and outpatient programs remains. Knowing that early therapy is important for inducing neuroplasticity post stroke[17] and that patients should be seen within 72 hours of discharge from a rehabilitation facility,[27] this 'gap' in service is frustrating for both patients and

therapists and although has been identified as being problematic at local stroke program meetings, has yet to be resolved. In some cases, SaeboFlex training is not initiated as an inpatient at Riverview Health Centre due to the lack of immediate therapy follow-up after discharge, potentially affecting upper extremity outcomes.

STUDY DESIGN

This mixed methods study combined a quantitative single subject ABA design and qualitative post study individual interviews that captured quantitative information on the effectiveness of the SaeboFlex intervention and then qualitative data on the value of the intervention. Specifically it was an explanatory sequential mixed methods study in which the quantitative component was completed first, followed by qualitative interviews that built on and further explained the quantitative data.[87] Mixed method research can provide a stronger understanding of the research questions than research using solely quantitative or qualitative data.[87] Single subject design studies provide a structured and controlled approach to the study of a single case or multiple cases as well as the opportunity to observe subtle changes during clinical treatment, without the inter-subject variability often seen in group designs[88] and are useful for determining the individual effectiveness of an intervention or treatment modality.[89,90] Unlike larger group designs, where one or two observations are made of several patients, single subject designs use several observations of one or a few patients.[89] Since the data is not combined, the researcher can distinguish characteristics of those patients who responded favorably to treatment, characteristics that may be missed in larger group studies with combined data.[88,90] In single subject study designs, where each participant acts as his/her

own control,[88,91,92] the target behaviours are measured repeatedly in a pre-treatment baseline phase, and during the intervention phase.[88,90,92] Repeated baseline assessment provides a standard of comparison for evaluating the potential relationship between the intervention and target behaviour and baseline and intervention outcomes are compared to detect possible treatment effects.[90,92] The baseline phase serves to describe the level of performance prior to the intervention and also serves as the basis for predicting the future level of performance if the intervention is not provided, an important consideration when evaluating whether the intervention leads to a change in performance.[89] The baseline assessments in this study were completed by a trained research assistant, in the participants' homes, within one week of discharge from Riverview Health Centre. Reassessments were completed after 4 and 8 weeks of intervention, by the same research assistant, followed by individual interviews in the participants' homes. Ethics approval was obtained from the Health Research Ethics Board (HREB) at the University of Manitoba, as well as from the Riverview Research Committee. Health Sciences Centre Impact Analysis was completed. This study was registered with clinicaltrials.gov.

PARTICIPANTS

Two participants were recruited and provided written consent prior to discharge from the Riverview Health Centre inpatient stroke rehabilitation program. Although it was hoped that three participants would be recruited for the study, only two met the inclusion criteria during the timeframe of the study. Inclusion criteria for the study were: adults aged 18 years or older who had had a first stroke within the previous 6 months; had been admitted to Riverview

Health Centre for stroke rehabilitation and were discharged to home locations within the city of Winnipeg; were fit with and started using a custom SaeboFlex orthosis as an inpatient at Riverview Health Centre after having met the active and passive movement criteria required to use the SaeboFlex orthosis (ie. able to achieve passive wrist extension of the paretic upper extremity to at least 15 degrees with all finger joints passively extended with no more than slight force required to achieve extension and have at least 15 degrees of active shoulder and elbow flexion as well as at least ½ active finger flexion); were referred to outpatient occupational therapy at the Health Sciences Centre for ongoing upper extremity rehabilitation using a SaeboFlex orthosis; were able to commit to the time requirements of the study; had a premorbid fully functional upper extremity; were able to speak and understand English; were able to follow multistep commands and understand the purpose and required use of the orthosis; were able to stand unsupported for at least 10 minutes; and had three times per week access to a caregiver to assist with donning the orthosis at home if required. Exclusion criteria for the study were: Chedoke McMaster Stroke Assessment, Impairment Inventory (CMSA-II) (Shoulder Pain section) score of 1-3; Modified Ashworth Scale (MAS) score of 3 or more for the elbow, wrist and finger flexors of the paretic upper extremity; swan neck deformities or contractures of the fingers or wrist of the paretic upper extremity; history of skin breakdown on the paretic upper extremity or a score of less than 6 out of 12 on the Sensation Section of the Fugl-Meyer Upper Extremity assessment; significant cognitive impairment as determined by a score of 21 or less on the Montreal Cognitive Assessment (MoCA); and able to fully extend fingers 10 times in a position of maximal shoulder flexion and elbow extension with a neutral

wrist (upper extremity is too functional and would not benefit from the use of a SaeboFlex orthosis).

RECRUITMENT AND CONSENT

Potential participants, who met eligibility criteria, received a flyer providing information about the study from the Riverview Health Centre occupational therapist. Participants or their therapist contacted the principal investigator to discuss the study, including their eligibility, and any questions or concerns. A screening appointment was then set up with the principal investigator to confirm eligibility. A screening checklist was used (see **Appendix A**). Those individuals who met the eligibility criteria and chose to participate in the study, were then provided with an information package with a copy of the informed consent and a schedule of study events. The participants were asked to sign informed consent prior to their baseline assessment (see **Appendix B**).

DATA COLLECTION

Participant demographics including age, gender, time post stroke, type of stroke, paretic side and hand dominance, as well as individual Montreal Cognitive Assessment (MoCA) scores (taken at admission to Riverview Health Centre) and Chedoke McMaster Stroke Assessment, Impairment Inventory (CMSA-II) scores, Hand, Arm and Shoulder Pain sections (taken at admission to and discharge from Riverview Health Centre) were recorded (see **Appendix C**). Hand dominance was included as a dominant side paretic hand may result in better upper extremity motor recovery.[93] Participants were instructed to record the time spent doing each task with the SaeboFlex orthosis per session and the total number of repetitions of SaeboFlex

use per session in the provided participant logbook. Participants were also instructed to record their participation in other upper extremity interventions and therapies during the time of the study in the provided logbook. All outcome measurements, with the exception of the Canadian Occupational Performance Measure (COPM), were taken by a trained research assistant (a College of Rehabilitation Sciences occupational therapy student) in the participants' homes including measures of impairment, activity and participation and results were recorded on a data capture sheet (see **Appendix D**). As this was a single subject design evaluation, three series of all primary baseline outcome measures, done approximately two days apart, were completed initially to determine stability (consistency of the response) and trend (direction of change initially due to the effects of other treatments and spontaneous recovery) of the targeted outcomes[88] followed by reassessment completed three times, approximately two days apart, after 4 and 8 weeks of intervention. The COPM was administered once at baseline, after 4 weeks of intervention and after 8 weeks of intervention by the principal investigator, in the participants' homes. Because the purpose of the study was to evaluate the effect of use of the SaeboFlex orthosis at home soon after discharge, the baseline interventions were completed the week after discharge, in the participants' homes, to ensure minimal time between discharge and the start of the intervention. A minimum of three to four data points were required in each phase of the study;[88] three data points in each phase have recently been used in single subject design studies of upper extremity edema post stroke.[94,95] Measurements that are completed repeatedly at each assessment time can validate assessments that are taken less

frequently, particularly in the case of more lengthy assessments of motor function such as those used post stroke.[90]

OUTCOME MEASURES

The Arm Activity Measure (ArmA) (see **Appendix E**) and Chedoke Arm and Hand Activity Inventory-7 (CAHAI-7) (see **Appendix F**) both measure *upper extremity activity performance* post stroke and were the primary outcome measures for this study. Both assessments were completed three times each, approximately 2 days apart, at baseline, 4 and 8 weeks. The ArmA was chosen because it is one of the few tests that provides a comprehensive assessment at the activity level of both active and passive upper extremity function, which are both important to the achievement of clinically relevant goals.[96] The ArmA is a self-report tool designed for use with spasticity management interventions and has an 8 item passive function subscale (Section A) and a 13 item active function subscale (Section B) and uses an ordinal scale ranging from 0 (no difficulty) to 4 (unable to do activity) for each scale item.[96] The passive function subscale ranges from 0 to 32 and the active function subscale ranges from 0 to 52, where lower scores indicate higher function.[96] High internal consistency, convergent and divergent validity, as well as test-retest reliability have been demonstrated in both subscales.[97] The CAHAI-7 is a commonly used upper extremity functional assessment post stroke.[98] It is comprised of seven bilateral functional tasks. Each task in the CAHAI-7 is scored on a 7-point (1-7) ordinal scale for a total value of 49, where higher scores indicate higher function.[98] The paretic upper extremity is scored according to its positioning and functioning during test performance. The CAHAI-7 has excellent test-retest reliability, interrater reliability and internal consistency.[99,100] The Stroke

Impact Scale (SIS) version 3.0, Stroke Recovery subscale (see **Appendix G**), was completed three times, approximately 2 days apart, at baseline, 4 and 8 weeks, to measure the participants' perception of their post-stroke recovery. The Stroke Recovery subscale of the SIS has been used as the anchor during the calculation of clinically important difference calculations because the score directly reflects the viewpoint of the patient.[101] The Stroke Recovery subscale is scored on a 0-100 scale where 0 = no recovery and 100 = full recovery and has been widely used in stroke intervention studies as an outcome measure.[102,103] Three assessments of *upper extremity impairment* were also administered. The Fugl-Meyer Assessment – Upper Extremity section (FMA-UE), the Modified Ashworth Scale (MAS), and grip strength (average of 3 trials) were completed 3 times each at baseline, 4 and 8 weeks. The FMA-UE (see **Appendix H**) is one of the most widely used quantitative measures of motor impairment and has a standardized training procedure for consistent administration.[104] The FMA-UE was administered in a seated position with scoring based on direct observation of performance. The FMA-UE is comprised of 33 items related to upper extremity movement, with a maximum score of 66. All movements are graded on a three point ordinal scale (0=cannot perform, 1=performs partially, 2=performs fully) where higher scores indicate better movement abilities.[105] The FMA-UE has excellent inter-rater and test-retest reliability as well as construct validity in patients with stroke.[105-107] The MAS (see **Appendix I**) assesses the resistance to passive movement and is widely used clinically and in research.[108] The MAS was administered in the seated position to the paretic elbow, wrist and finger flexors. The degree of resistance to passive muscle stretch is graded and scored on a 6 point ordinal scale ranging from 0 (no increase in muscle tone) to 4 (the paretic

part is in rigid flexion or extension).[109] The MAS has moderate reliability for the assessment of arm spasticity[108-112] and has adequate convergent validity with the FMA-UE.[113] Measurement of grip strength is common after stroke[114] and was done with participants seated with their paretic shoulder at 0 degrees of shoulder flexion and paretic elbow flexed to 90 degrees. The mean of three trials was recorded in kilograms. Grip strength measurement using a Jamar dynamometer and in a standardized position has good to excellent test-retest reliability,[114-115] excellent intra-rater reliability in chronic stroke,[116] correlates well with other tests of upper extremity function[116] and has established minimal clinically important difference values.[117] The Canadian Occupational Performance Measure (COPM) is a client-centred outcome measure that was used to determine change over time in participants' self-perception of their performance and satisfaction with their self-identified upper extremity occupational performance issues in the areas of self-care, productivity and leisure.[118] As the COPM (www.thecopm.ca) was also used as a goal setting tool to assist in choosing tasks to practice during the SaeboFlex intervention and during the intervention time immediately after removal of the SaeboFlex orthosis, it was administered by the principal investigator, once at baseline with reassessment at 4 and at 8 weeks. The COPM uses a semi-structured interview format and structured scoring method. Performance and satisfaction scores were identified for each of the top five upper extremity occupational performance issues identified by the participant using a 1-10 point rating scale. Higher scores indicate better performance and greater satisfaction with performance of the previously identified occupational performance issues. The five performance and five satisfaction scores were summed separately and then divided by five (the

number of occupational performance issues) to determine the mean score for each. The COPM has been found to be a valid and responsive measure of occupational performance[119,120] and has excellent test-retest reliability.[120] The Stroke Self-Efficacy Questionnaire (SSEQ) was used to assess stroke specific self-efficacy related to functional performance and self-management. Assessment with the SSEQ occurred three times, approximately 2 days apart at baseline, 4 and 8 weeks. The SSEQ (see **Appendix J**) was developed to measure "stroke-specific self-efficacy in terms of self-reported confidence in functional performance after stroke"[61] and allows therapists to monitor individual responses to therapy interventions including self-management interventions.[62] Rasch analysis of the SSEQ with stroke survivors an average of four months post stroke recently demonstrated that the scale measures two separate constructs, 'functional activities' and 'self-management' which should be evaluated separately and the scores not combined.[62] The 'functional activities' scale was used to evaluate participants' self-perception of their ability to complete everyday tasks and is composed of the first eight questions of the SSEQ. The 'self-management' scale was used to evaluate participants' self-efficacy with their own self-management of stroke related activities and is composed of the final five questions of the SSEQ. Each of the items in both subscales is rated on a 4-point ordinal scale ranging from 0 (not at all confident) to 3 (very confident). The revised SSEQ demonstrates good construct validity as demonstrated by correlations with other outcome measures including the Falls Efficacy Scale and the Hospital Anxiety and Depression Scale.[62] Reliability has been shown to be good.[62] Moderate correlation with the Southampton Stroke Self-Management Questionnaire, a

new measure of self-management post stroke, has also been demonstrated.[69] See **Appendix K** for a list of the study's outcomes measures and their psychometric properties.

INTERVENTION

After consent was signed at Riverview Health Centre, the principal investigator evaluated the fit of the SaeboFlex orthosis, to ensure adequate fit prior to the start of the study. Minor adjustments to thumb position were made to both devices at that time. Participant 1 was discharged from Riverview Health Centre with a trial SaeboFlex orthosis, which he had used at Riverview and was used for the first 2 intervention visits in week 1, with the principal investigator. Participant 1 received his own SaeboFlex orthosis from the providing orthotist prior to the 3rd visit in week 1. Minor adjustments were made to the thumb angle and bead lines (each bead line was tightened by one bead) of his own SaeboFlex orthosis at visit 3 in week 1, by the principal investigator. Participant 2 received his own SaeboFlex orthosis prior to his discharge from Riverview Health Centre. Minor positioning adjustments were made to the thumb angle and bead lines (each bead line was tightened by one bead), during the first week of intervention. Education on donning the orthosis occurred prior to the study by the inpatient therapists at Riverview Health Centre, when the orthosis was initially provided (as time permitted) but was also reviewed as needed with the two participants during the first week of intervention. Because Participants 2's wife was present for all intervention visits in week 1 and she was available to assist Participant 2 don the device, donning instructions were reviewed with her as well. Both participants also received 10-4" therapy balls with their SaeboFlex orthosis and a small piece of shelf liner was provided to wear under the device, on the forearm,

for improved stability of the device and to eliminate slipping. After the baseline assessments were completed, the principal investigator saw Participant 1 in his home and Participant 2 in his hotel room for one hour, three times a week for 2 weeks for set-up and progression of their SaeboFlex home program and then for one hour once a week for 6 weeks for ongoing progression of their SaeboFlex home program, while they were waiting to get into outpatient occupational therapy at the Health Sciences Centre in Winnipeg, Manitoba. The participants were requested to use their SaeboFlex orthosis for a minimum of three times per week, for the 8 weeks of the study, to assist with practicing the four movement components required for most upper extremity tasks, "reaching for, grasping, moving/manipulating and then releasing an object".[33] Specifically, participants were instructed to use the SaeboFlex orthosis to assist with practicing 5 grasp and release tasks for 10 minutes each, for a total of 50 minutes, three times per week for 8 weeks, using 4" therapy balls. (See **Appendix L** for the study's Schedule of Events.) The intervention followed the SaeboFlex protocol[121] and was graded weekly by the principal investigator to provide optimal upper extremity challenge and progressed at a rate that was individually appropriate, based on the participants' upper extremity strength, spasticity and standing tolerance. Examples of grading task difficulty included increasing the height or distance required to release a therapy ball, combining movement patterns, increasing the speed of movement (completing more repetitions) and adjusting the SaeboFlex spring tension to allow for more or less help with opening the hand. Both participants started with a red (medium resistance) spring but were later progressed to a less resistive (yellow or silver) spring based on the goal of the assigned grasp-release task. Neither participant used the most

resistive (blue) spring during any of the grasp-release tasks. Although grasp-release tasks combined with shoulder flexion were trialed with both participants in standing, compensatory movements were noted and tolerance for this task was low. Both participants were therefore encouraged to initially complete shoulder flexion tasks in sitting, grasping the ball in a position of neutral shoulder and elbow extension (ie. arm by their side) or if this was difficult in a position of slight shoulder extension with the elbow in extension. An upside down plastic bin was used as a "table" for the ball in these positions. Both participants were later progressed to shoulder flexion tasks in standing, positioned with their paretic side to a low table (when available) so the arm position during grasping the ball was the same as when completing the task in sitting. Both participants were encouraged to complete bilateral grasp-release tasks (ie. using both hands at the same time) if compensatory movements were noted. Completing tasks in front of a mirror or window was also encouraged to minimize compensatory movements, as visual feedback could then be incorporated. Both participants were also encouraged to let their paretic arm rest by their side, between grasp-release repetitions, if they felt that their hand was tightening up or if they noticed it was harder/took longer to release the 4" therapy balls. (See **Appendix M** for information on task progression using the SaeboFlex orthosis). Following the 50-minute session, participants removed the SaeboFlex orthosis and attempted to use their paretic upper extremity for 10 minutes for individual grasp and release tasks which were based on previously identified occupational performance issues from baseline assessment with the COPM. If the identified occupational performance issue was too difficult, a component of the chosen task was practiced instead.[33] Adaptive equipment was used as necessary to facilitate

completion of the task, ie. cylindrical foam to increase the size of cutlery, dycem to prevent an object from moving. Changes in body position were also encouraged to allow continued practice with grasp-release tasks after removal of the SaeboFlex orthosis. Both participants were encouraged to sit for this practice initially as sitting appeared to relax the arm and allowed more grasp-release repetitions without the orthosis. Participants were encouraged to 'think through' any challenges encountered with their upper extremity program as a way to encourage individual problem solving[41] and were also encouraged to use their paretic upper extremity for other tasks throughout the day between SaeboFlex sessions. In addition, the four main ways of improving self-efficacy[76] were incorporated into the one hour treatment sessions including: mastery experience (the addition of more complex tasks once easier tasks are accomplished); vicarious experience (hearing about the improvements that others have made); verbal persuasion (providing positive feedback about task performance) and physiological feedback (normalizing and reframing physiological symptoms that are common post stroke). A logbook was provided for participants to record the time spent and number of repetitions completed of the assigned grasp-release tasks (one page per day) as well as any comments related to use of the orthosis at home and any additional therapy interventions received. Specific grasp-release tasks were assigned each week, including the springs to be used for the assigned tasks. Participants were also encouraged to record the tasks completed once the orthosis was removed. Extra logbook pages were left with participants in the event that they used the SaeboFlex orthosis more than the minimum requirement of three times per week. (See **Appendix N** for a sample page from the participant logbook.)

QUALITATIVE INTERVIEWS

Upon completion of the 8-week intervention and final assessments, participants participated in a 1-hour interview. Participant 1 was interviewed by the principal investigator in his home; Participant 2 was interviewed in his hotel room. The goal of the individual interviews was to generate discussion about the perceived usability of the SaeboFlex orthosis in the home environment, the perceived effect on upper extremity recovery as well as the perceived relationship between self-efficacy and use of the SaeboFlex orthosis in the home environment. Individual interviews are useful for developing our knowledge about clinical issues;[122] however they have not been frequently used with those recovering from upper extremity deficits post stroke.[123] The individual interviews were conducted using a semi-structured interview guide (see **Appendix O**) using open-ended questions and probes to encourage further elaboration of information discussed.[87] Prior to the conclusion of the interview, the principal investigator summarized key points from the interview as well as any emerging themes to check for completeness and accuracy with the participant. The interviews were audio-recorded, transcribed verbatim and anonymized using pseudonyms. Participant 1's interview was transcribed by the principal investigator. Participant 2's interview was transcribed by a transcriptionist.

DATA ANALYSIS

QUANTITATIVE DATA ANALYSIS

As this was a single subject design study, with each participant acting as his/her own control, outcome data was plotted and analyzed individually. Baseline data was evaluated visually for

stability and trend while data between phases was analyzed for the level of change and direction of change to help determine the benefit of the intervention.[88] As additional statistical methods are recommended if baseline fluctuations are expected or if new interventions are being tested,[124] celeration line analysis in combination with two-standard deviation band analysis were also completed, to supplement the visual analysis.[88,92,124] Multiple approaches to single subject design data analysis are important as there is "limited consistency across different quantitative methods of analyzing single-subject data".[124] Visual analysis is seen as limiting by some authors in that it "considers only those effects that in the plotted data can easily be seen as significant".[125] Relatively weak but still important treatment effects may therefore be overlooked if only visual analysis is used.[125]

Celeration line analysis is intended to demonstrate whether data are accelerating, decelerating or stationary by applying a line of best-fit to the baseline data points and extending the line to the intervention phase to evaluate the effect of the intervention on the participants' performance.[124] If no difference between phases is found, 50% of the data in the intervention phase will fall on or above the line and 50% will fall below the line; the extended line will not fit this pattern if a real change in observed behavior has occurred.[88] After the data was plotted, a vertical line was drawn dividing the baseline phase data points in half. Each half of the baseline phase was then divided in half again. The median value was then computed from the y-axis for each half of the baseline phase. The two median values were then connected with a straight line, this celeration line was then extended to the intervention phase.[124, 125] It is suggested that the celeration line should divide the baseline data points in half and therefore be adjusted up or

down (keeping parallel to the original line) to obtain a split middle line;[124, 125] however, this was difficult to determine visually with only three data points in the baseline phase. The split middle line is therefore considered to be the celeration line for this data analysis.

The data collected in single subject design studies is "invariably of a repeated nature".[125] Serial dependency of the data points where "sequential responses emitted by the same individual will be correlated"[125] results in a reduction in variability in participant scores in a given outcome measure. Celeration line analysis "takes into account most kinds of serial dependency involved in autocorrelation"[126] and is therefore useful for data analysis of single subject data. Use of the C statistic to estimate trends in the data would have been appropriate since the C statistic "is not affected by autocorrelation in the data series"[88] however use of the C statistic requires at least 8 observations for each data collection phase.[88]

Two-standard deviation band analysis was also used in this study as it can be used with "relatively small baselines"[127] and can be used with baseline data that are fluctuating or have a high degree of variability,[127] which is then translated into a wider band of performance that can be used to evaluate intervention effects.[126] The mean and standard deviation were computed for the baseline data; the data was plotted and the mean and two standard deviation bands (above and below the mean) were drawn horizontally through the baseline and intervention phases of the graph and evaluated as per the protocol for this test.[88,124] If at least two consecutive data points fall outside the two standard deviation range in the intervention phase, a statistically significant change has occurred between the baseline and intervention phases.[92,126-128]

Portney and Watkins suggest a minimum of 3 to 4 data points per phase which has been recently used by other researchers in stroke recovery[88,94,95] however other authors suggest a minimum of 7 to 10 data points per phase, particularly for celeration line analysis as "a small number of baseline observations reduces the accuracy of the trend line computed from the baseline data."[127] Results from celeration line analysis in this study should therefore be interpreted with caution, as only 3 data points were collected in each phase. As this study evaluated participants' function soon after discharge from inpatient stroke rehabilitation with the need for continued use of the SaeboFlex intervention with little disruption in time and the chosen outcome measures have good reliability, the outcome measures (CAHAI-7, ArmA, SIS – Overall Recovery subscale, FMA-UE, MAS, grip strength and SSEQ) were completed three times each at baseline, 4 and 8 weeks and were analyzed as outlined above. Ottenbacher notes that "it is possible to record performance too frequently" especially when some assessments, including motor assessments done post stroke, are lengthy and are prone to practice effects.[129]

For assessment scales that were clearly ordinal (i.e. MAS scores for the elbow, wrist and finger flexors), calculations of the median and interquartile range were completed instead of two-standard deviation analysis.[126] After the median scores were calculated for each phase of the study, the scores at the 25th and 75th percentiles were calculated and parallel lines drawn to represent these scores on each phase of the plotted data, thus creating interquartile bands. If the interquartile bands between each phase of the study do not overlap, a meaningful change has occurred between phases.[126]

To supplement the visual and statistical analysis, comparison of change in mean scores between phases was also done for each outcome measure, which is most useful when comparing stable data with scores that cluster around the mean;[125] these change in mean scores were compared to known minimal clinically important difference (MCID) and minimal detectable change (MDC) scores for each outcome measure. MCID has been defined as, "the smallest change in an outcome measure that is perceived as beneficial to patients"[117] while MDC has been defined as, "the minimal amount of change in a score that likely reflects true change rather than a variation in measurement."[101] A minimal important change (MIC) score was reported for the ArmA (active and passive function subscales), however since the method to determine the MIC was based on parametric assumptions, the established MIC "can only provide a preliminary indication of interpretability for the ArmA," which is an ordinal scale.[97] See **Appendix K** for a list of the study's outcomes measures and their established MCID/MDC/MIC values.

COPM scores for Performance and Satisfaction were plotted; comparison of baseline, 4 and 8-week data was done (administered once at each time point) to determine possible effect of the intervention.

The total number of repetitions recorded by each participant each week (intensity per week) was plotted and analyzed visually. Although it was expected that the amount of time using the SaeboFlex orthosis per week would be recorded in the participant logbooks, this was inconsistently done. It was decided to instead calculate the number of SaeboFlex sessions

completed by each participant each week, assuming that an approximate time of ten minutes for five tasks (ie. 50 minutes) is the amount of time the SaeboFlex orthosis was used each session. The number of SaeboFlex sessions completed each week was plotted and analyzed visually for each participant.

QUALITATIVE DATA ANALYSIS

Qualitative data from the post-intervention interviews was analyzed using conventional content analysis, defined "as a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns".[130] Conventional content analysis is useful when research on a given topic area is limited because it allows the researcher to immerse themselves in the data, allowing codes and categories or themes to emerge.[130] Conventional content analysis allows the researcher to gather information from study participants without using a preconceived framework or categories[130] and is used "to provide knowledge and understanding of the phenomenon under study".[131] Since conventional content analysis relies on an inductive approach, concepts of interpretive description methodology were also used in the data analysis. Interpretive description "provides direction in the creation of an interpretive account that is generated on the basis of informed questioning, using techniques of reflective, critical examination, and which will ultimately guide and inform disciplinary thought in some manner".[132] The product of interpretive description, being a comprehensive account of what the themes within the data signify and extending beyond what is seen in an individual case, can be used to inform clinical

reasoning and decision making, and therefore has potential practical applications for other therapists working in similar practice areas.[132]

At the start of the analysis process, each interview was transcribed verbatim from its digital audio-recording. The principal investigator read and re-read the interview transcripts to identify relevant statements related to the research questions. Transcripts were then re-read and conventional content analysis was used to analyze the text data. Words were highlighted in the text that appeared to capture key concepts; these words or statements were coded and labeled with descriptive words and phrases in the margin of the text document. Codes were then grouped with other codes with similar meanings to form themes. Closely related themes were collapsed together. Themes were defined and supported by direct quotations from the participants. Subthemes emerged for one of the themes for one participant; these were defined and supported by direct quotations as well. The transcripts were read again and any uncoded information related to the research questions was coded. The principal investigator was mindful during this process to try not to fit any remaining statements into the previously established themes, but to let new patterns emerge from the data. Themes were analyzed for overlap and definitions were re-evaluated. Relationships between themes were then explored and a model was developed for the data emerging from the two participants. During the data analysis process, the principal investigator took care to shift back and forth between the data collected from the transcripts and the emerging themes to ensure that the iterative process was maintained by allowing the data itself and the analysis process to inform each other, as is required in interpretive description.[132] The principal investigator also took time to reflect on any

thoughts or assumptions involving the study intervention itself, to ensure that any prior assumptions regarding use of the SaeboFlex orthosis did not affect analysis of the data and "to prevent premature closure a way of making sense of the emerging conceptualizations."[132] In addition, rigour was maintained by debriefing with thesis committee member (Dr. J. Ripat), who has expertise in qualitative data analysis, on several occasions throughout the data analysis process including two face-to-face meetings and several e-mail communications, to assist with triangulation of the qualitative results as they emerged. An audit trail was maintained of all documentation, starting with the initial transcripts and including the processes of coding and theme development, as well as the thematic relationships as they evolved. This audit trail tracked decisions made during the analysis process and ensured that the themes and subthemes that emerged were grounded in the interview data. Participants' comments during the intervention period and captured in the weekly participant logbooks, as well as comments recorded verbatim from each participant and/or their family member during the 8-week intervention, further informed the qualitative analysis of the post-intervention interviews.

MIXED METHOD DATA ANALYSIS

As this study was an explanatory sequential mixed methods study, the quantitative data collection was completed first. This was followed by qualitative data collection from individual interviews in order to build on and further explain the quantitative data.[87] Thus, the qualitative data was used to help provide more insight and depth into the quantitative results.[87]

Specifically, as the qualitative data analysis progressed, themes emerged that, combined with comments obtained from the participant logbooks, were then used to further describe and

explain the data obtained from the quantitative data analysis. During the mixed method analysis, the principal investigator considered the following questions, “In what ways do the qualitative data help to explain the quantitative results?” and “How do the qualitative results explain the outcomes?”[133]

Validity was maximized during the mixed method data analysis by using the same participants for each phase of the study and by following up on significant results in the quantitative phase with the questions chosen for the qualitative phase.[133]

Ethics approval for this study was obtained from the Health Research Ethics Board (HREB) at the University of Manitoba; ethics number HS19985 (H2016:285).

RESULTS

PARTICIPANT DEMOGRAPHICS AND DESCRIPTIVE CHARACTERISTICS

The two participants in the study were both male and both had right paretic upper extremities post stroke. For Participant 1 this was his non-dominant hand and for Participant 2 this was his dominant hand. Both passed all of the screening criteria for the study; however, Participant 2 was not being discharged to a ‘home location within the city of Winnipeg’ but rather to a hotel, as his home was three hours away, to facilitate attendance at medical appointments and physiotherapy, which started soon after discharge from Riverview Health Centre. The hotel was determined to be his ‘home’ for several weeks after discharge. During the screening that took place to determine eligibility for the study, both participants scored 12/12 on the Sensation

Section of the FMA-UE, indicating that both participants had intact sensation. **Table 1** outlines the participant demographics.

Table 1: Participant Demographics

Variable	**Participant 1**		**Participant 2**	
Age (years)	58		49	
Gender	male		male	
Time post stroke	8.5 weeks		9 weeks	
Type of stroke	Left basal ganglia infarct		Left lacunar infarct	
Paretic side	right		right	
Dominant side	left		right	
Montreal Cognitive Assessment score (at admission to Riverview)	26/30		22/30	
Chedoke McMaster Stroke Assessment, Impairment Inventory, score (out of 7)	At admission to Riverview	At discharge from Riverview	At admission to Riverview	At discharge from Riverview
Arm	3	3	1	4
Hand	3	3	1	2
Shoulder Pain	6	6	6	6

PARTICIPANT 1

Participant 1 is married and has worked in the area of computer system design for many years. He started outpatient physiotherapy the first week of the study intervention and typically attended physiotherapy once or twice a week for the duration of the study intervention, with the exception of week 2, when his physiotherapy appointments were cancelled and week 3 when he had conflicting medical appointments. Per his report, physiotherapy consisted of work on his balance and walking, strengthening exercises for his leg and stretching (arm and leg). Participant 1 reported some mild shoulder discomfort after some of the stretching sessions. Participant 1 had used a SaeboFlex orthosis during his inpatient occupational therapy sessions at Riverview Health Centre and although his own orthosis was ordered, he did not receive it until partway through the first week of the study intervention. He borrowed a SaeboFlex orthosis from Riverview Health Centre to use at home until his own arrived. Participant 1 donned and doffed the SaeboFlex orthosis on his own each time he used it.

PARTICIPANT 2

Participant 2 is married and has worked as a security guard for many years in his home town. He started outpatient physiotherapy the first week of the study intervention and typically attended physiotherapy twice a week for the duration of the study intervention. Per his report, physiotherapy consisted of work on his balance and walking, strengthening exercises for his leg and stretching (arm and leg). Participant 2 frequently reported shoulder discomfort after some of the stretching sessions and also after nights that were reportedly spent sleeping poorly. Participant 2 had used a SaeboFlex orthosis during his inpatient treatment sessions at Riverview

Health Centre and received his own orthosis from the prescribing orthotist prior to the start of the study intervention. Participant 2 reported having a bad chest cold during week 4, which delayed his first visit back to his home community. As mentioned, Participant 2 stayed in a hotel room for the duration of the study intervention. Due to factors beyond his control, he was moved to a different hotel during week 7, spent one night there and then moved to yet another hotel, where he remained for the duration of the study intervention. Participant 2's wife was with him throughout these moves. Participant 2 was ill during weeks 7 and 8, which required medical attention; the final intervention appointment and final outcome measure appointments were rescheduled for several days later. While Participant 2 occasionally donned and doffed the SaeboFlex orthosis on his own, his wife often willingly helped him with this task.

QUANTITATIVE DATA RESULTS

ANALYSIS OF QUANTITATIVE DATA

Celeration line analysis and two-standard deviation band analysis were completed for all of the outcomes measures used in this study (with the exception of the MAS and the COPM); the data analysis is presented below. Visual analysis of the data and change in mean scores between the data phases were also reviewed. Outcome measure data was collected 3 times, approximately two days apart in each phase, i.e., at baseline (Pre-intervention A phase), 4-weeks (Intervention B phase) and 8-weeks (Post-intervention A phase). For the MAS (elbow, wrist and finger flexors), because it is clearly an ordinal scale, median/interquartile range analysis was used to analyze the data instead of two-standard deviation band analysis.[126] For the COPM,

Performance and Satisfaction data was collected once in each phase of the study and is plotted below.

In celeration line analysis, the celeration line was extended from the Pre-intervention A phase to the Intervention B and Post-intervention A phases. If the treatment had no effect, the celeration line would continue to divide the data in half (i.e., equal number of data points above and below the celeration line in the Intervention B and Post-intervention A phases). If the intervention produced a real change in observed behavior, the number of data points above/below the line would not be equal.[88, 127]

In two-standard deviation band analysis, if at least two consecutive data points fall outside the two-standard deviation range in the Intervention B and Post-intervention A phases, a statistically significant change has occurred between the Pre-intervention and Intervention/Post-intervention phases.[92,126,127] The two-standard deviation graphs shown below outline the mean (solid line) and two-standard deviation (dotted lines) for each of the outcome measures.

In median/interquartile range analysis, meaningful change is thought to have occurred if the interquartile bands for each phase of the study do not overlap.[126] The median/interquartile range graphs shown below outline the median (solid line) and 25th and 75th percentile (dotted lines) for the MAS (elbow, wrist and finger flexors).

The number of repetitions completed each week and the number of sessions completed each week are plotted below for each participant.

PARTICIPANT 1

CHEDOKE ARM AND HAND ACTIVITY INVENTORY–7 (CAHAI-7)

The CAHAI-7 was one of the primary outcome measures used in this study and measured the amount of use of the paretic arm and hand in bilateral functional tasks. The score range for the CAHAI-7 is 7-49, where 7=total assist and 49=complete independence. Figures 1 and 2 show the celeration line analysis and two-standard deviation band analysis respectively for the CAHAI-7 for Participant 1.

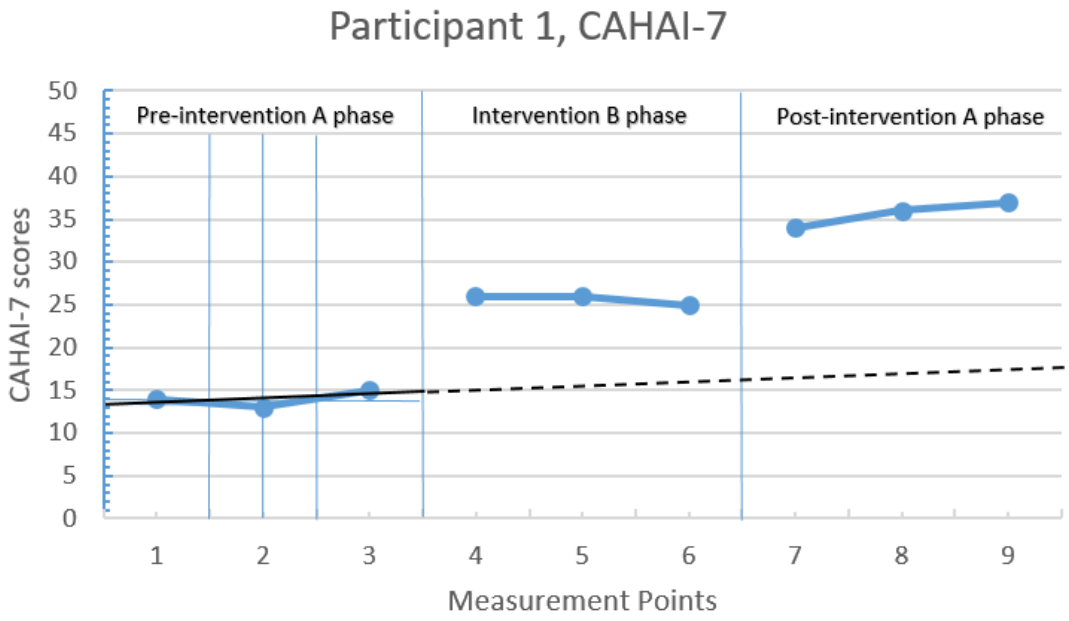

Figure 1: Celeration Line Analysis for Participant 1, CAHAI-7

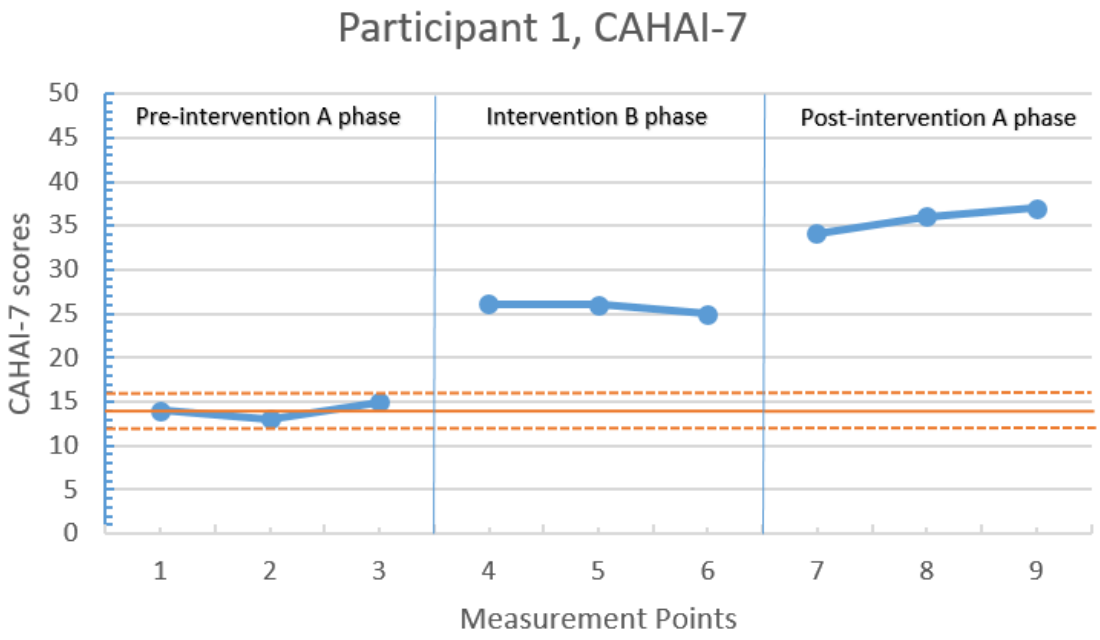

Figure 2: 2SD Band Analysis for Participant 1, CAHAI-7

Visual analysis of the plotted data shows that there is a distinct change in level between all three phases (comparing the last data point of one phase with the first data point of the next phase) and minimal variability of the data within phases. Celeration line analysis shows all 6 data points in the Intervention B and Post-intervention A phases are above the celeration line. Two-standard deviation band analysis shows all 6 data points in the Intervention B and Post-intervention A phases are above the 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are 14.0 (SD=1.0, 2SD=2.0), 25.7 and 35.7 respectively with an increase of 11.7 points between the first two phases and a further increase of 10.0 points between the second and third phase for a total change of 21.7 points between the Pre-intervention A and Post-intervention A phases.

ARM ACTIVITY MEASURE (ARMA), ACTIVE FUNCTION SUBSCALE

The ArmA, active function subscale, was one of the primary outcome measures used in this study and measured participants' self-report of use of the paretic arm in functional tasks. The score range for the ArmA, active function subscale, is 0-52, where 0=no difficulty with the 13 tasks and 52=unable to do the 13 tasks. Figures 3 and 4 show the celeration line analysis and two-standard deviation band analysis respectively for the ArmA, active function subscale for Participant 1.

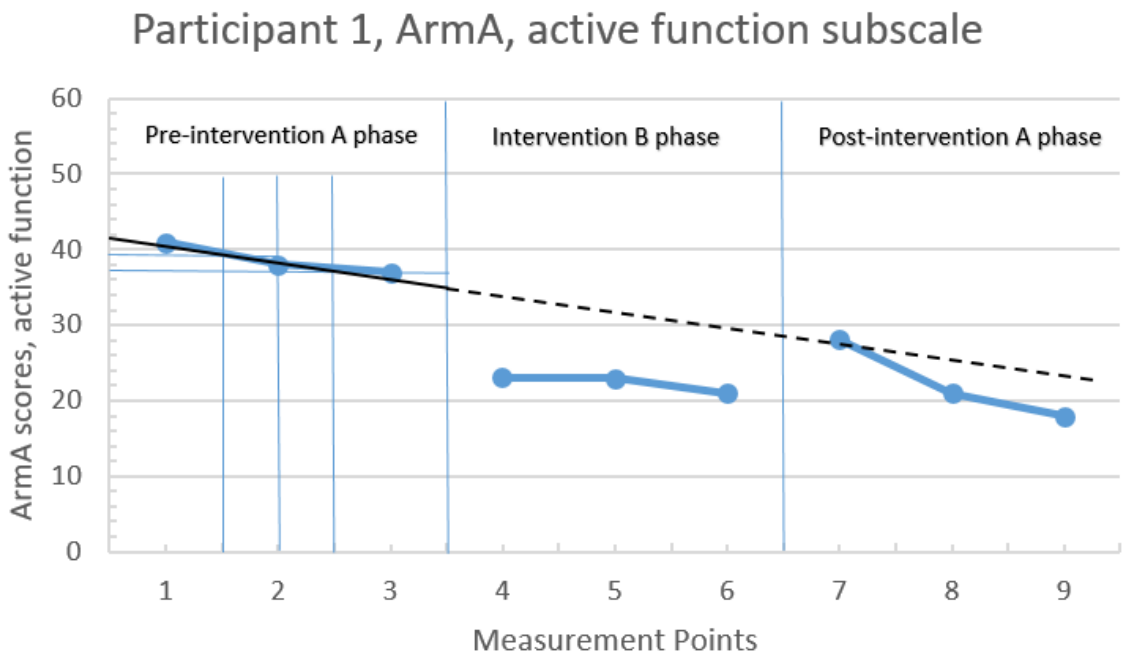

Figure 3: Celeration Line Analysis for Participant 1, ArmA (active function subscale)

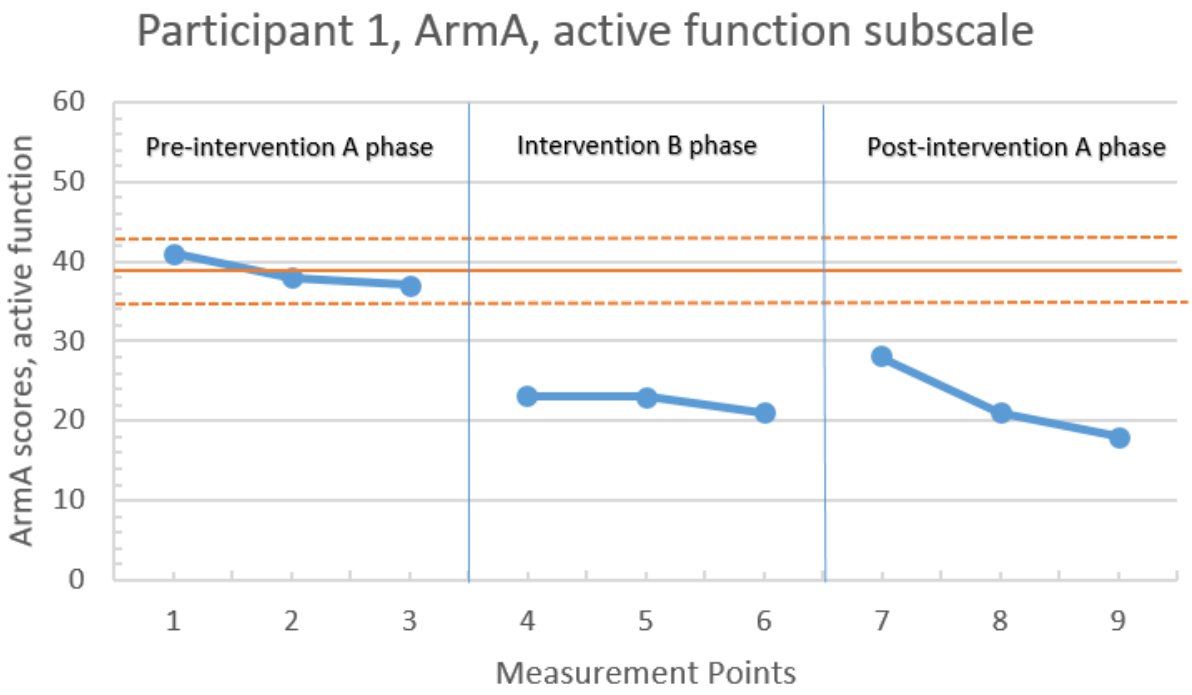

Figure 4: 2SD Band Analysis for Participant 1, ArmA (active function subscale)

Visual analysis of the plotted data shows that there is a change in level between phases, particularly between the Pre-intervention A phase and the Intervention B phase, as well as some variability in the data within phases. The Pre-intervention A phase shows a slight decelerating trend. Celeration line analysis shows that 5 of the 6 data points in the Intervention B and Post-intervention A phases are below the celeration line. Two-standard deviation band analysis shows all 6 data points in the Intervention B and Post-intervention A phases are below the 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are: 38.7 (SD=2.1, 2SD=4.2), 22.3 and 22.3 respectively, with a decrease of 16.4 points between the first and second phases; no additional change in mean scores was noted between the second and third phases.

ARM ACTIVITY MEASURE (ARMA), PASSIVE FUNCTION SUBSCALE

The ArmA, passive function subscale, was one of the primary outcome measures used in this study and measured participants' self-report of caring for the paretic arm and hand during functional tasks. The score range for the ArmA, passive function subscale, is 0-32, where 0=no difficulty with the 8 tasks and 32=unable to do the 8 tasks. Figures 5 and 6 show the celeration line analysis and two-standard deviation band analysis respectively for the ArmA, passive function subscale for Participant 1.

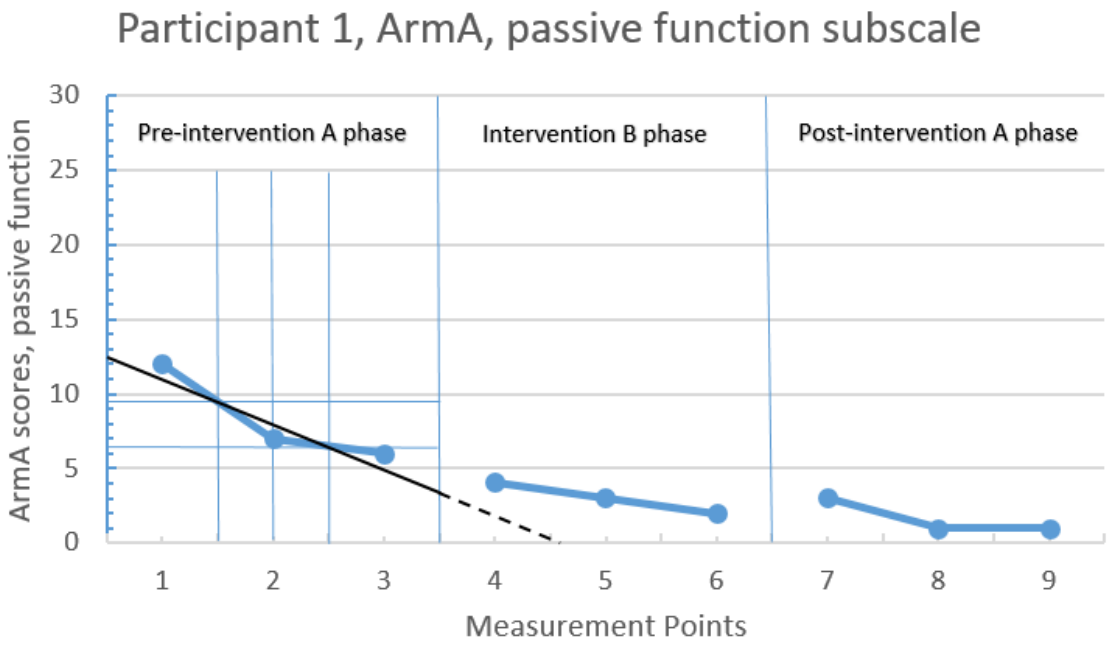

Figure 5: Celeration Line Analysis for Participant 1, ArmA (passive function subscale)

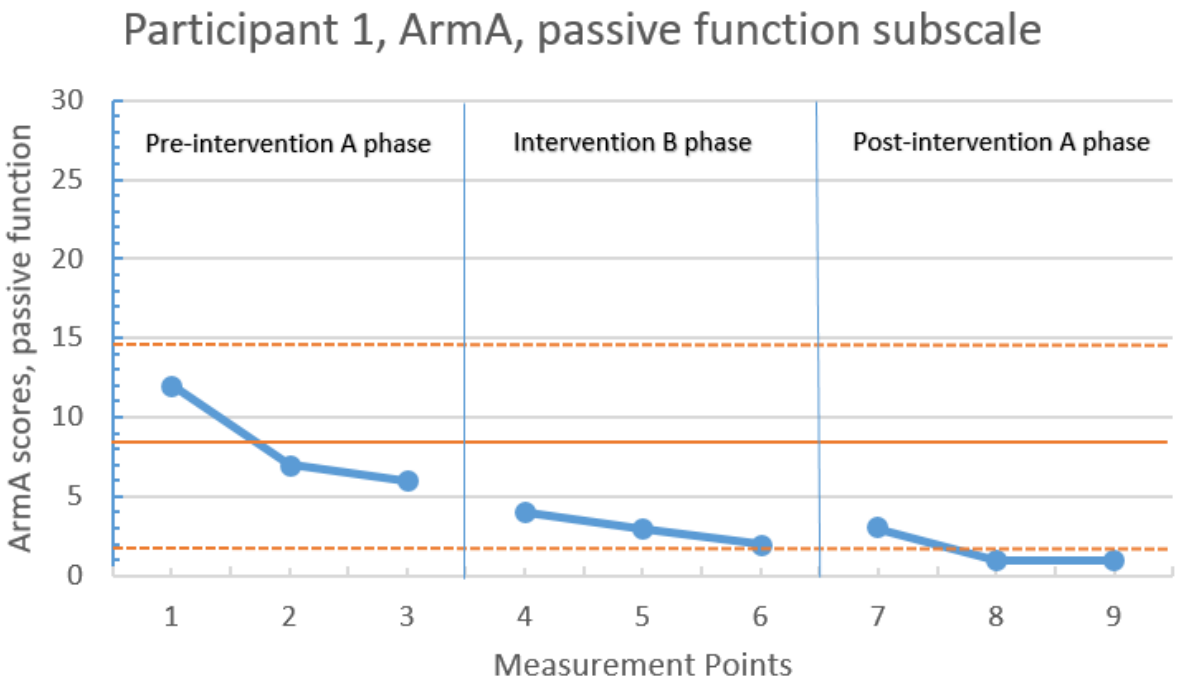

Figure 6: 2SD Band Analysis for Participant 1, ArmA (passive function subscale)

Visual analysis of the plotted data shows that there is minimal change in level between all 3 phases. Variability within phases is noted. The Pre-intervention A phase data is not stable and has an obvious decelerating trend. Celeration line analysis is not plausible with this data. Two-standard deviation band analysis shows 2 consecutive data points below the 2SD line in the Post-intervention A phase. The mean values for the Pre-intervention, Intervention and Post-intervention data are 8.3 (SD=3.2, 2SD=6.4), 3.0 and 1.7 respectively, with a decrease of 5.3 and 1.3 points between subsequent phases, for a total decrease of 6.6 points between the Pre-intervention A and Post-intervention A phases.

STROKE IMPACT SCALE (SIS), STROKE RECOVERY SCALE

The SIS, Stroke Recovery scale was used in this study to measure participants' perception of their post-stroke recovery. The score range for the SIS, Stroke Recovery scale is 0-100, where 0=no recovery and 100=full recovery. Figures 7 and 8 show the celeration line analysis and two-standard deviation band analysis respectively for the SIS, Stroke Recovery scale for Participant 1.

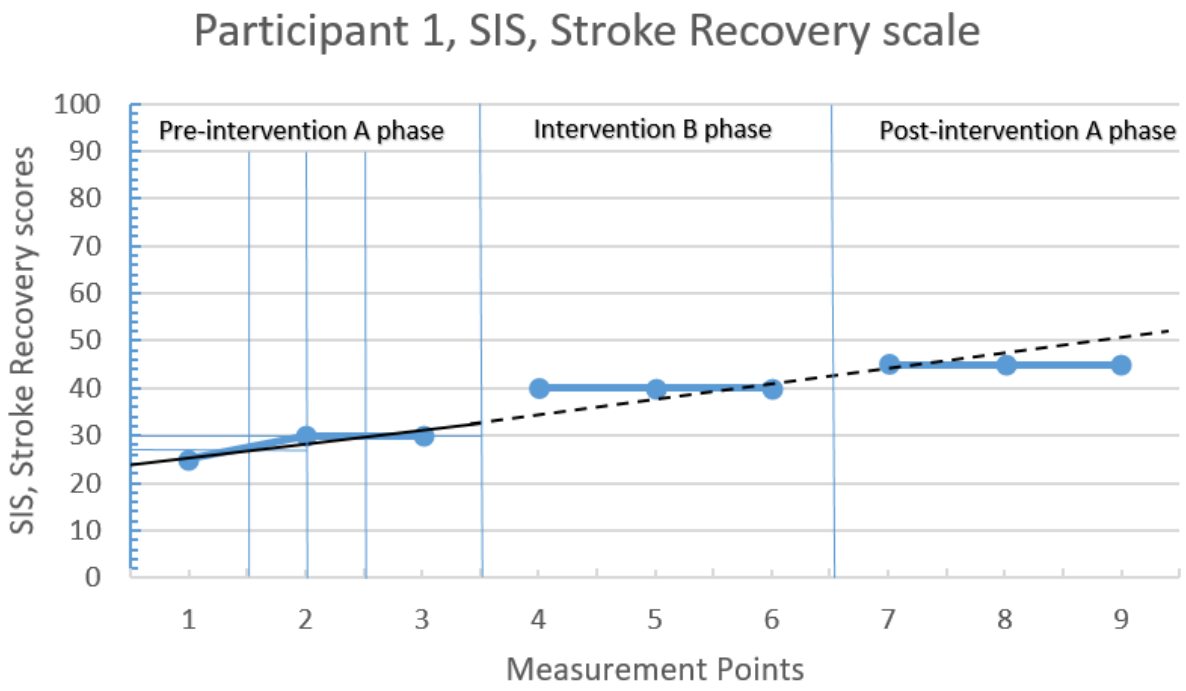

Figure 7: Celeration Line Analysis for Participant 1, SIS (Stroke Recovery scale)

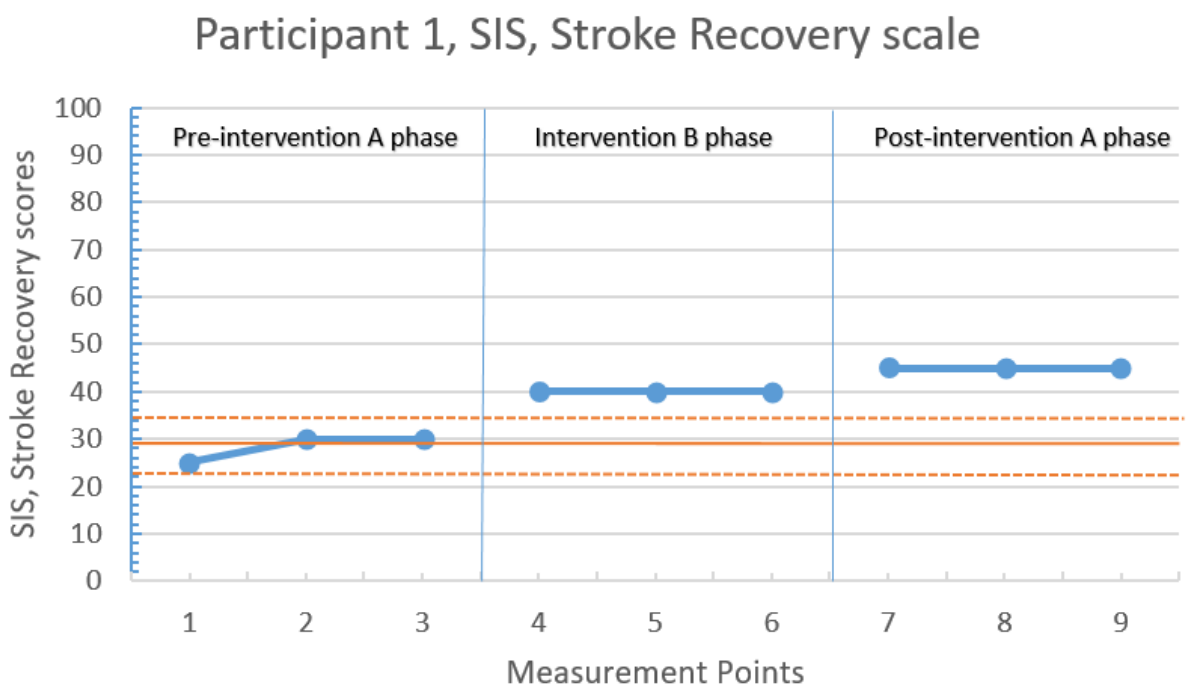

Figure 8: 2SD Band Analysis for Participant 1, SIS (Stroke Recovery scale)

Visual analysis of the plotted data shows that there is minimal change in level between all 3 phases. The Pre-intervention A phase data demonstrates a slight accelerating trend. Celeration line analysis shows that 3 of the data points are above the celeration line and 3 are below the celeration line in the final two phases. Two-standard deviation band analysis shows that all 6 data points in the Intervention B and Post-intervention A phases are above the 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are 28.3 (SD=2.9, 2SD=5.8), 40.0 and 45.0 respectively, with a change of 11.7 and 5.0 points between subsequent phases, for a total increase of 16.7 points between the Pre-intervention A and Post-intervention A phases.

FUGL-MEYER, UPPER EXTREMITY (FMA-UE)

The FMA-UE assessment was used in this study to measure motor impairment of the paretic upper extremity. The score range for the FMA-UE is 0-66, where a higher score means less upper extremity impairment. Figures 9 and 10 show the celeration line analysis and two-standard deviation band analysis respectively for the FMA-UE for Participant 1.

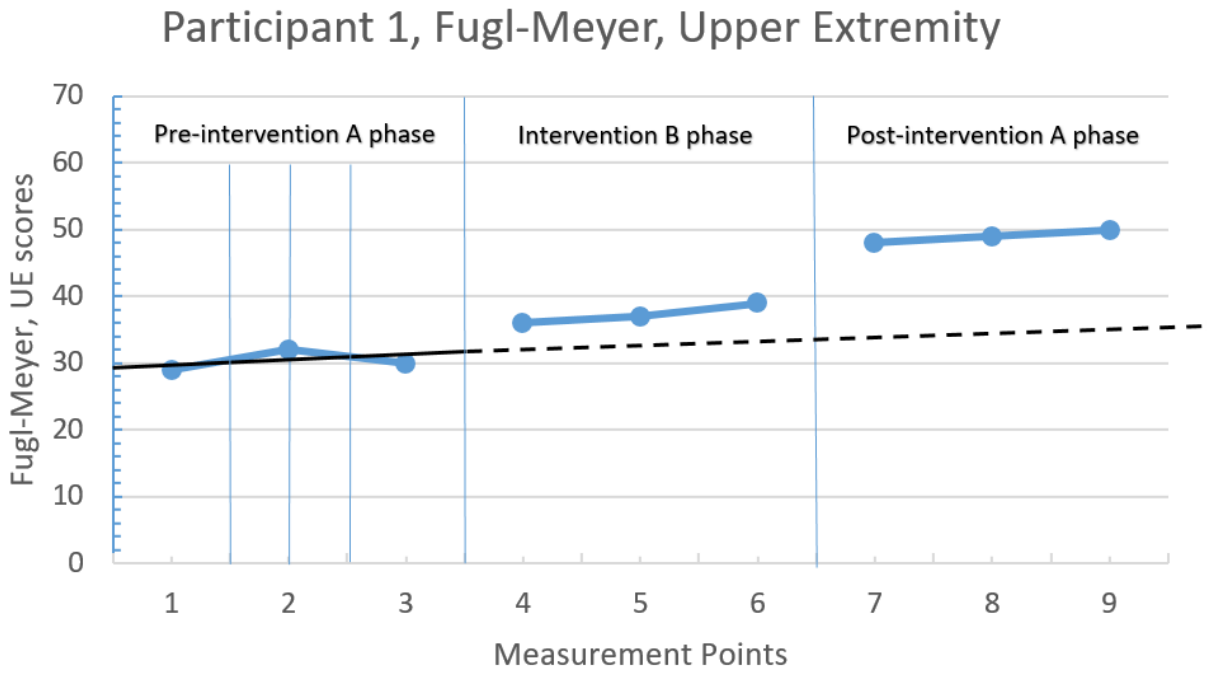

Figure 9: Celeration Line Analysis for Participant 1, FMA-UE

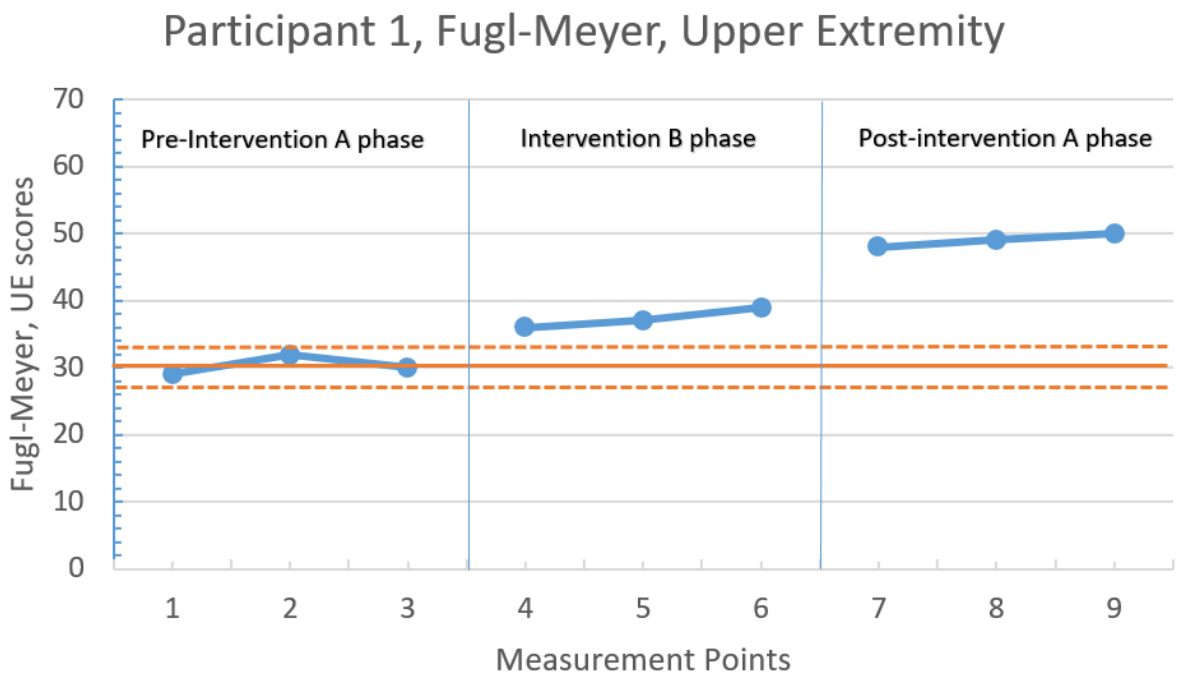

Figure 10: 2SD Band Analysis for Participant 1, FMA-UE

Visual analysis of the plotted data shows that there is some change in level between each of the three phases. Minimal variability is observed in each phase. The Pre-Intervention A phase data is fairly stable. Celeration line analysis shows all 6 data points in the Intervention B and Post-intervention A phases are above the celeration line. Two-standard deviation band analysis shows all 6 data points in the Intervention B and Post-intervention A phases are above the 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are 30.3 (SD=1.5, 2SD=3.0), 37.3 and 49.0 respectively, with an increase of 7.0 points between the first two phases and a further increase of 11.7 points between the second and third phases for a total change of 18.7 points between the Pre-intervention A and Post-intervention A phases.

GRIP STRENGTH

Grip strength measurement was used in this study to measure strength of the participants' paretic hand. Grip strength was measured three times at each assessment, therefore each data point represents an average of three grip strength measurements, in kilograms. Figures 11 and 12 show the celeration line analysis and two-standard deviation band analysis respectively for the grip strength measurements for Participant 1.

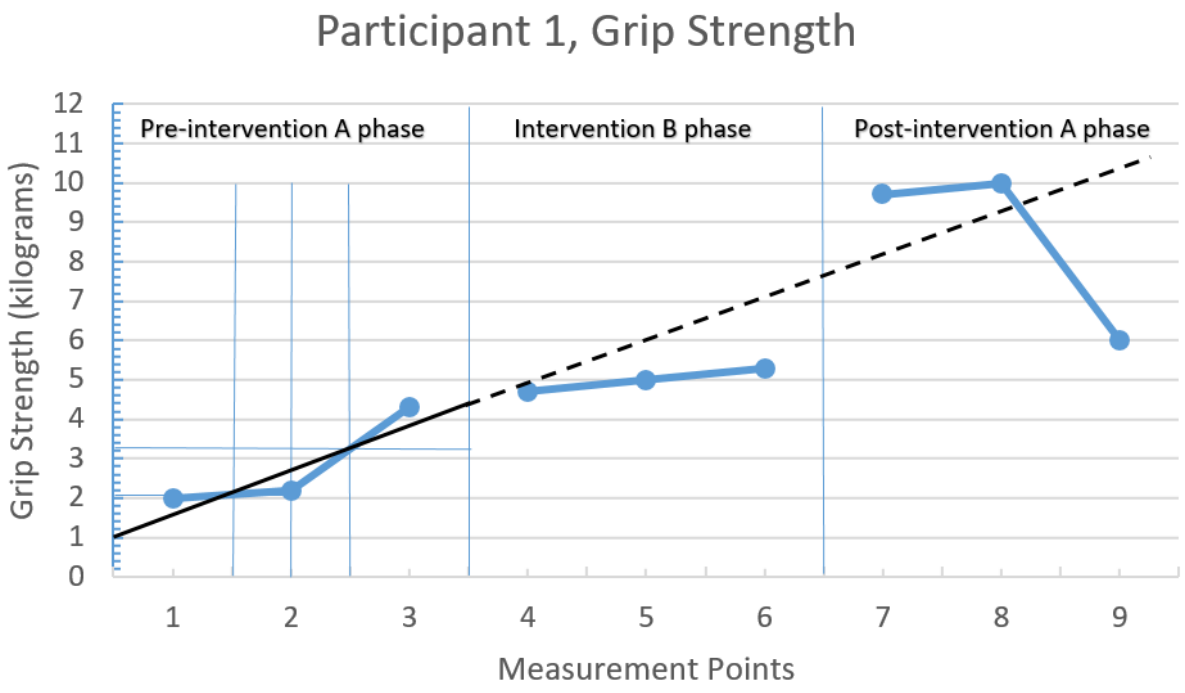

Figure 11: Celeration Line Analysis for Participant 1, Grip Strength

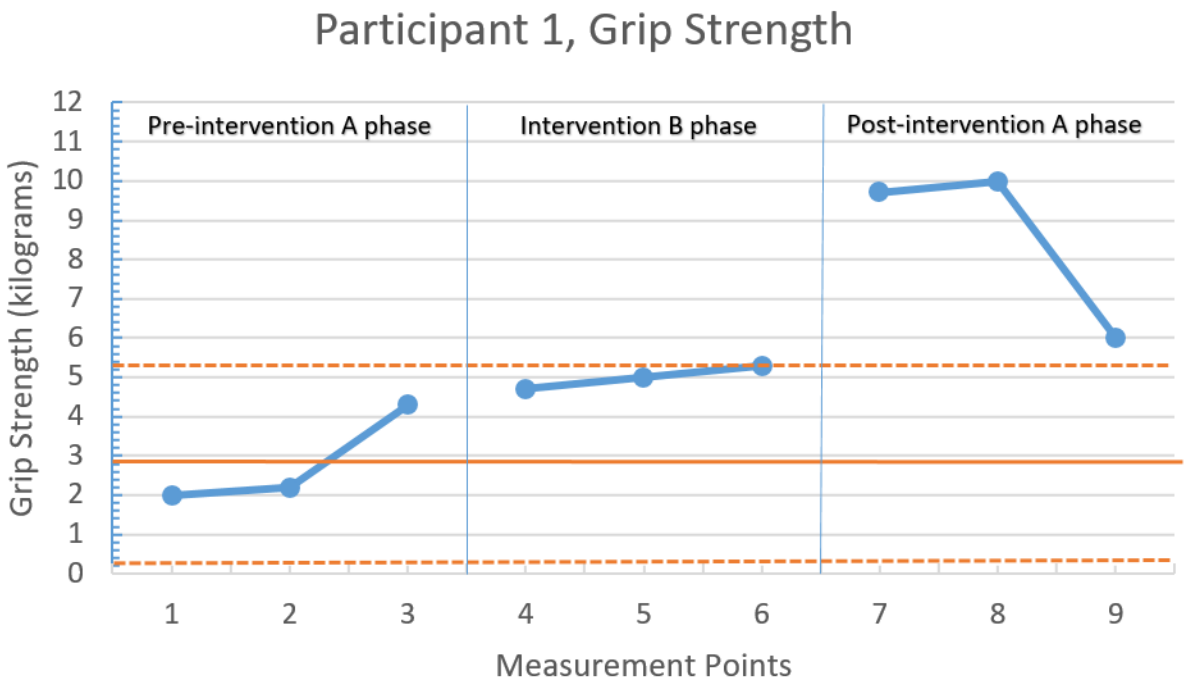

Figure 12: 2SD Band Analysis for Participant 1, Grip Strength

Visual analysis of the plotted data shows that there is a marked change in level between the Intervention B and Post-intervention A phases, with minimal change in level between the Pre-intervention A and Intervention B phases. There is variability in both the Pre-intervention A and Post-intervention A phases, with the Pre-intervention A phase demonstrating an accelerating trend. Celeration line analysis shows 2 data points above the celeration line and 4 below the celeration line. Two-standard deviation band analysis shows 3 consecutive data points in the Post-intervention A phase above the 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are 2.8 (SD=1.3, 2SD=2.6), 5.0 and 8.6 kilograms respectively, with a change of 2.2 kilograms and 3.6 kilograms between subsequent phases, for a total increase of 5.8 kilograms between the Pre-intervention A and Post-intervention A phases.

MODIFIED ASHWORTH SCALE (MAS), ELBOW FLEXORS

The MAS was used in this study to measure the resistance to passive movement of three upper extremity muscle groups, the elbow flexors, wrist flexors and finger flexors. The score range for the MAS is 0-4, where 0=no increase in muscle tone and 4=affected part is in rigid flexion. However, since the scale is a 6-point ordinal scale (0,1,1+,2,3,4), for the purpose of plotting the data points and analyzing the results, the scale was adjusted to 0-5, where 1+=2, 2=3, 3=4, 4=5. Figures 13 and 14 show the celeration line analysis and median/interquartile range analysis respectively for the adjusted scoring of the MAS, elbow flexors for Participant 1.

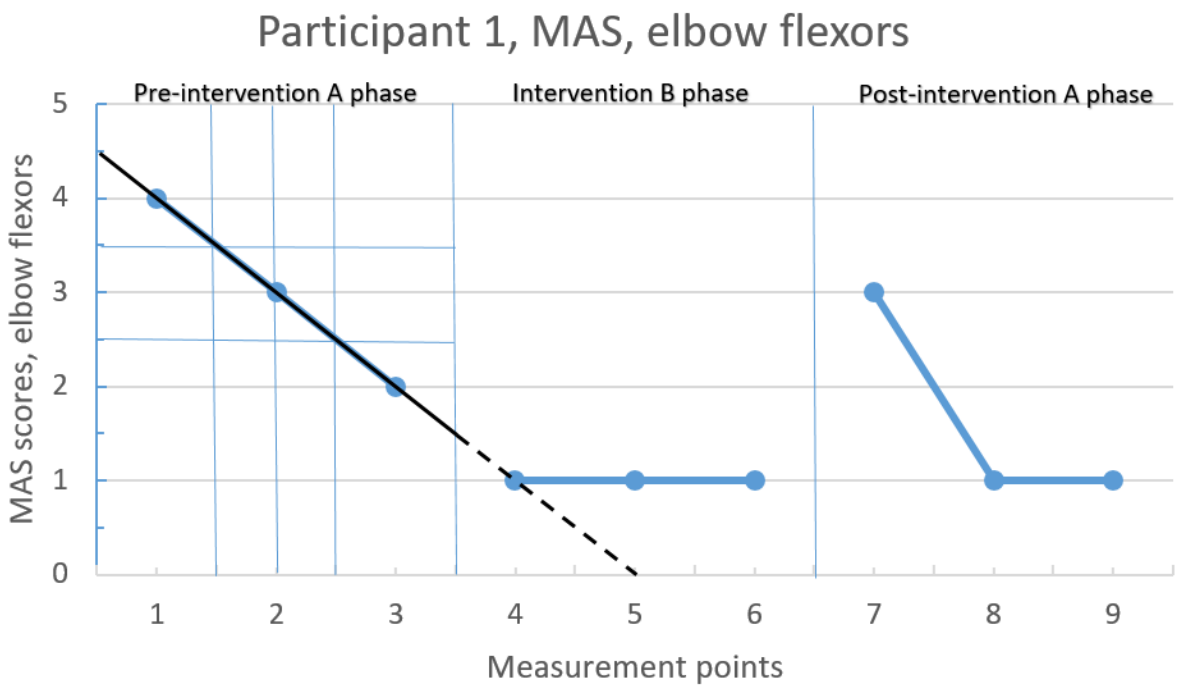

Figure 13: Celeration Line Analysis for Participant 1, MAS (elbow flexors)

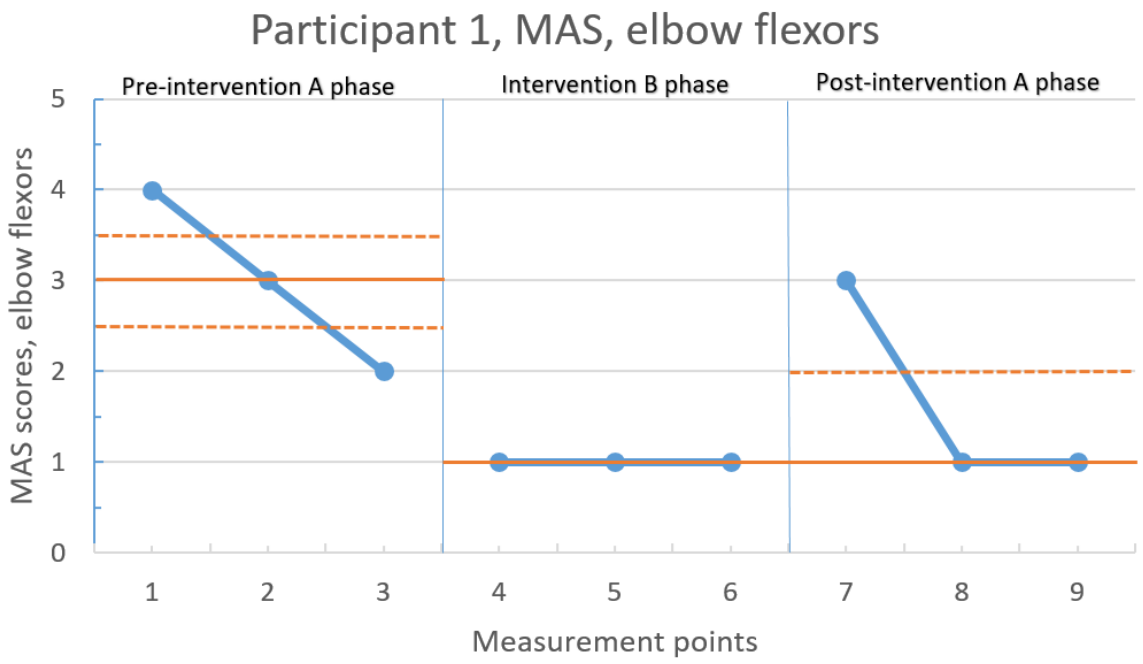

Figure 14: Median/Interquartile Range Analysis for Participant 1, MAS (elbow flexors)

Visual analysis of the plotted data shows that there is some change in level between phases, especially between the second and third phases. The Pre-intervention A phase data is not stable and has an obvious decelerating trend. Celeration line analysis is not plausible with this data. Median/interquartile range analysis shows that there is no overlap between the interquartile bands of the Pre-intervention A phase and the Post-intervention A phase. The median values for the Pre-intervention, Intervention and Post-intervention data are 3.0, 1.0 and 1.0 respectively, for a total median decrease of 2.0 points between the Pre-intervention A and Post-intervention A phases.

MODIFIED ASHWORTH SCALE (MAS), WRIST FLEXORS

The MAS was used in this study to measure the resistance to passive movement of three upper extremity muscle groups, the elbow flexors, wrist flexors and finger flexors. The score range for the MAS is 0-4, where 0=no increase in muscle tone and 4=affected part is in rigid flexion. However, since the scale is a 6-point ordinal scale (0,1,1+,2,3,4), for the purpose of plotting the data points and analyzing the results, the scale was adjusted to 0-5, where 1+=2, 2=3, 3=4, 4=5. Figures 15 and 16 show the celeration line analysis and median/interquartile range analysis respectively for the adjusted scoring of the MAS, wrist flexors for Participant 1.

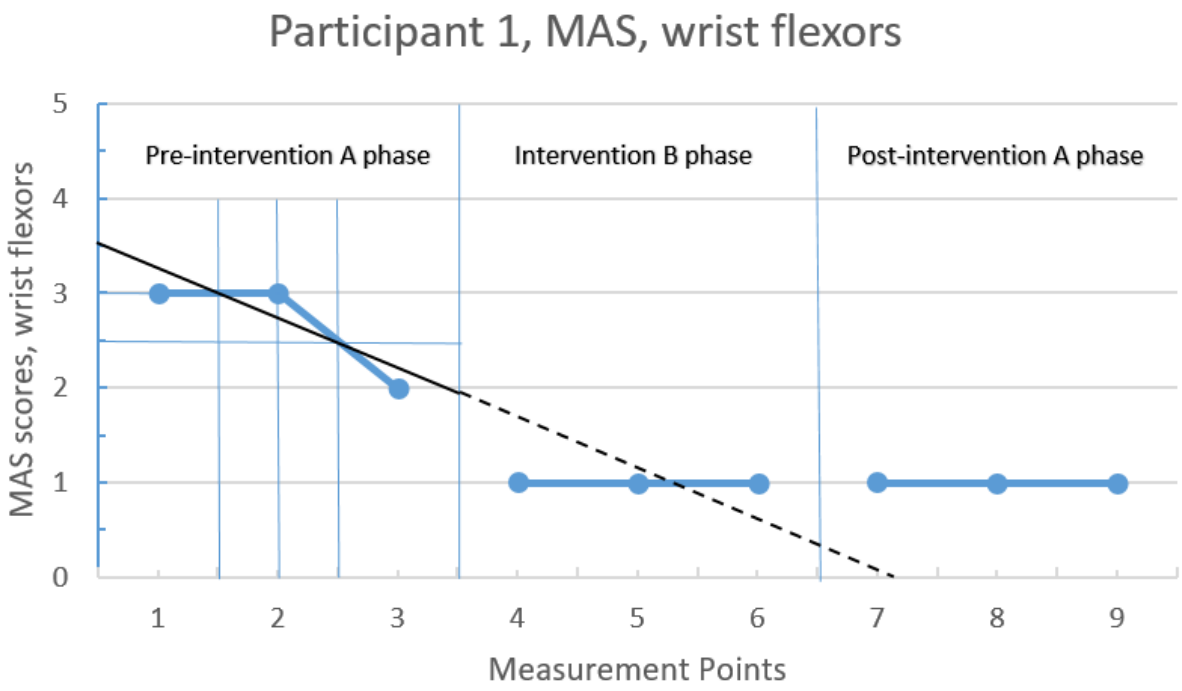

Figure 15: Celeration Line Analysis for Participant 1, MAS (wrist flexors)

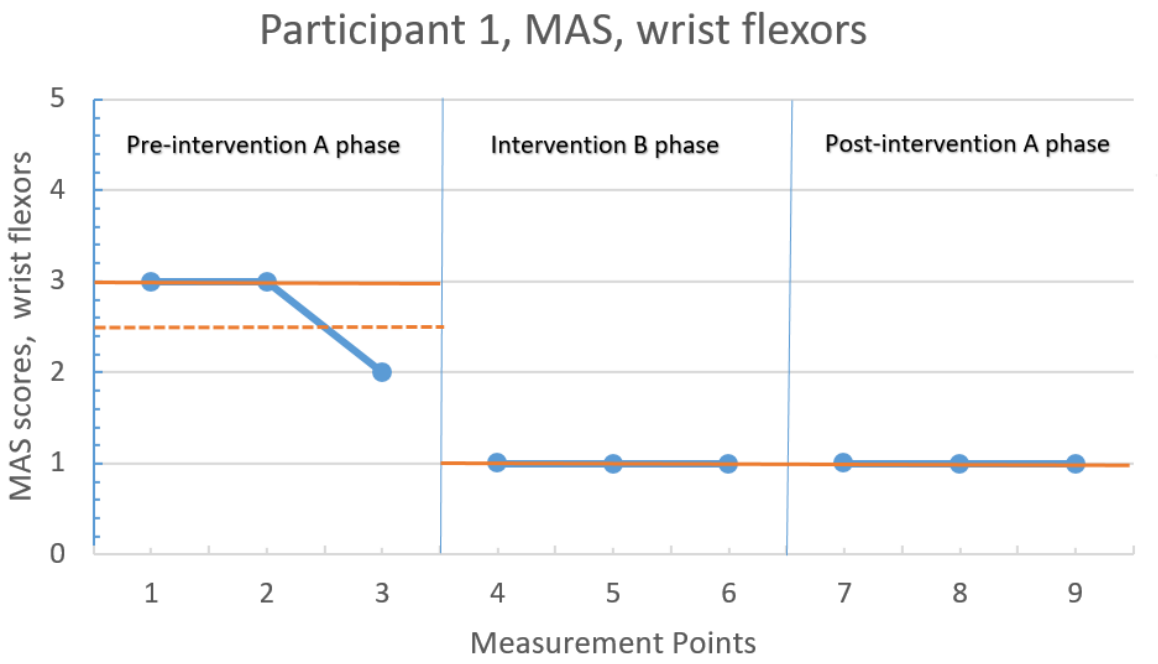

Figure 16: Median/Interquartile Range Analysis for Participant 1, MAS (wrist flexors)

Visual analysis of the plotted data shows that there is a marked change in level between the Pre-intervention A and Intervention B phases and no change in level between the Intervention B and Post-intervention A phases. The data in the final two phases is stable while the data in the first phase has a decelerating trend. Celeration line analysis is not plausible with this data. Median/interquartile range analysis shows that there is no overlap between the interquartile bands of the Pre-intervention A phase and the Post-intervention A phase; there are no interquartile bands for the Intervention B phase and the Post-intervention A phase as the data is stable. The median values for the Pre-intervention, Intervention and Post-intervention data are 3.0, 1.0 and 1.0 respectively, for a median decrease of 2.0 points between the first and second phases only.

MODIFIED ASHWORTH SCALE (MAS), FINGER FLEXORS

The MAS was used in this study to measure the resistance to passive movement of three upper extremity muscle groups, the elbow flexors, wrist flexors and finger flexors. The score range for the MAS is 0-4, where 0=no increase in muscle tone and 4=affected part is in rigid flexion. However, since the scale is a 6-point ordinal scale (0,1,1+,2,3,4), for the purpose of plotting the data points and analyzing the results, the scale was adjusted to 0-5, where 1+=2, 2=3, 3=4, 4=5. Figures 17 and 18 show the celeration line analysis and median/interquartile range analysis respectively for the adjusted scoring of the MAS, finger flexors for Participant 1.

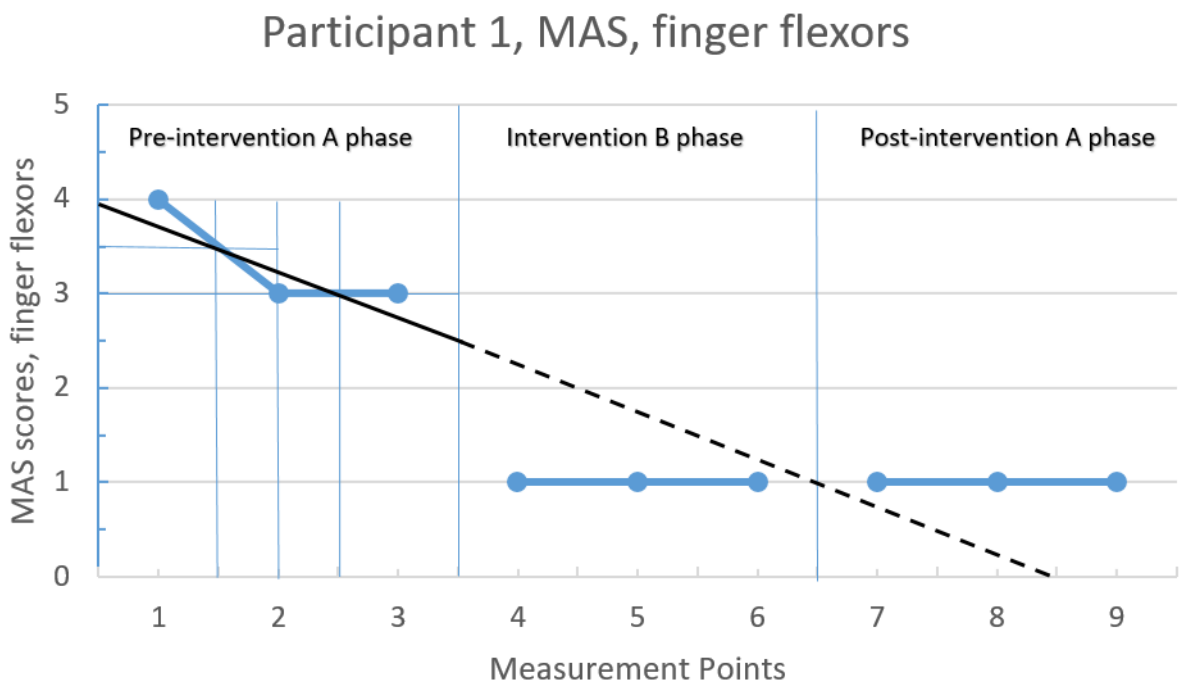

Figure 17: Celeration Line Analysis for Participant 1, MAS (finger flexors)

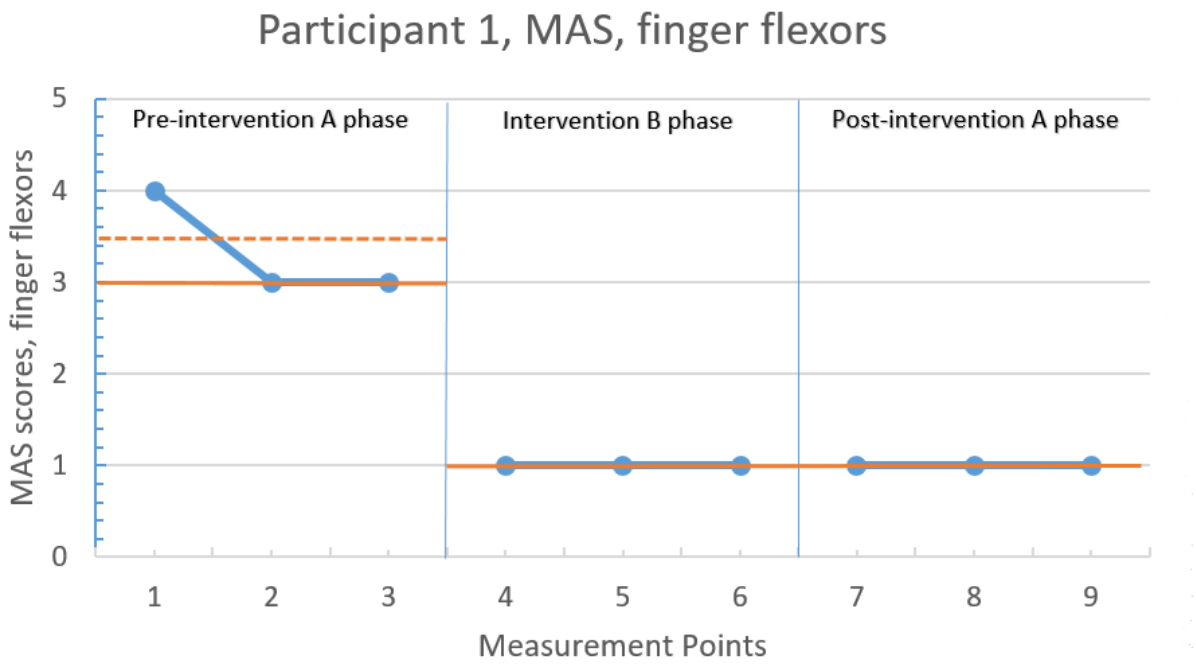

Figure 18: Median/Interquartile Range Analysis for Participant 1, MAS (finger flexors)

Visual analysis of the plotted data shows that there is a marked change in level between the Pre-intervention A and Intervention B phases and no change in level between the Intervention B and Post-intervention A phases. The data in the final two phases is stable while the data in the first phase has a decelerating trend. Celeration line analysis is not plausible with this data. Median/interquartile range analysis shows that there is no overlap between the interquartile bands of the Pre-intervention A phase and the Post-intervention A phase; there are no interquartile bands for the Intervention B phase and the Post-intervention A phase as the data is stable. The median values for the Pre-intervention, Intervention and Post-intervention data are 3.0, 1.0 and 1.0 respectively, with a median decrease of 2.0 points between the first and second phases only.

STROKE SELF-EFFICACY QUESTIONNAIRE (SSEQ), ACTIVITY SCALE

The SSEQ, Activity scale was used in this study to measure participants' self-reported confidence in completing functional tasks. The score range for the SSEQ, Activity scale is 0-24, where 0=not at all confident with performance on 8 functional tasks and 24=very confident with performance on 8 functional tasks. Figures 19 and 20 show the celeration line analysis and two-standard deviation band analysis respectively for the SSEQ, Activity scale for Participant 1.

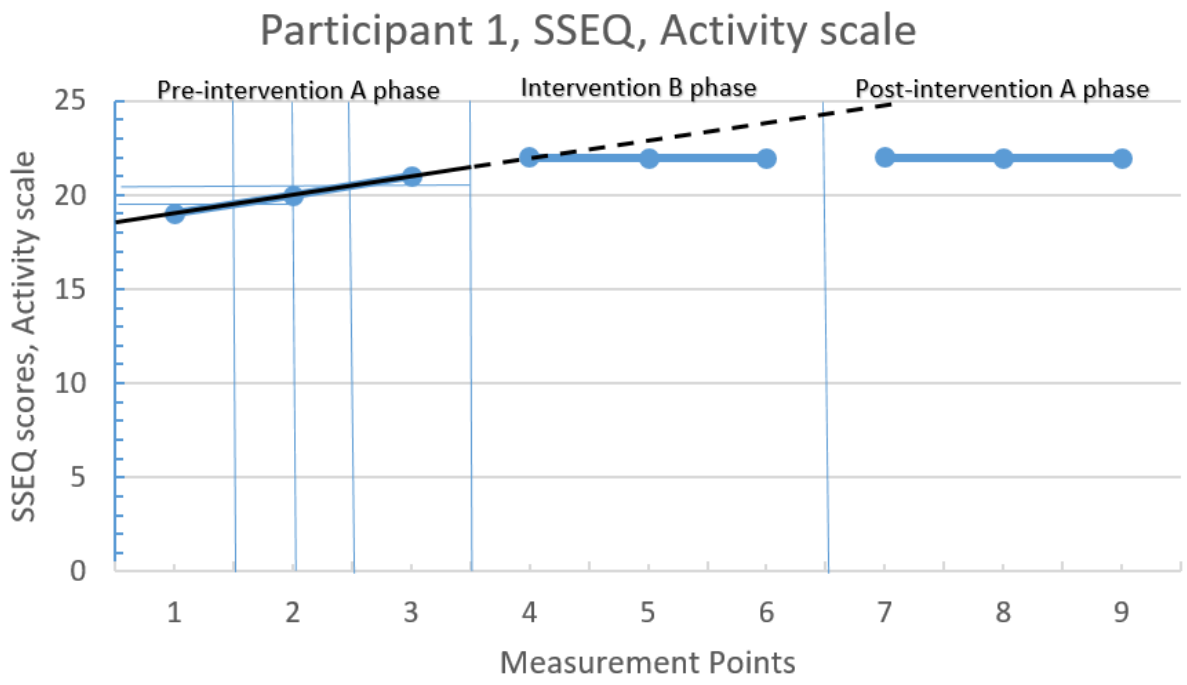

Figure 19: Celeration Line Analysis for Participant 1, SSEQ (Activity scale)

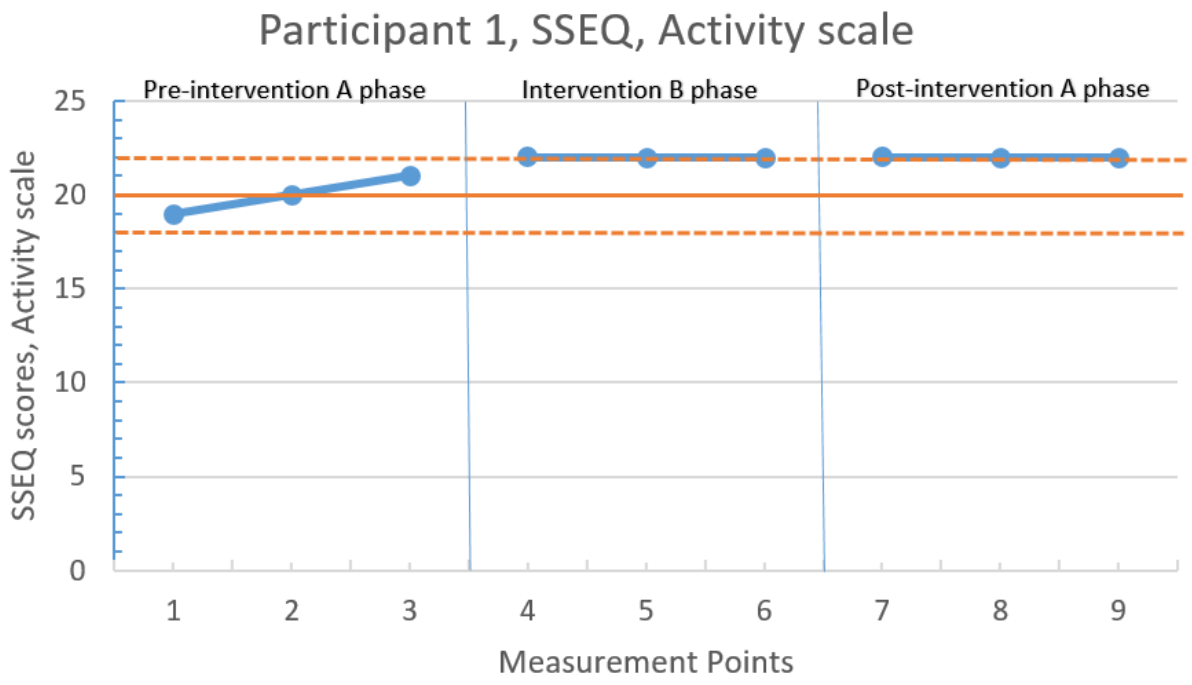

Figure 20: 2SD Band Analysis for Participant 1, SSEQ (Activity scale)

Visual analysis of the plotted data shows that there is a slight change in level between the Pre-intervention A and Intervention B phases and no change in level between the Intervention B and Post-intervention A phases. Most of the data appears at the top of the graph. The data in the final two phases is stable while the data in the first phase is accelerating. Celeration line analysis is not plausible with this data. Two-standard deviation band analysis shows that the six data points in the Intervention B and Post-intervention A phases are on the upper 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are 20.0 (SD=1.0, 2SD=2.0), 22.0 and 22.0 respectively, with a change of 2.0 points between the first and second phases only.

STROKE SELF-EFFICACY QUESTIONNAIRE (SSEQ), SELF-MANAGEMENT SCALE

The SSEQ, Self-management scale was used in this study to measure participants' self-reported confidence in completing self-management activities. The score range for the SSEQ, Self-management scale is 0-15, where 0=not at all confident with performance on 5 self-management tasks and 15=very confident with performance on 5 self-management tasks. Figures 21 and 22 show the celeration line analysis and two-standard deviation band analysis respectively for the SSEQ, Self-management scale for Participant 1.

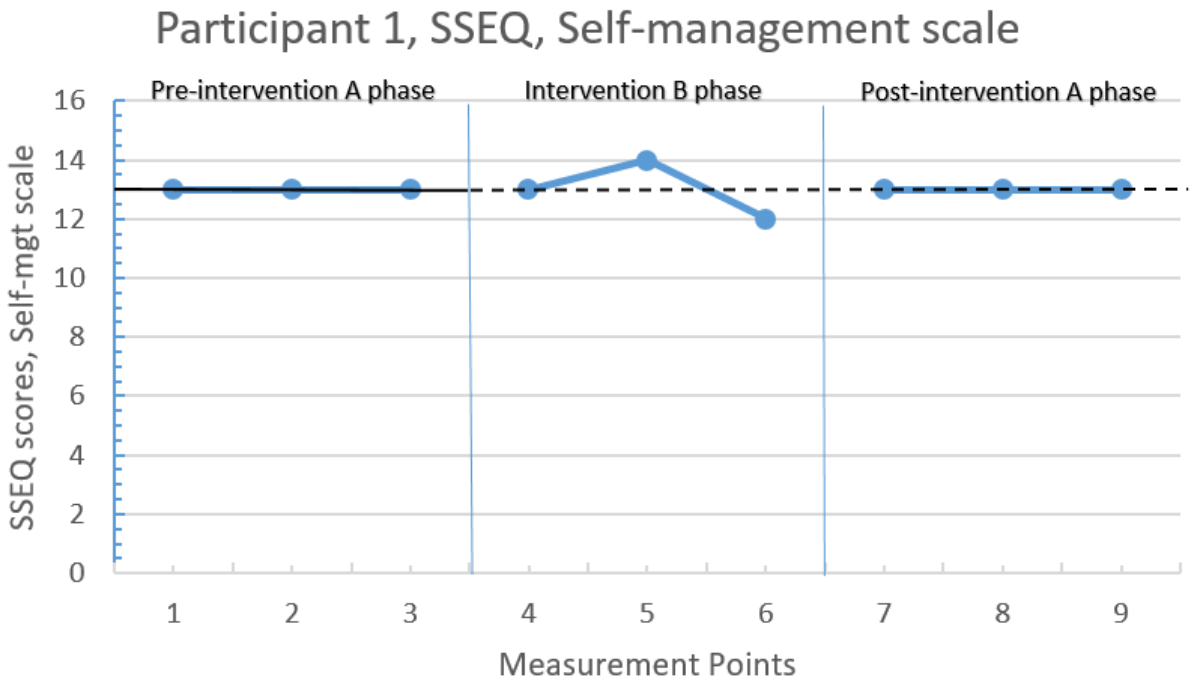

Figure 21: Celeration Line Analysis for Participant 1, SSEQ (Self-management scale)

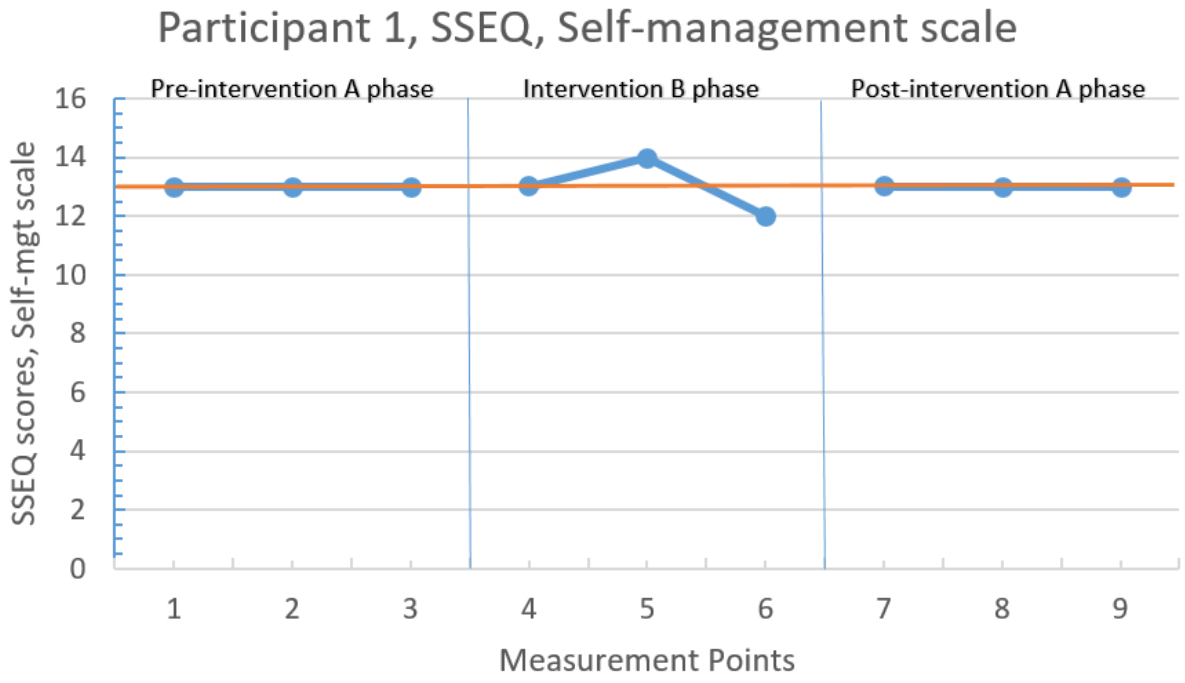

Figure 22: 2SD Band Analysis for Participant 1, SSEQ (Self-management scale)

Visual analysis of the plotted data shows that the data is very stable with little variation within or between phases. Because the three data points in the Pre-intervention A phase are all the same, celeration line analysis produces a horizontal line through the remaining six data points and the standard deviation is zero. The mean values for the Pre-intervention, Intervention and Post-intervention data are 13.0 (SD=0), 13.0 and 13.0 respectively, with no change in means throughout the three phases.

CANADIAN OCCUPATIONAL PERFORMANCE MEASURE (COPM)

The COPM was used in this study to determine participants' occupational performance issues (OPI's) related to upper extremity function, as well as their self-perceived performance and satisfaction with these OPI's. The COPM was administered once in the Pre-intervention A phase, the Intervention B phase and the Post-intervention A phase. Performance and Satisfaction scores were determined based on the top five upper extremity OPI's identified by the participant in the Pre-intervention A phase. The OPI's identified by Participant 1 at the Pre-intervention A phase assessment were:

1. Wash entire left arm with right arm
2. Use computer keyboard with right hand
3. Hold vegetables with right hand (while cuts vegetables with left hand)
4. Hold fork in right hand to stabilize meat (while cuts meat with left hand)
5. Hold handle of pot steady on stove with right hand when cooking

The score range for the COPM is 1-10 for each OPI, where 1=not able to do the task/not satisfied with ability to do the task and 10=able to do the task extremely well/extremely satisfied with performance of the task. The five Performance and five Satisfaction scores were summed separately and then divided by the number of OPI's (five) to determine the mean score for each. Figures 23 and 24 show the Performance and Satisfaction COPM scores for Participant 1.

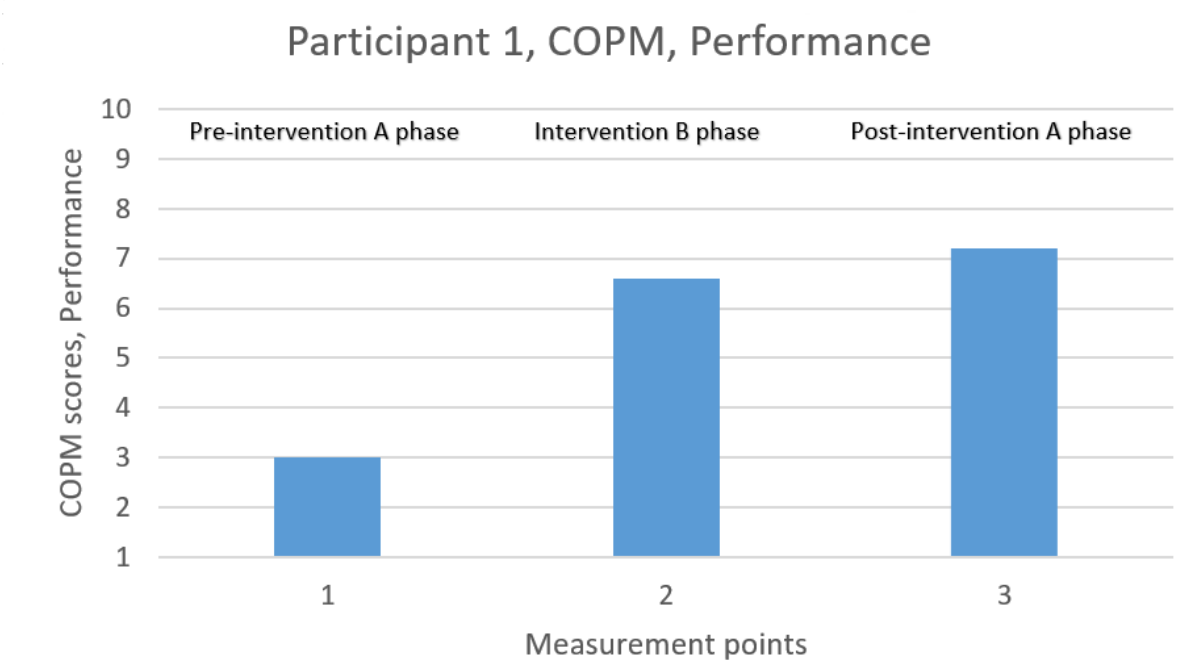

Figure 23: Analysis of COPM scores (Performance) for Participant 1

The COPM scores for *Performance* were 3.0, 6.6 and 7.2 with an increase between subsequent phases of 3.6 and 0.6 points respectively and a total increase of 4.2 points between the Pre-intervention A phase and the Post-intervention A phase.

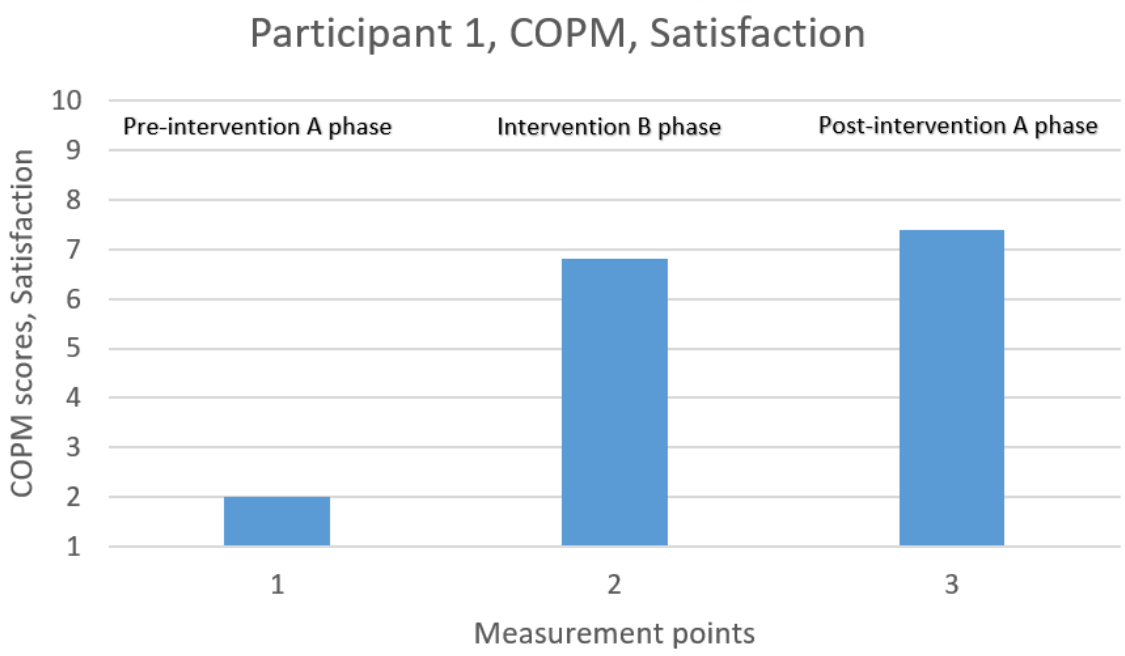

Figure 24: Analysis of COPM scores (Satisfaction) for Participant 1

The COPM scores for *Satisfaction* were 2.0, 6.8 and 7.4 with an increase between subsequent phases of 4.8 and 0.6 points respectively and a total increase of 5.4 points between the Pre-intervention A phase and the Post-intervention A phase.

USE OF SAEBOFLEX ORTHOSIS AT HOME

Participant 1 recorded (in his logbook) the *number of repetitions* of each task completed with the SaeboFlex orthosis each session. This included SaeboFlex use during visits from the principal investigator as well as repetitions completed on his own time. The total number of repetitions completed each week was calculated and plotted. The *number of SaeboFlex sessions* completed each week by Participant 1 was determined by examining the participant's logbook. This included sessions completed with the principal investigator (if the session met the amount of

use criteria for the study) and sessions completed on his own time. The total number of sessions completed each week was calculated and plotted. Figure 25 shows the Repetitions of SaeboFlex use over the 8 weeks of the study. Figure 26 shows the number of sessions the SaeboFlex was used during the 8 weeks of the study.

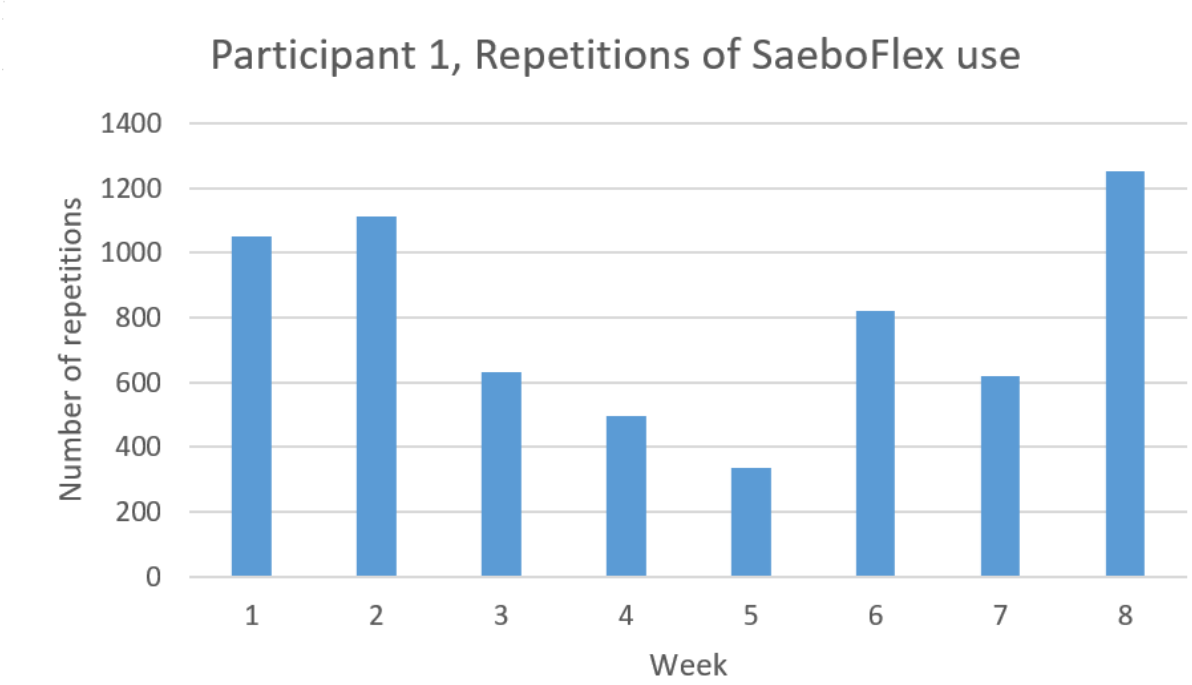

Figure 25: Repetitions of SaeboFlex use for Participant 1

Participant 1 completed 6320 repetitions (recorded) with the SaeboFlex orthosis during the 8 weeks of the study. He completed the most repetitions (1251) in week 8 and the fewest repetitions (337) in week 5.

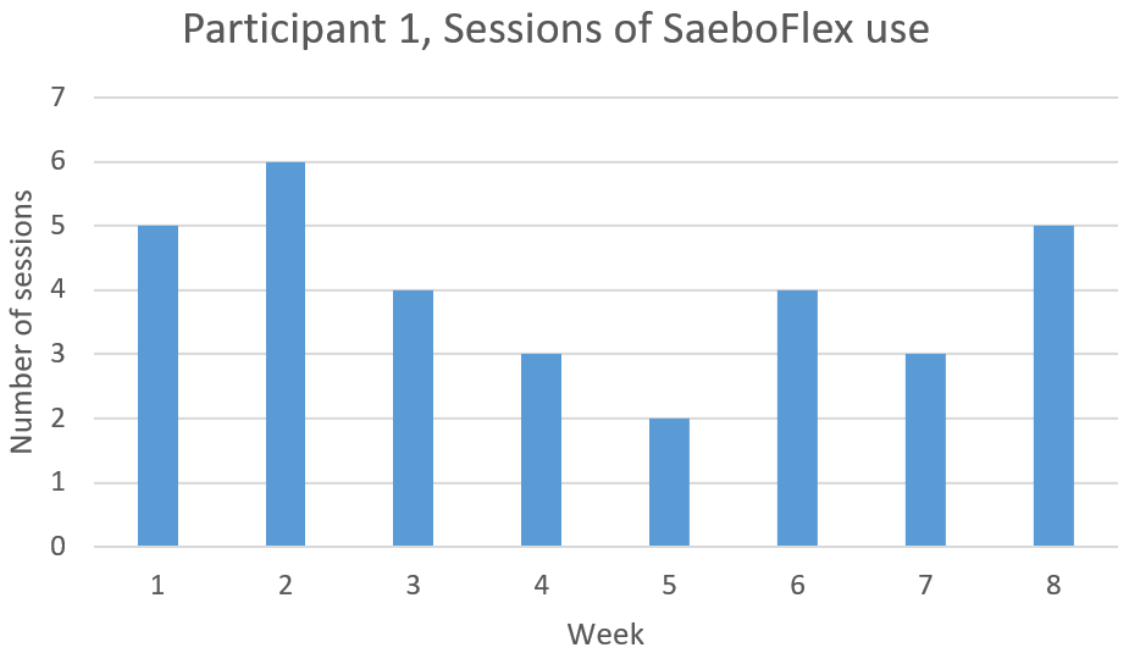

Figure 26: Sessions of SaeboFlex use for Participant 1

Participant 1 completed 32 sessions (recorded) with the SaeboFlex orthosis during the 8 weeks of the study. He completed the most sessions in week 2 (6 sessions) and the fewest sessions in week 5 (2 sessions).

OTHER TASKS COMPLETED AT HOME

Participant 1 attempted to use his paretic hand for continued practice of grasp and release tasks for 10 minutes after the SaeboFlex orthosis was removed each session, as well as for tasks or portions of tasks identified through baseline assessment with the COPM. Grasp-release tasks were attempted first in sitting, with a smaller therapy ball (on his lap), and progressed to standing after a few sessions. In addition to the practice of tasks identified in the COPM, Participant 1 also attempted to use his right arm/hand for other daily tasks such as flushing the

toilet, holding a container of fish food while feeding the fish with his left hand, attempting to eat small snacks and opening the fridge. Cylindrical foam was provided to increase the handle size of his cutlery and pot handles to facilitate practice of the OPI's identified on the COPM.

SUMMARY OF QUANTITATIVE DATA

As described above, celeration line analysis and two-standard deviation band analysis were completed for most of the outcomes measures used in this study. Median/interquartile range analysis was used for the MAS, as it is an ordinal scale. Visual analysis was also completed. Several of the data sets had variable data in the Pre-intervention A phase. Some data sets demonstrated greater variability than others in this first phase. The outcome measures that had variable data in the Pre-intervention A phase were the: ArmA (active and passive function subscales), the SIS (Stroke Recovery subscale), Grip Strength, the MAS (elbow, wrist and finger flexors) and the SSEQ (activity subscale). Two standard deviation band analysis can be used with variable or fluctuating baseline data[127] and may provide a more accurate analysis of the data than celeration line analysis, when baseline data is variable. Comparison of change in mean scores between phases to established MCID/MDC/MIC values was also done.

During two-standard deviation band analysis, at least two consecutive data points fell outside the two-standard deviation range in several of the outcome measures: CAHAI-7, FMA-UE, ArmA (active and passive function subscales), SIS (Stroke Recovery subscale), and grip strength indicating that a statistically significant change had occurred between the Pre-intervention and Intervention/Post-intervention phases.[92,126-128]

Celeration line analysis of the two data sets with stable Pre-intervention phase data (CAHAI-7 and FMA-UE) indicated that a real change in observed behaviour occurred as all the data points were above the celeration line.[88,127] Celeration line analysis wasn't plausible with the following data sets due to variability in the baseline data: ArmA (passive function subscale), MAS (elbow, wrist and finger flexors), SSEQ (activity scale).

Median/interquartile range analysis indicated that a meaningful change had occurred when evaluating the MAS data for the elbow, wrist and finger flexors, as the interquartile bands between phases did not overlap.[126]

Comparison of change in mean/median scores between phases is illustrated below in **Table 2**. Established MCID/MDC/MIC values are also shown, as in **Appendix K.**

Table 2: Change in Mean/Median Scores, Participant 1

Outcome Measure	**Change in mean scores between Pre-intervention A and Intervention B phases**	**Change in mean scores between Intervention B and Post-intervention A phases**	**Total change in mean scores between Pre-intervention A and Post-intervention A phases**	**MCID/MDC/MIC**
CAHAI-7	11.7	10.0	21.7	MDC=6.3 points for 13 point scale[99]
ArmA, active function subscale	-16.4	0	-16.4	MIC=1.1[97]

Outcome Measure	**Change in mean scores between Pre-intervention A and Intervention B phases**	**Change in mean scores between Intervention B and Post-intervention A phases**	**Total change in mean scores between Pre-intervention A and Post-intervention A phases**	**MCID/MDC/MIC**
ArmA, passive function subscale	-5.3	-1.3	-6.6	MIC=2.5[97]
SIS, Stroke Recovery scale	11.7	5.0	16.7	Change of 10-15 points is clinically meaningful[102]
FMA-UE	7.0	11.7	18.7	MCID=9.0[18] MDC=5.2[107]
Grip strength	2.2 kg	3.6 kg	5.8 kg	MCID=6.2 kg for paretic non-dominant hand[117]
SSEQ, Activity subscale	2	0	2	Not established
SSEQ, Self-management subscale	0	0	0	
COPM, Performance	3.6	0.6	4.2	2-point increase is considered

Outcome Measure	Change in mean scores between Pre-intervention A and Intervention B phases	Change in mean scores between Intervention B and Post-intervention A phases	Total change in mean scores between Pre-intervention A and Post-intervention A phases	MCID/MDC/MIC
COPM, Satisfaction	4.8	0.6	5.4	clinically significant[118]
Outcome Measure	**Change in median scores between Pre-intervention A and Intervention B phases**	**Change in median scores between Intervention B and Post-intervention A phases**	**Total change in median scores between Pre-intervention A and Post-intervention A phases**	**MCID/MDC/MIC**
MAS, elbow flexors	-2.0	0	-2.0	1 point decrease is generally seen as a clinically important difference[112]
MAS, wrist flexors	-2.0	0	-2.0	
MAS, finger flexors	-2.0	0	-2.0	

Legend: MCID = minimal clinically important difference, MDC = minimal detectable change, MIC = minimal important change, CAHAI-7 = Chedoke Arm and Hand Activity Inventory-7, ArmA = Arm Activity Measure, SIS = Stroke Impact Scale, FMA-UE = Fugl-Meyer, Upper Extremity, MAS = Modified Ashworth Scale, SSEQ = Stroke Self-Efficacy Questionnaire, COPM = Canadian Occupational Performance Measure

PARTICIPANT 2

CHEDOKE ARM AND HAND ACTIVITY INVENTORY-7 (CAHAI-7)

The CAHAI-7 was one of the primary outcome measures used in this study and measured the amount of use of the paretic arm and hand in bilateral functional tasks. The score range for the CAHAI-7 is 7-49, where 7=total assist and 49=complete independence. Figures 27 and 28 show the celeration line analysis and two-standard deviation band analysis respectively for the CAHAI-7 for Participant 2.

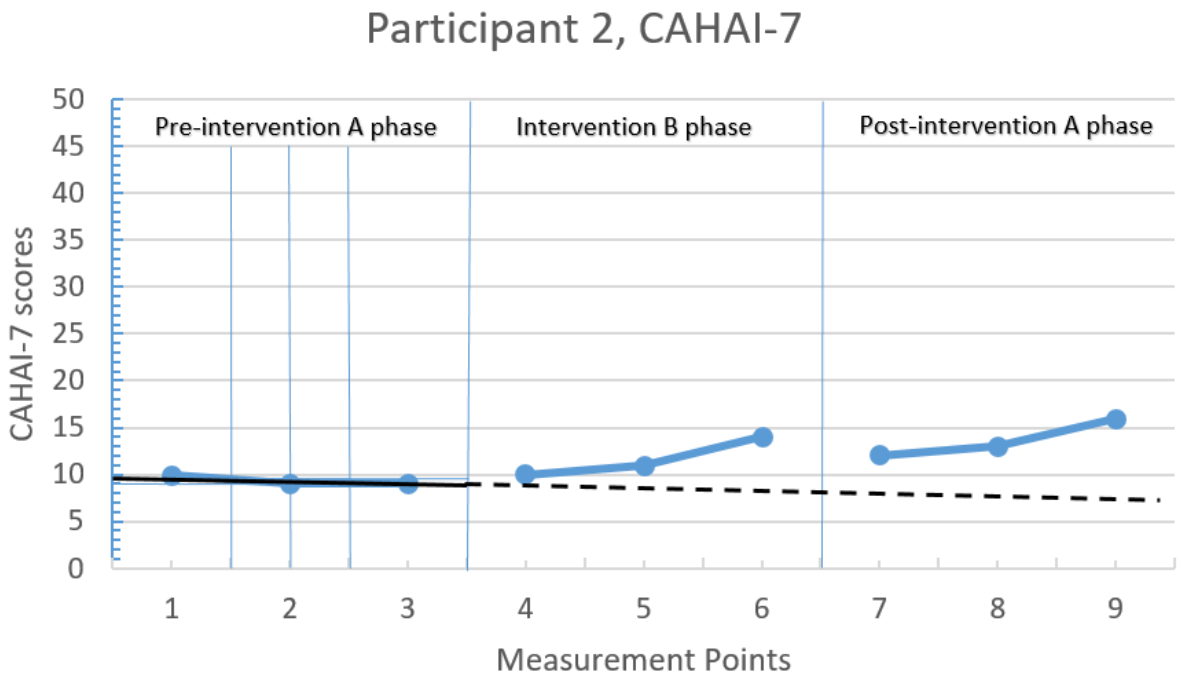

Figure 27: Celeration Line Analysis for Participant 2, CAHAI-7

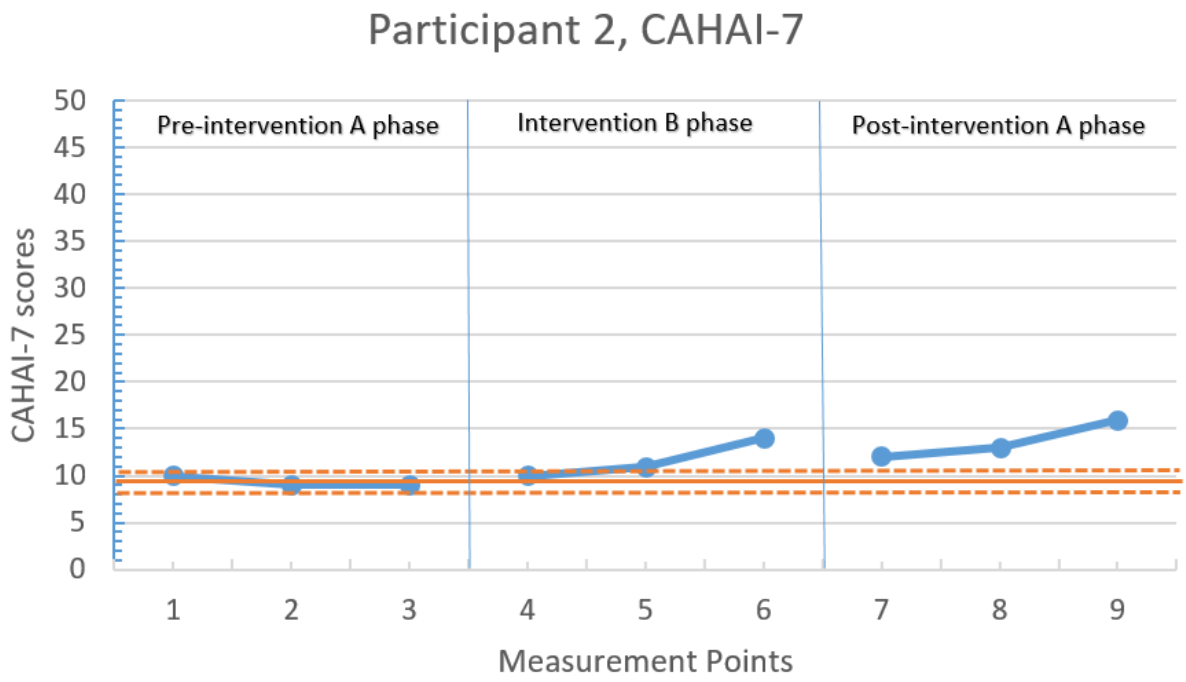

Figure 28: 2SD Band Analysis for Participant 2, CAHAI-7

Visual analysis of the plotted data shows that there is minimal change in level between phases and fairly stable data in the Pre-intervention A phase. Celeration line analysis shows all 6 data points in the Intervention B and Post-intervention A phases are above the celeration line. Two standard deviation band analysis shows 4 consecutive data points in the final two phases above the 2SD line. The mean values for the Pre-intervention, Intervention and Post-intervention data are 9.3 (SD=0.6, 2SD=1.2), 11.7 and 13.7 respectively, with an increase of 2.4 points between the first two phases and a further increase of 2.0 points between the second and third phases for a total increase of 4.4 points between the Pre-intervention A and Post-intervention A phases.

ARM ACTIVITY MEASURE (ARMA), ACTIVE FUNCTION SUBSCALE

The ArmA, active function subscale, was one of the primary outcome measures used in this study and measured participants' self-report of use of the paretic arm in functional tasks. The score range for the ArmA, active function subscale, is 0-52, where 0=no difficulty with the 13 tasks and 52=unable to do the 13 tasks. Figures 29 and 30 show the celeration line analysis and two-standard deviation band analysis respectively for the ArmA, active function subscale for Participant 2.

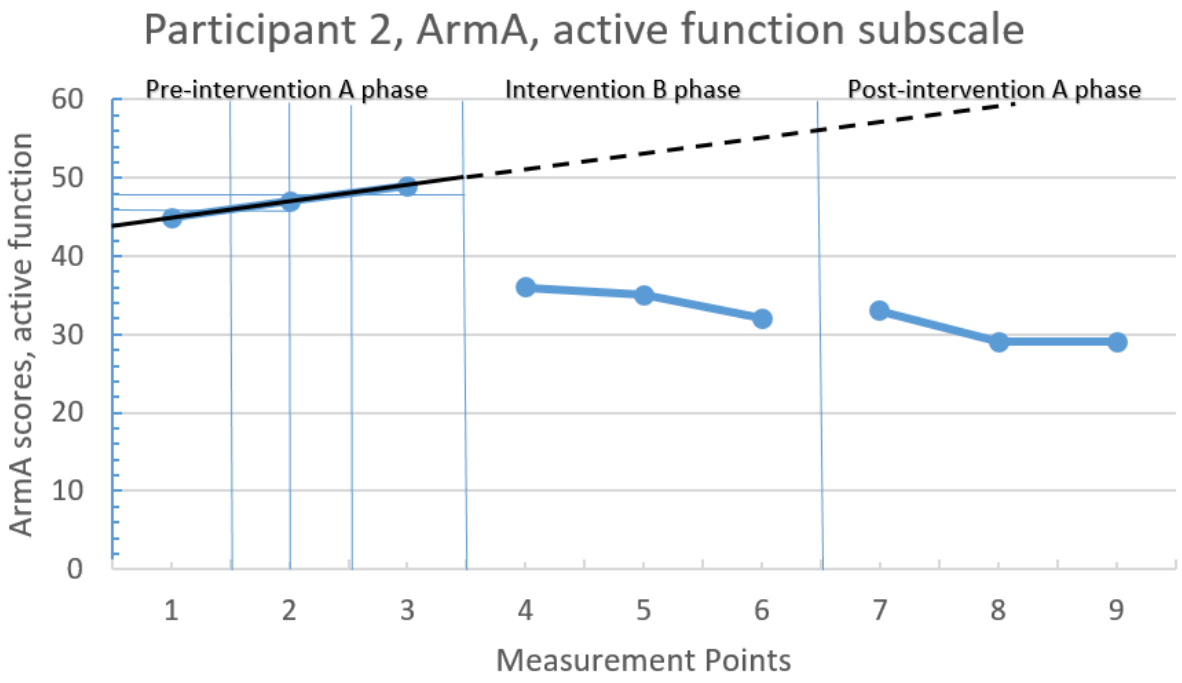

Figure 29: Celeration Line Analysis for Participant 2, ArmA (active function subscale)

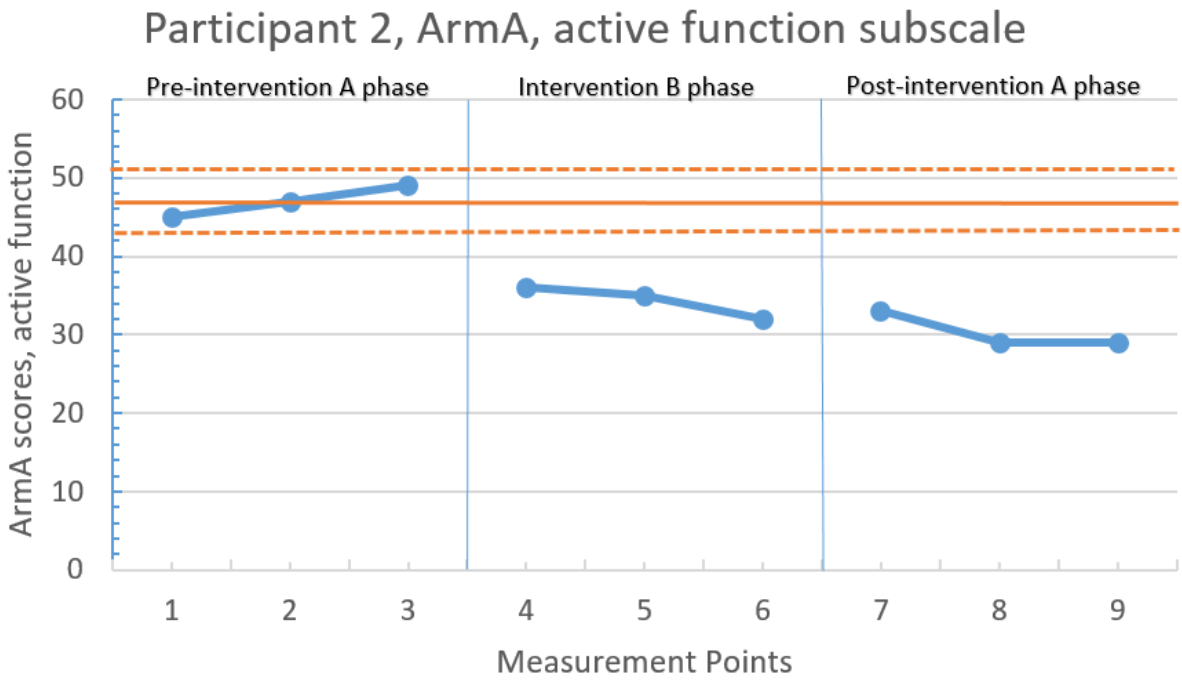

Figure 30: 2SD Band Analysis for Participant 2, ArmA (active function subscale)

Visual analysis of the plotted data shows that there is some change in level between the Pre-intervention A phase and the Intervention B phase. The Pre-intervention A phase data demonstrate an accelerating trend. Celeration line analysis is not plausible in this case because of this trend. Two-standard deviation band analysis shows 6 consecutive data points below the 2SD line in the Intervention B and Post-intervention A phases. The mean values for the Pre-intervention, Intervention and Post-intervention data are 47.0 (SD=2.0, 2SD=4.0), 34.3 and 30.3 respectively, with a decrease of 12.7 and 4.0 points between subsequent phases, for a total decrease of 16.7 points between the Pre-intervention A and Post-intervention A phases.

ARM ACTIVITY MEASURE (ARMA), PASSIVE FUNCTION SUBSCALE

The ArmA, passive function subscale, was one of the primary outcome measures used in this study and measured participants' self-report of caring for the paretic arm and hand during functional tasks. The score range for the ArmA, passive function subscale, is 0-32, where 0=no difficulty with the 8 tasks and 32=unable to do the 8 tasks. Figures 31 and 32 show the celeration line analysis and two-standard deviation band analysis respectively for the ArmA, passive function subscale for Participant 2.

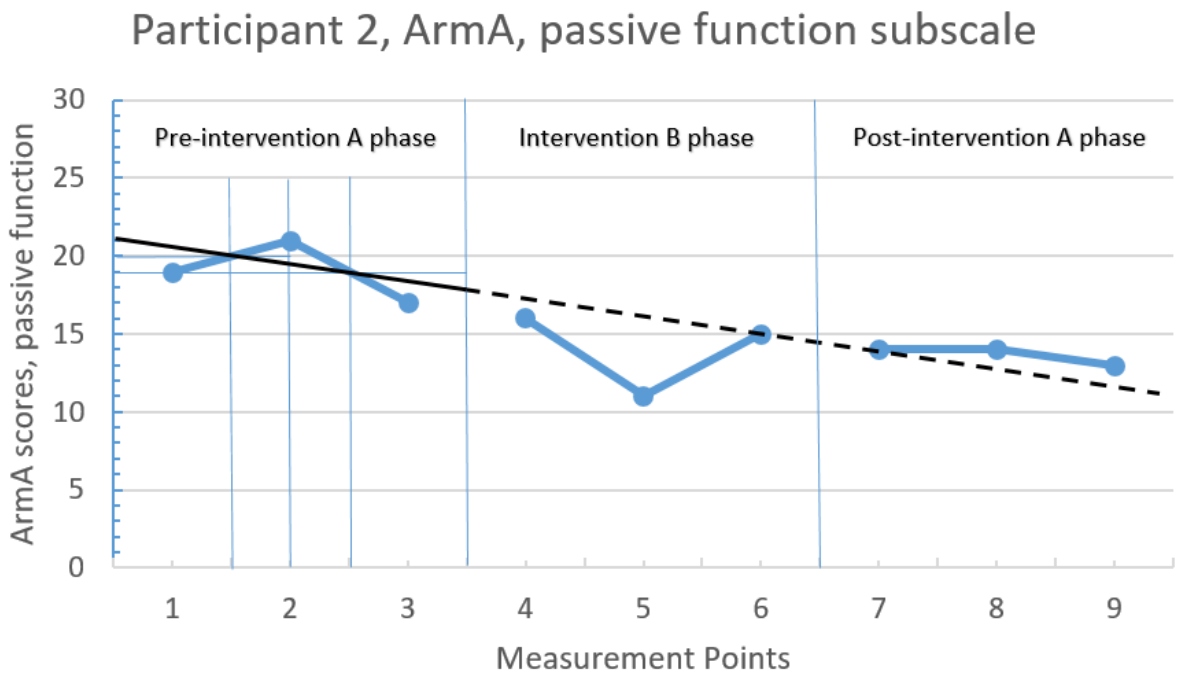

Figure 31: Celeration Line Analysis for Participant 2, ArmA (passive function subscale)

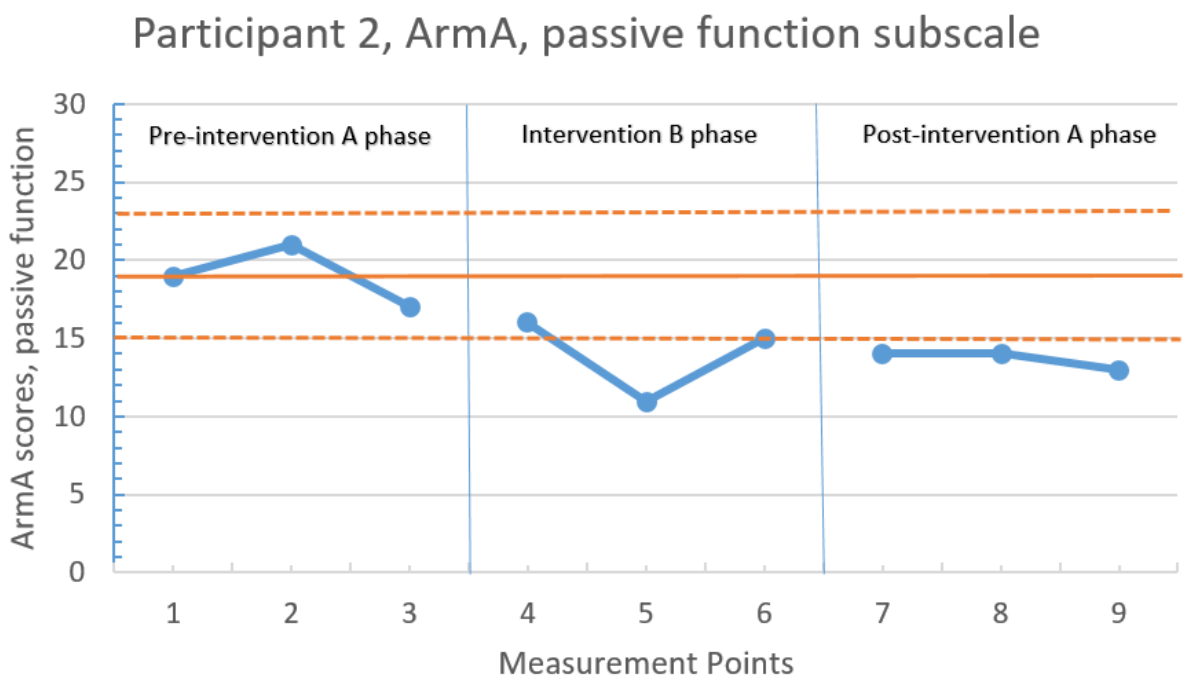

Figure 32: 2SD Band Analysis for Participant 2, ArmA (passive function subscale)

Visual analysis of the plotted data shows that there is little change in level between the three phases however the data in the Pre-intervention A phase and Intervention B phase is variable. Celeration line analysis shows 2 data points above the line, 2 below the line and 2 on the line in the Intervention B and Post-intervention A phases. Two standard deviation band analysis shows 3 consecutive data points below the 2SD line in the final phase. The mean values for the Pre-intervention, Intervention and Post-intervention data are 19.0 (SD=2.0, 2SD=4.0), 14.0 and 13.7 respectively, with a decrease of 5.0 points between the first two phases and an additional 0.3 points between the final two phases, for a total decrease of 5.3 points between the Pre-intervention and Post-intervention phases.

STROKE IMPACT SCALE (SIS), STROKE RECOVERY SCALE

The SIS, Stroke Recovery scale was used in this study to measure participants' perception of their post-stroke recovery. The score range for the SIS, Stroke Recovery scale is 0-100, where 0=no recovery and 100=full recovery. Figures 33 and 34 show the celeration line analysis and two-standard deviation band analysis respectively for the SIS, Stroke Recovery Scale for Participant 2.

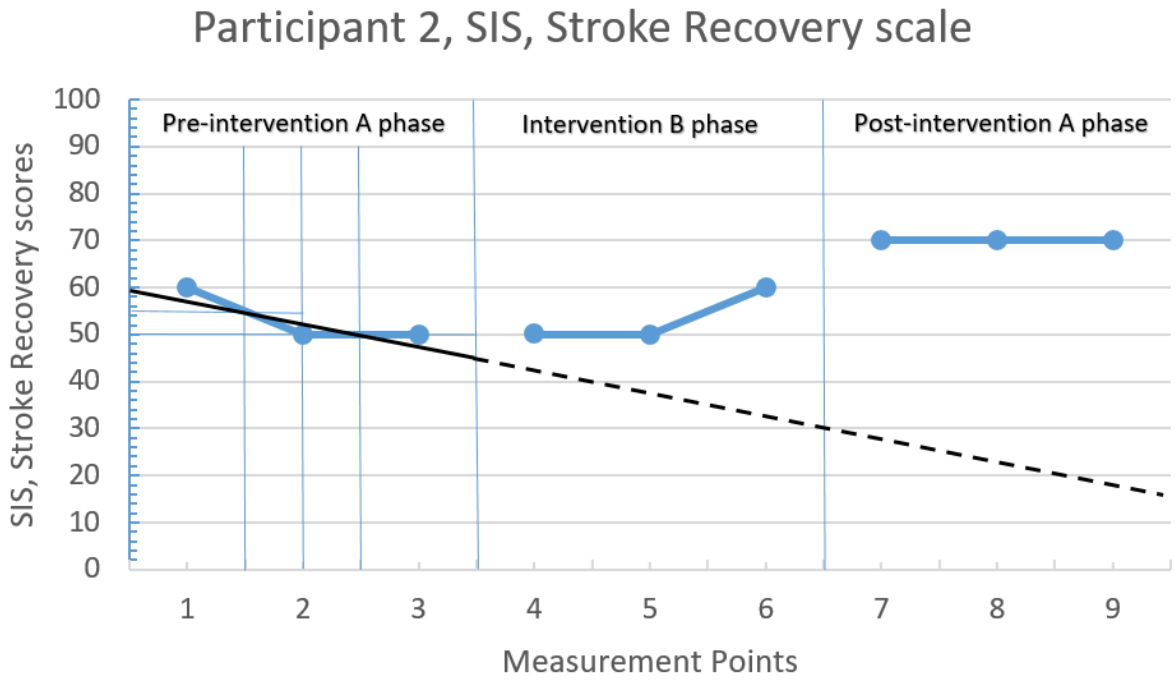

Figure 33: Celeration Line Analysis for Participant 2, SIS (Stroke Recovery scale)

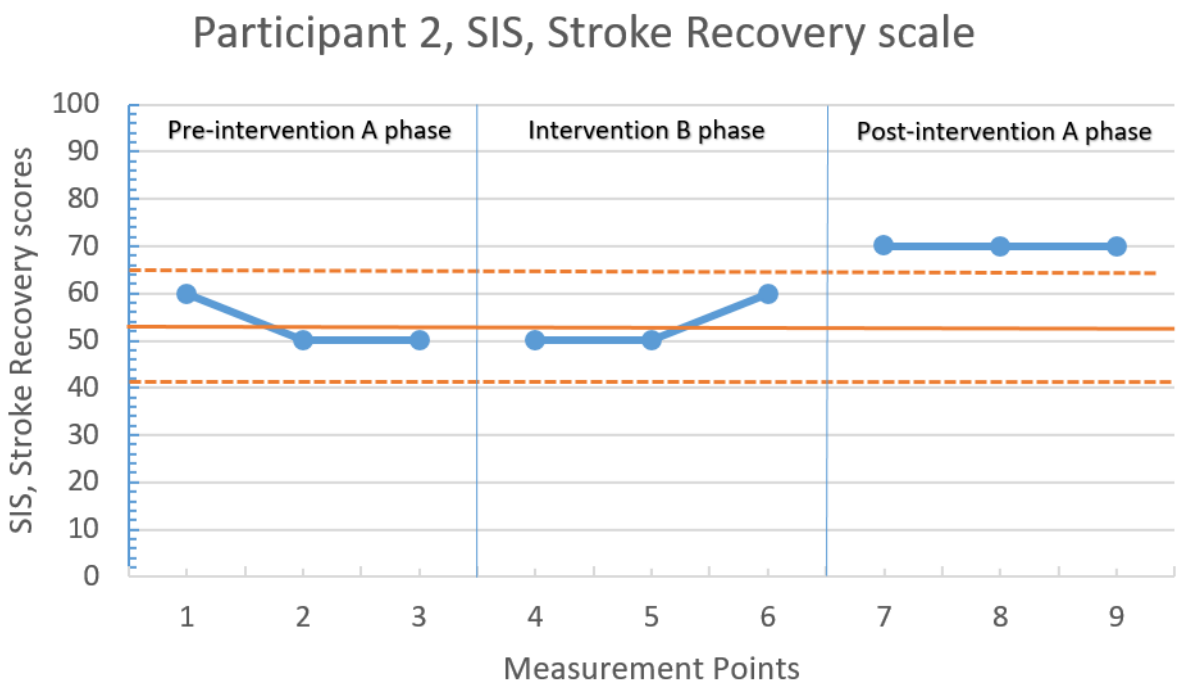

Figure 34: 2SD Band Analysis for Participant 2, SIS (Stroke Recovery scale)

Visual analysis of the plotted data shows that there is change in level from the Intervention B phase to the Post-intervention A phase. The first and second phases have some variability in the data while the third phase is stable. Celeration line analysis shows 6 data points above the celeration line in the second and third phases of the study. Two standard deviation band analysis shows 3 consecutive data points above the 2SD line in the Post-intervention A phase. The mean values for the Pre-intervention, Intervention and Post-intervention data are 53.3 (SD=5.8, 2SD=11.6), 53.3 and 70.0 respectively with the first two phases having the same mean and then an increase of 16.7 points is seen between the Intervention B and the Post-intervention A phases.

FUGL-MEYER, UPPER EXTREMITY (FMA-UE)

The FMA-UE assessment was used in this study to measure motor impairment of the paretic upper extremity. The score range for the FMA-UE is 0-66, where a higher score means less upper extremity impairment. Figures 35 and 36 show the celeration line analysis and two-standard deviation band analysis respectively for the FMA-UE for Participant 2.

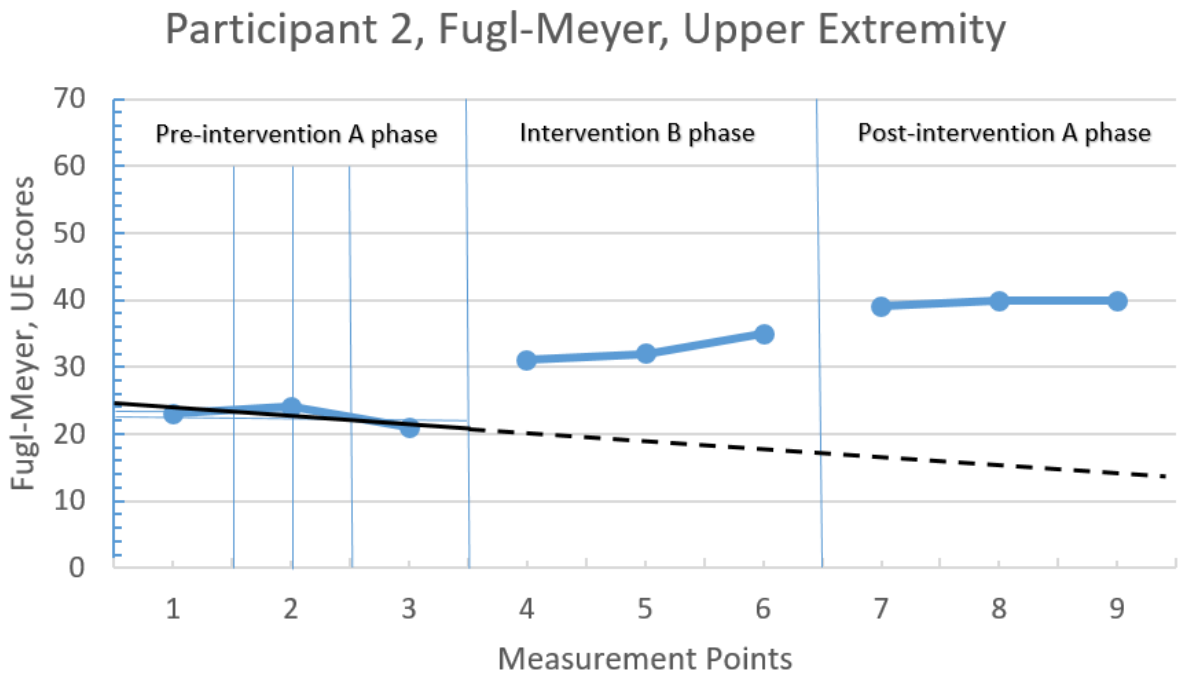

Figure 35: Celeration Line Analysis for Participant 2, FMA-UE

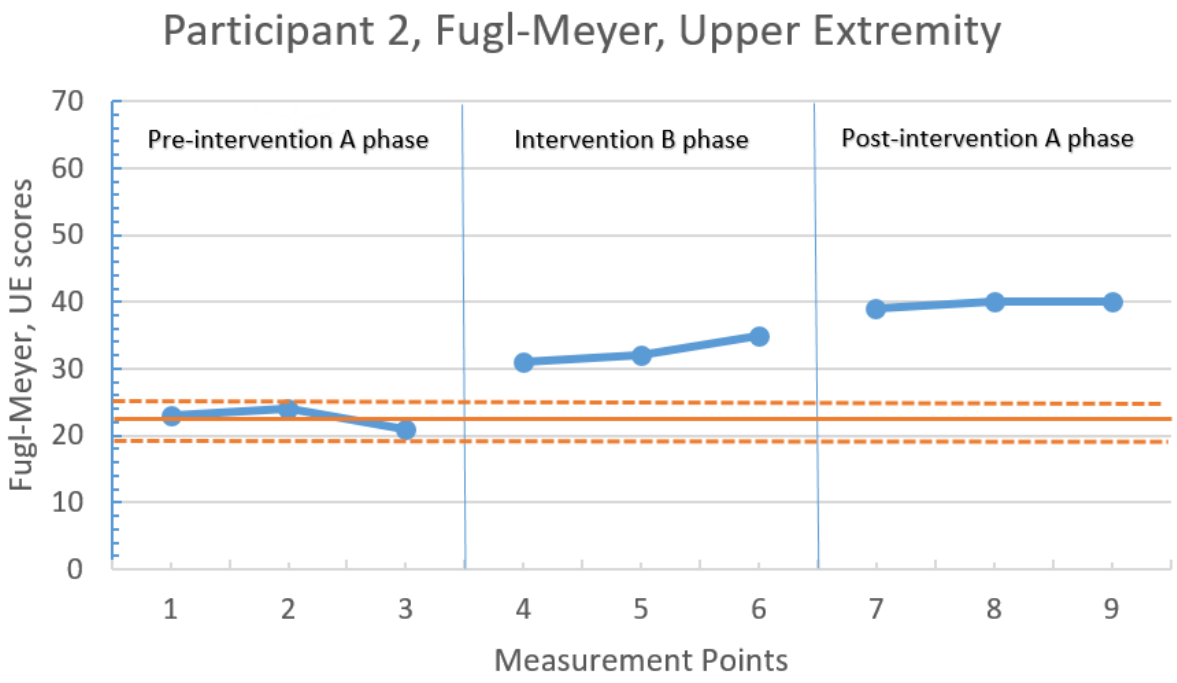

Figure 36: 2SD Band Analysis for Participant 2, FMA-UE

Visual analysis of the plotted data shows that there is some change in level between all three phases but particularly between the Pre-intervention A and Intervention B phases. The Pre-intervention A and Intervention B phases have some variability. Celeration line analysis shows 6 data points above the celeration line in phases two and three. Two standard deviation band analysis shows 6 consecutive data points above the 2SD line in the Intervention/Post-intervention phases. The mean values for the Pre-intervention, Intervention and Post-intervention data are 22.7 (SD=1.5, 2SD=3.0), 32.7 and 39.7 respectively with an increase of 10.0 points between the first two phases and an additional increase of 7.0 points between phases two and three for a total increase of 17.0 points between the Pre-intervention A and Post-intervention A phases.

GRIP STRENGTH

Grip strength measurement was used in this study to measure strength of the participants' paretic hand. Grip strength was measured three times at each assessment, therefore each data point represents an average of three grip strength measurements, in kilograms. Figures 37 and 38 show the celeration line analysis and two-standard deviation band analysis respectively for the grip strength measurements for Participant 2.

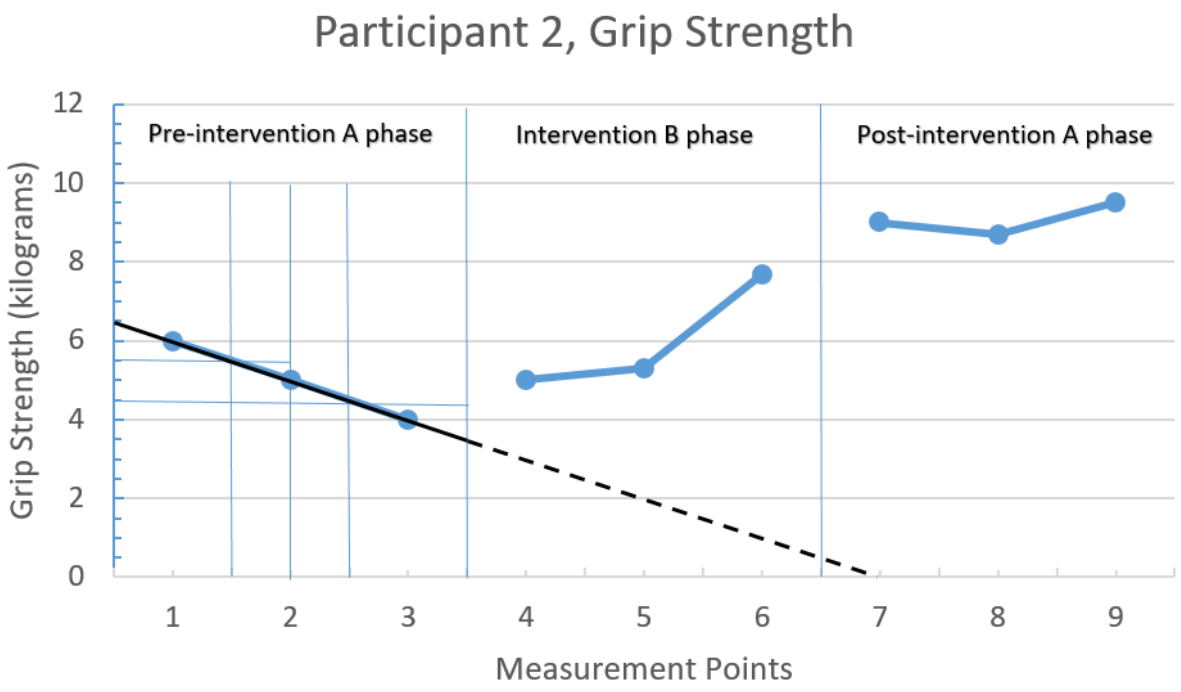

Figure 37: Celeration Line Analysis for Participant 2, Grip Strength

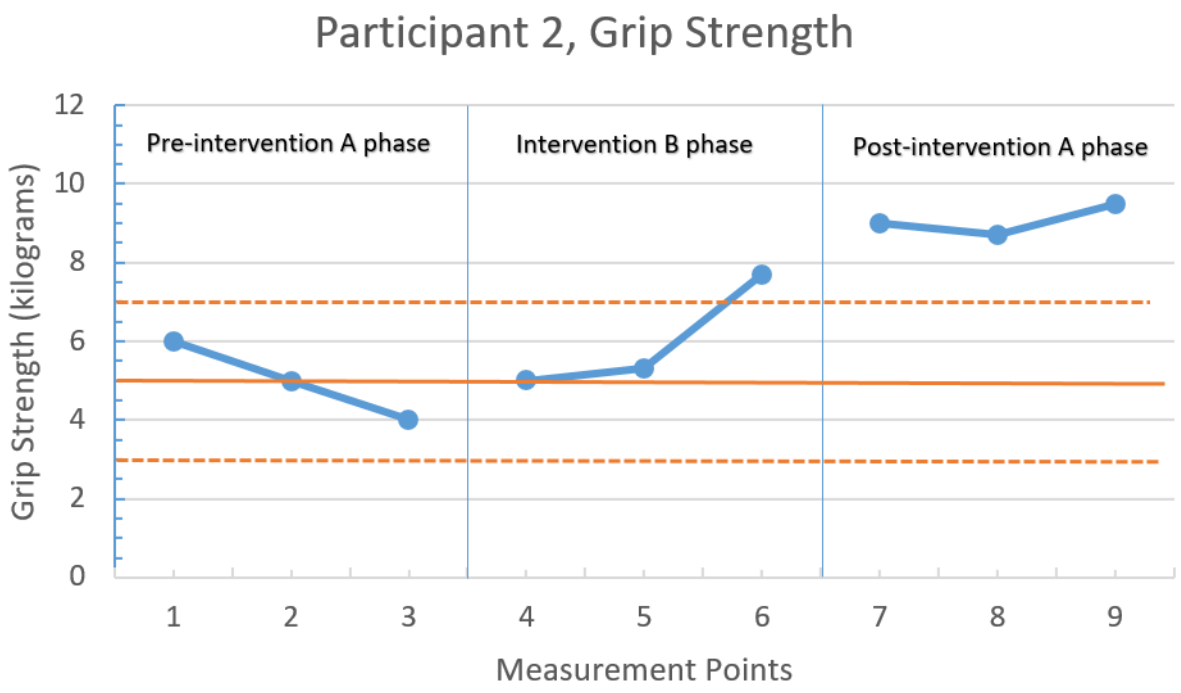

Figure 38: 2SD Band Analysis for Participant 2, Grip Strength

Visual analysis of the plotted data shows that there is some change in level between all phases. The Pre-intervention A phase and Intervention B phase data demonstrate some variability while the Post-intervention A phase data is more stable. The Pre-intervention A phase data demonstrate a decelerating trend. Celeration line analysis is not plausible because of this trend. Two standard deviation band analysis shows 4 consecutive data points above the 2SD line in the Intervention B and Post-intervention A phases. The mean values for the Pre-intervention, Intervention and Post-intervention data are 5.0 kg (SD=1.0 kg, 2SD=2.0 kg), 6.0 kg and 9.1 kg respectively with an increase of 1.0 kg between the first two phases and a further increase of 3.1 kg between the second and third phases for a total increase of 4.1 kg between the Pre-intervention and Post-intervention phases.

MODIFIED ASHWORTH SCALE (MAS), ELBOW FLEXORS

The MAS was used in this study to measure the resistance to passive movement of three upper extremity muscle groups, the elbow flexors, wrist flexors and finger flexors. The score range for the MAS is 0-4, where 0=no increase in muscle tone and 4=affected part is in rigid flexion. However, since the scale is a 6-point ordinal scale (0,1,1+,2,3,4), for the purpose of plotting the data points and analyzing the results, the scale was adjusted to 0-5, where 1+=2, 2=3, 3=4, 4=5. Figures 39 and 40 show the celeration line analysis and median/interquartile range analysis respectively for the adjusted scoring of the MAS, elbow flexors for Participant 2.

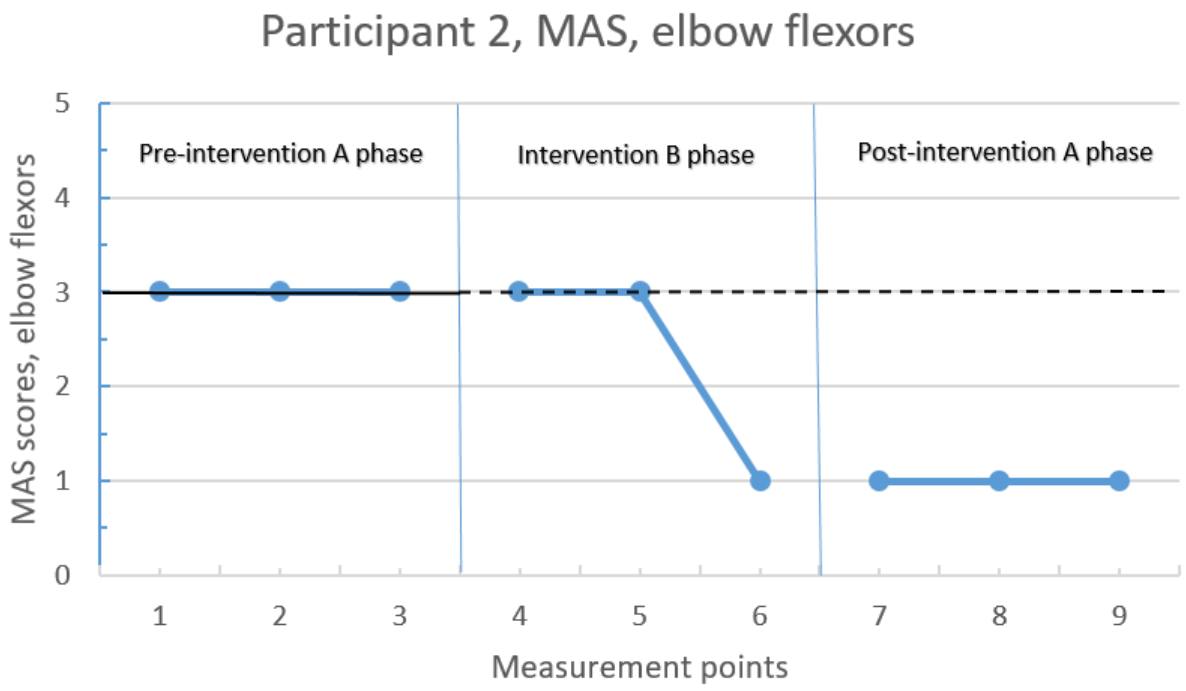

Figure 39: Celeration Line Analysis for Participant 2, MAS (elbow flexors)

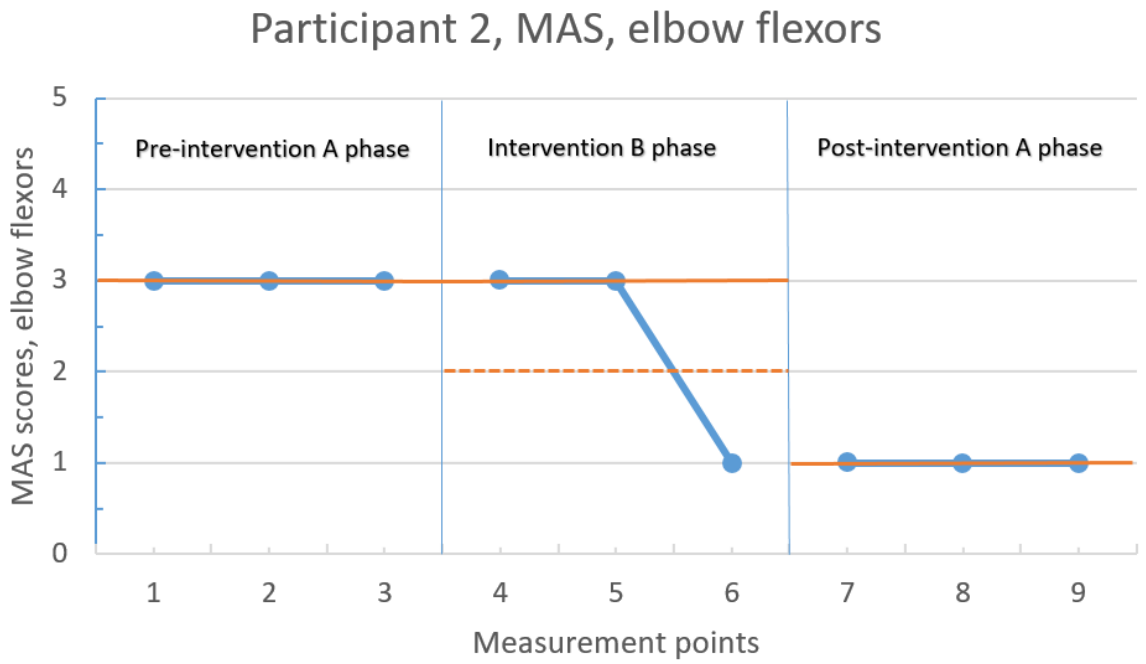

Figure 40: Median/Interquartile Range Analysis for Participant 2, MAS (elbow flexors)

Visual analysis of the plotted data shows that there is no change in level between phases however there is some variability in the data in the Intervention B phase. Because the three data points in the Pre-intervention A phase are all the same, celeration line analysis produces a horizontal line; there are four data points in phases two and three below the celeration line. Median/interquartile range analysis shows that the data is stable for the Pre-intervention A phase and Post-intervention A phase, so there are no interquartile bands. There is no overlap between the interquartile bands of the Intervention B phase and the median of the Post-intervention A phase. The median values for the Pre-intervention, Intervention and Post-intervention data are 3.0, 3.0 and 1.0 respectively, for a total median decrease of 2.0 points between the Pre-intervention A phase and the Post-intervention A phase.

MODIFIED ASHWORTH SCALE (MAS), WRIST FLEXORS

The MAS was used in this study to measure the resistance to passive movement of three upper extremity muscle groups, the elbow flexors, wrist flexors and finger flexors. The score range for the MAS is 0-4, where 0=no increase in muscle tone and 4=affected part is in rigid flexion. However, since the scale is a 6-point ordinal scale (0,1,1+,2,3,4), for the purpose of plotting the data points and analyzing the results, the scale was adjusted to 0-5, where 1+=2, 2=3, 3=4, 4=5. Figures 41 and 42 show the celeration line analysis and median/interquartile range analysis respectively for the adjusted scoring of the MAS, wrist flexors for Participant 2.

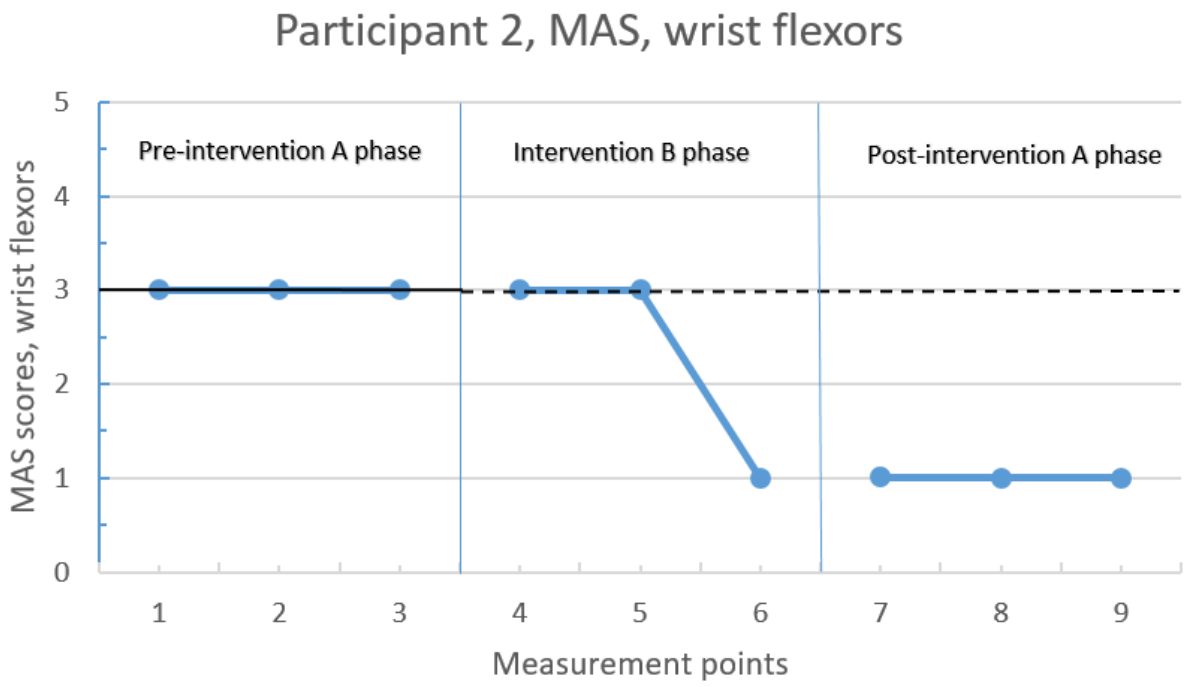

Figure 41: Celeration Line Analysis for Participant 2, MAS (wrist flexors)

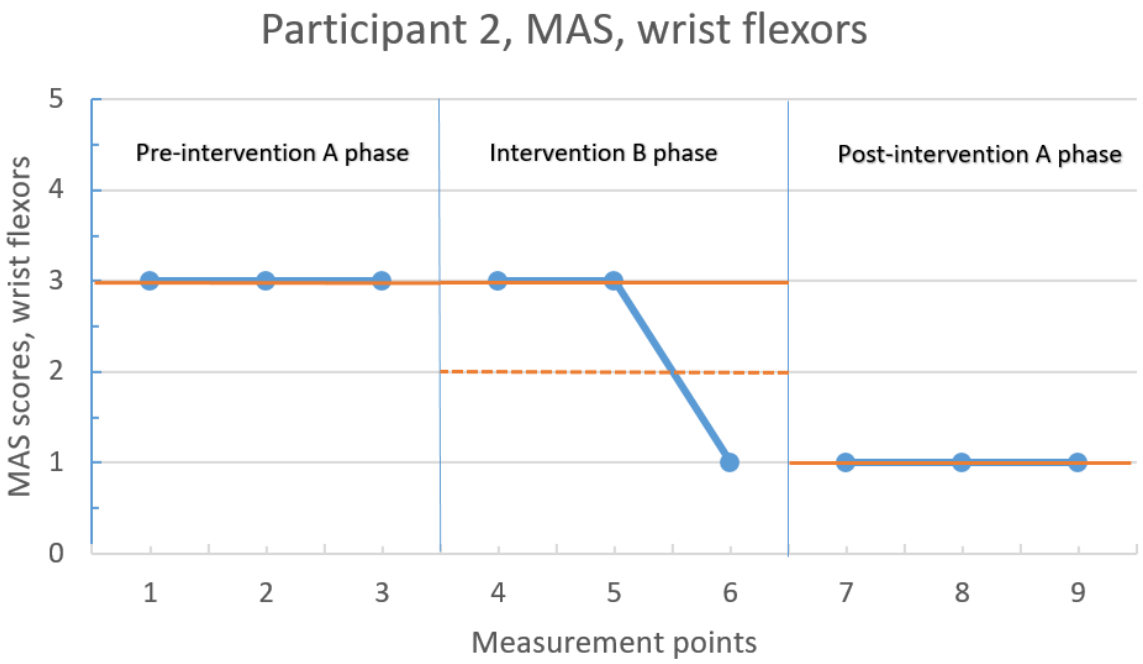

Figure 42: Median/Interquartile Range Analysis for Participant 2, MAS (wrist flexors)

Visual analysis of the plotted data shows that there is no change in level between phases however there is some variability in the data in the Intervention B phase. Because the three data points in the Pre-intervention A phase are all the same, celeration line analysis produces a horizontal line; there are four data points in phases two and three below the celeration line. Median/interquartile range analysis shows that the data is stable for the Pre-intervention A phase and Post-intervention A phase, so there are no interquartile bands. There is no overlap between the interquartile bands of the Intervention B phase and the median of the Post-intervention A phase. The median values for the Pre-intervention, Intervention and Post-intervention data are 3.0, 3.0 and 1.0 respectively, for a total median decrease of 2.0 points between the Pre-intervention A phase and the Post-intervention A phase.

MODIFIED ASHWORTH SCALE (MAS), FINGER FLEXORS

The MAS was used in this study to measure the resistance to passive movement of three upper extremity muscle groups, the elbow flexors, wrist flexors and finger flexors. The score range for the MAS is 0-4, where 0=no increase in muscle tone and 4=affected part is in rigid flexion. However, since the scale is a 6-point ordinal scale (0,1,1+,2,3,4), for the purpose of plotting the data points and analyzing the results, the scale was adjusted to 0-5, where 1+=2, 2=3, 3=4, 4=5. Figures 43 and 44 show the celeration line analysis and median/interquartile range analysis respectively for the adjusted scoring of the MAS, finger flexors for Participant 2.

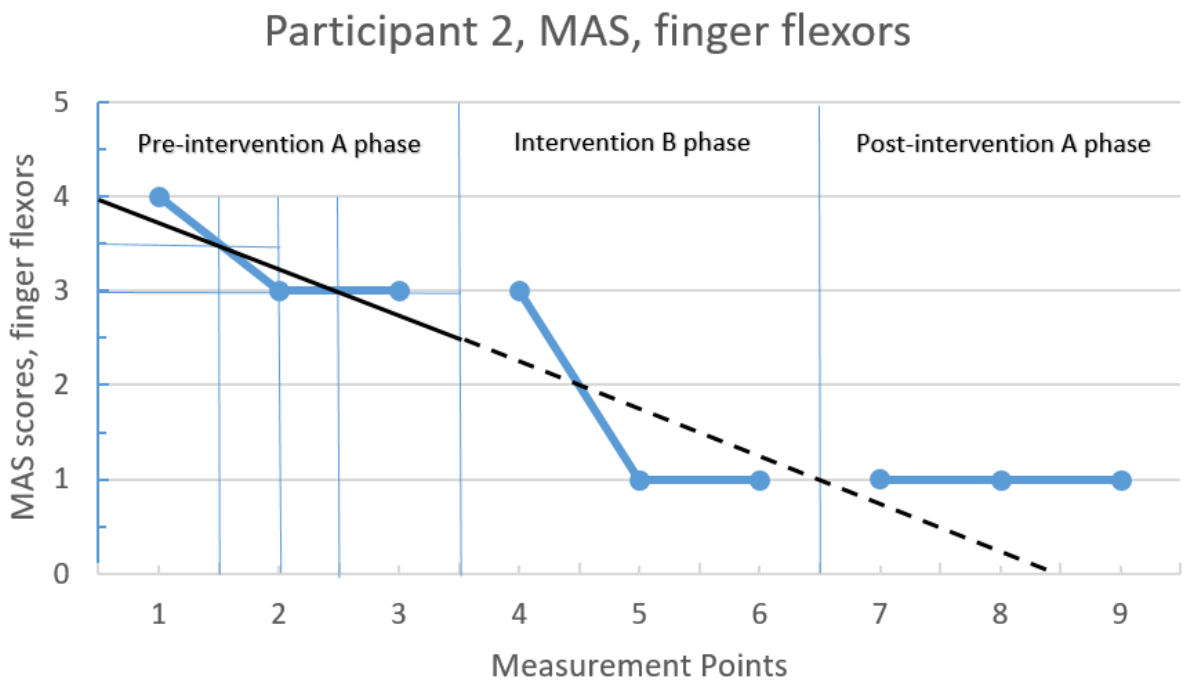

Figure 43: Celeration Line Analysis for Participant 2, MAS (finger flexors)

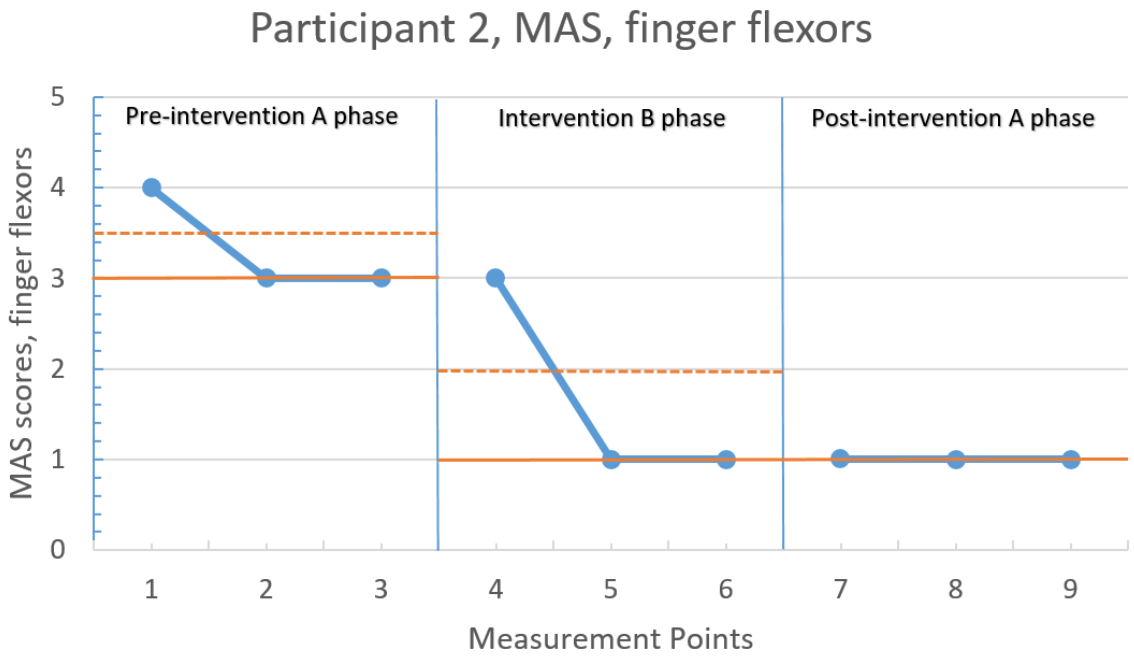

Figure 44: Median/Interquartile Range Analysis for Participant 2, MAS (finger flexors)

Visual analysis of the plotted data shows that although there is no change in level between phases, phases one and two data show some variability and a decelerating trend. The data in the third phase is stable. Celeration line analysis is not plausible with this data.

Median/interquartile range analysis shows that there is no overlap between the interquartile bands of the Pre-intervention A phase and the Intervention B and Post-intervention A phases. The median values for the Pre-intervention, Intervention and Post-intervention data are 3.0, 1.0 and 1.0 respectively for a total median decrease of 2.0 points between the Pre-intervention A and Post-intervention A phases.

STROKE SELF-EFFICACY QUESTIONNAIRE (SSEQ), ACTIVITY SCALE

The SSEQ, Activity scale was used in this study to measure participants' self-reported confidence in completing functional tasks. The score range for the SSEQ, Activity scale is 0-24, where 0=not at all confident with performance on 8 functional tasks and 24=very confident with performance on 8 functional tasks. Figures 45 and 46 show the celeration line analysis and two-standard deviation band analysis respectively for the SSEQ, Activity scale for Participant 2.

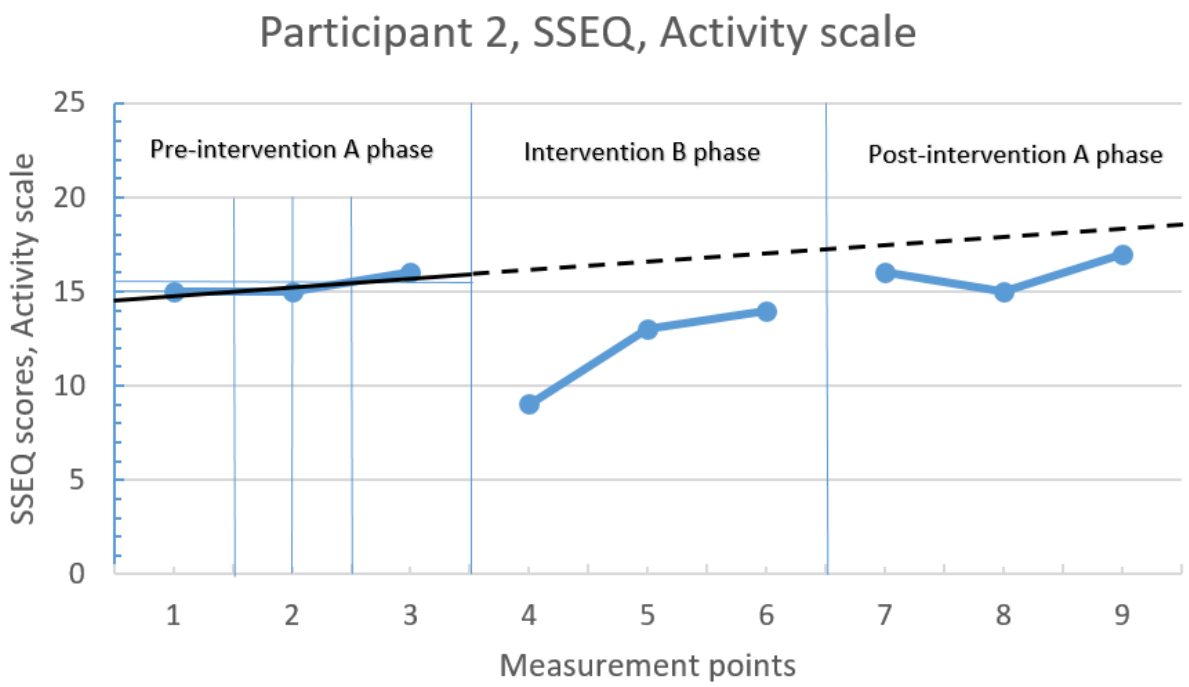

Figure 45: Celeration Line Analysis for Participant 2, SSEQ (Activity scale)

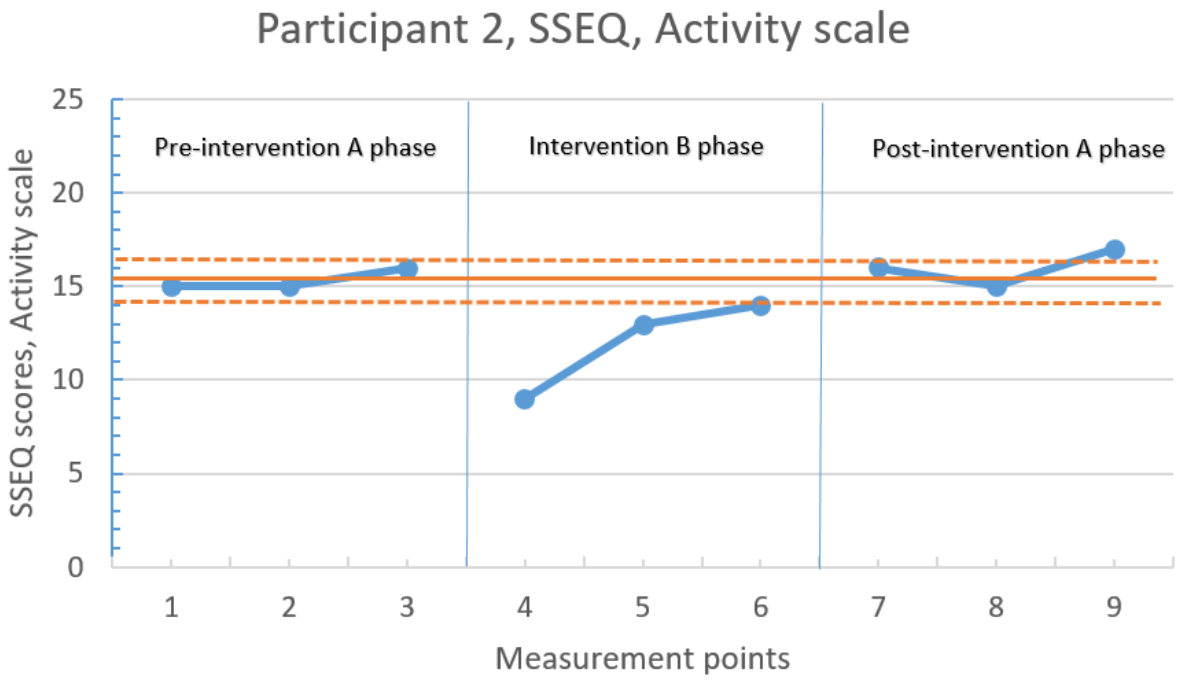

Figure 46: 2SD Band Analysis for Participant 2, SSEQ (Activity scale)

Visual analysis of the plotted data shows that there is a change in level between the Pre-intervention A phase and the Intervention B phase. There is also some variability in the data, particularly in the Intervention B phase. The Pre-intervention A phase also shows some slight variability. Celeration line analysis shows 6 data points below the celeration line. Two standard deviation band analysis shows 2 data points below the 2SD line in the Intervention B phase and 1 data point above the 2SD line in the Post-intervention A phase. The mean values for the Pre-intervention, Intervention and Post-intervention data are 15.3 (SD=0.6, 2SD=1.2), 12.0 and 16.0 respectively, with a decrease of 3.3 between the first two phases and an increase of 4.0 between the final two phases for a total increase of 0.7 points.

STROKE SELF-EFFICACY QUESTIONNAIRE (SSEQ), SELF-MANAGEMENT SCALE

The SSEQ, Self-management scale was used in this study to measure participants' self-reported confidence in completing self-management activities. The score range for the SSEQ, Self-management scale is 0-15, where 0=not at all confident with performance on 5 self-management tasks and 15=very confident with performance on 5 self-management tasks. Figures 47 and 48 show the celeration line analysis and two-standard deviation band analysis respectively for the SSEQ, Self-management scale for Participant 2.

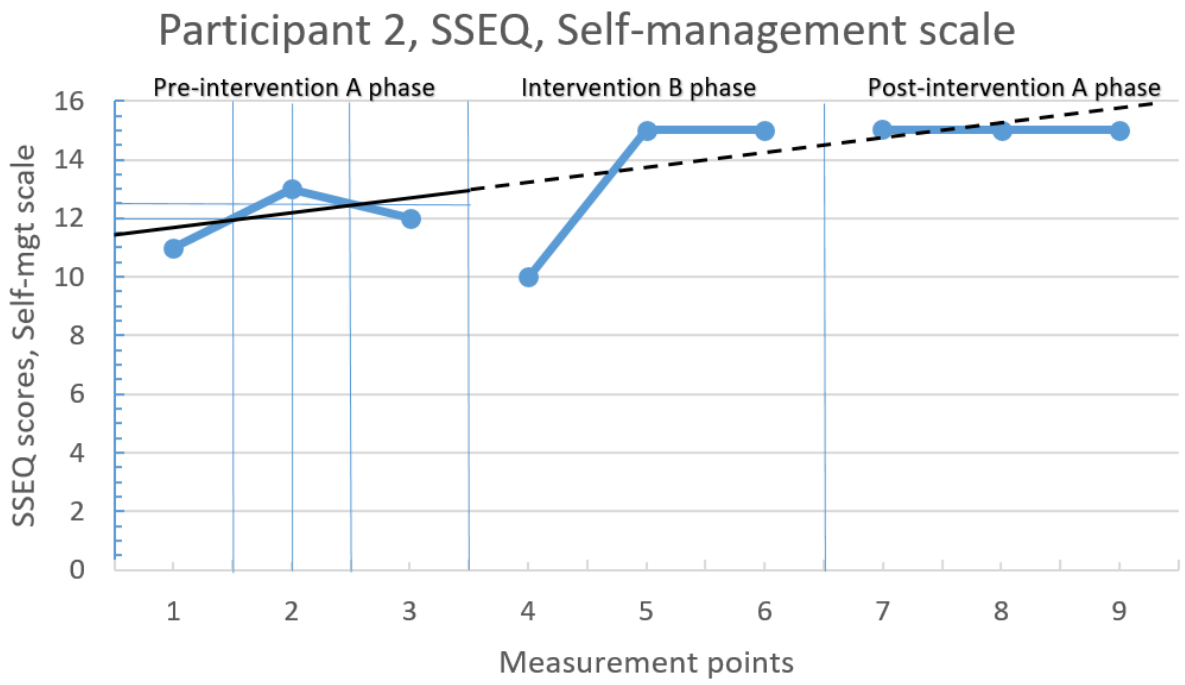

Figure 47: Celeration Line Analysis for Participant 2, SSEQ (Self-management scale)

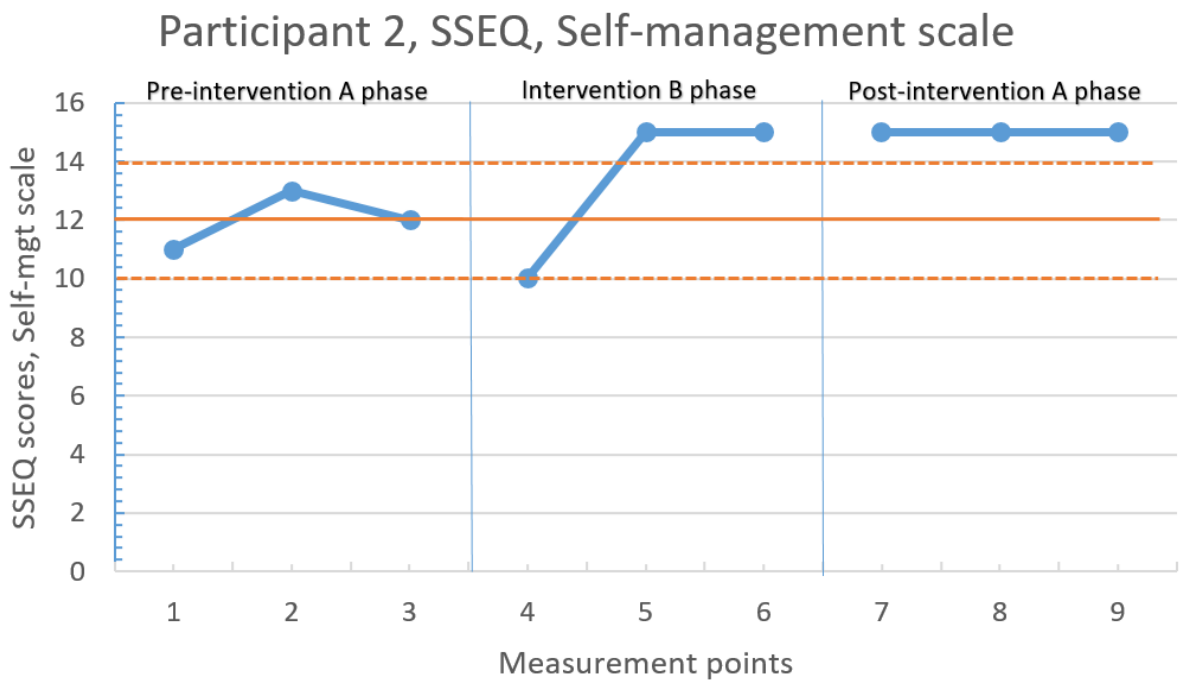

Figure 48: 2SD Band Analysis for Participant 2, SSEQ (Self-management scale)

Visual analysis of the plotted data shows that there is a change in level between the Pre-intervention A phase and Intervention B phase but no change in level between the Intervention B phase and the Post-intervention A phase. There is also some variability in the data in the first two phases. The Post-intervention phase has stable data. Celeration line analysis shows that there are 3 data points above the celeration line and 3 data points below the celeration line. Two standard deviation band analysis shows that there are 5 consecutive data points above the 2SD line in the final two phases. The mean values for the Pre-intervention, Intervention and Post-intervention data are 12.0 (SD=1.0, 2SD=2.0), 13.3 and 15.0 respectively with an increase of 1.3 points between the first two phases and a further increase of 1.7 points between the second and third phases for a total increase of 3.0 points between the Pre-intervention and Post-intervention phases.

CANADIAN OCCUPATIONAL PERFORMANCE MEASURE (COPM)

The COPM was used in this study to determine participants' occupational performance issues (OPI's) related to upper extremity function, as well as their self-perceived performance and satisfaction with these OPI's. The COPM was administered once in the Pre-intervention A phase, the Intervention B phase and the Post-intervention A phase. Performance and Satisfaction scores were identified based on the top five upper extremity OPI's identified by the participant in the Pre-intervention A phase. The OPI's identified by Participant 2 at the Pre-intervention A phase assessment were:

1. Use TV remote with right hand
2. Eat portion of meal with right hand
3. Write name with right hand
4. Hold drink with right hand and bring up to mouth
5. Hold bottle in right hand (for left hand to open)

The score range for the COPM is 1-10 for each OPI, where 1=not able to do the task/not satisfied with ability to do the task and 10=able to do the task extremely well/extremely satisfied with performance of the task. The five Performance and five Satisfaction scores were summed separately and then divided by the number of OPI's (five) to determine the mean score for each. Figures 49 and 50 show the Performance and Satisfaction COPM scores for Participant 2.

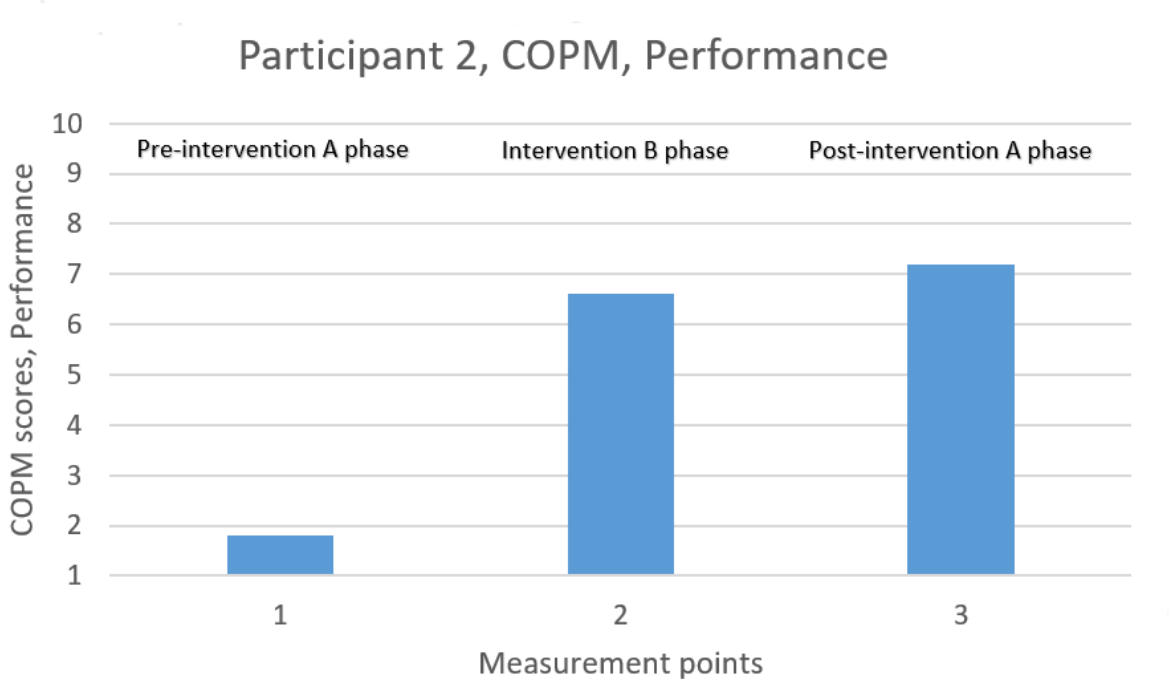

Figure 49: Analysis of COPM scores (Performance) for Participant 2

The COPM scores for *Performance* were 1.8, 6.6 and 7.2 with an increase between subsequent phases of 4.8 and 0.6 points respectively and a total increase of 5.4 points between the Pre-intervention A phase and the Post-intervention A phase.

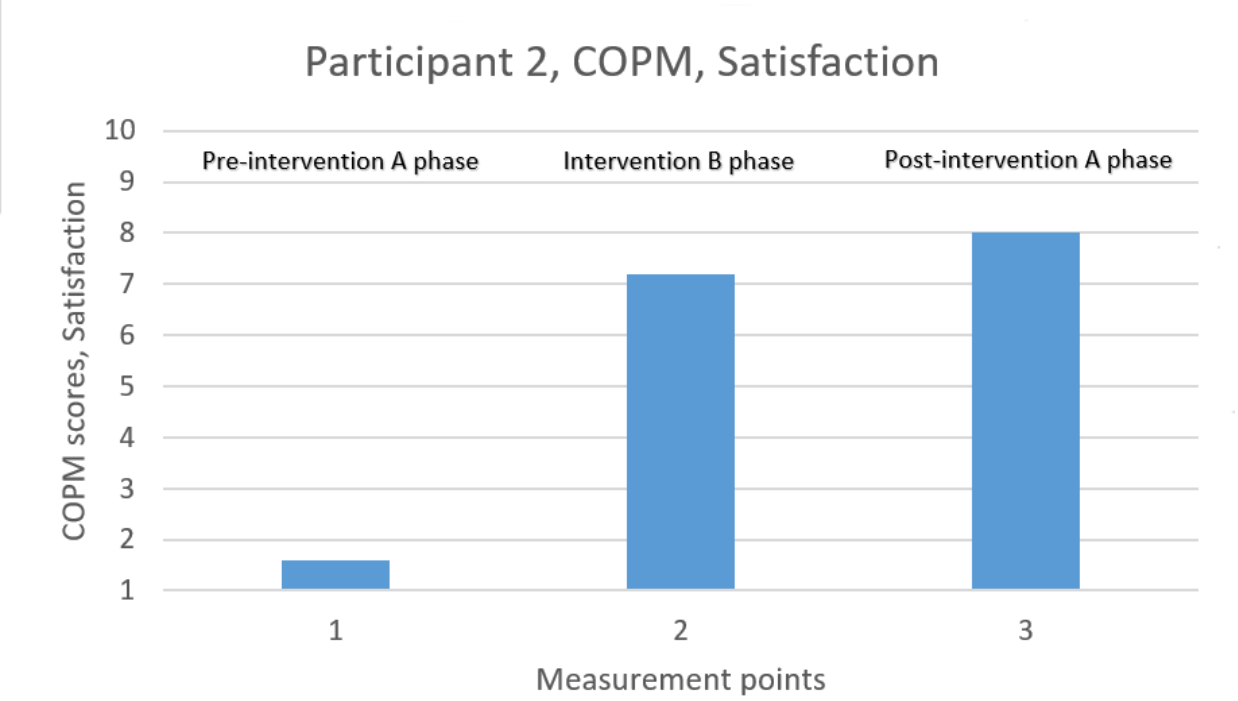

Figure 50: Analysis of COPM scores (Satisfaction) for Participant 2

The COPM scores for *Satisfaction* were 1.6, 7.2 and 8.0 with an increase between subsequent phases of 5.6 and 0.8 points respectively and a total increase of 6.4 points between the Pre-intervention A phase and the Post-intervention A phase.

USE OF SAEBOFLEX ORTHOSIS AT HOME

Participant 2, or his wife, recorded (in his logbook) the *number of repetitions* of each task completed with the SaeboFlex orthosis each session. This included SaeboFlex use during visits from the principal investigator as well as repetitions completed on his own time. The total number of repetitions completed each week was calculated and plotted. The *number of SaeboFlex sessions* completed each week by Participant 2 was determined by examining the participant's logbook. This included sessions completed with the principal investigator (if the

session met the amount of use criteria for the study) and sessions completed on his own time. The total number of sessions completed each week was calculated and plotted. Figure 51 shows the Repetitions of SaeboFlex use over the 8 weeks of the study. Figure 52 shows the number of sessions the SaeboFlex was used during the 8 weeks of the study.

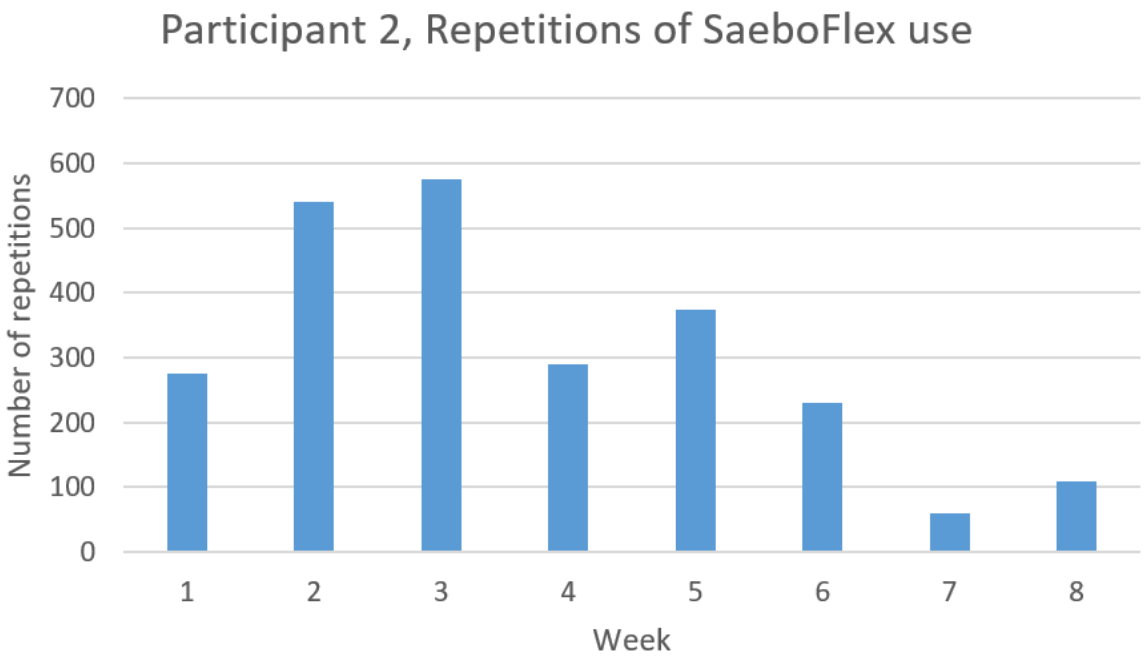

Figure 51: Repetitions of SaeboFlex use for Participant 2

Participant 2 completed 2455 repetitions (recorded) with the SaeboFlex orthosis during the 8 weeks of the study. He completed the most repetitions (575) in week 3 and the fewest repetitions (60) in week 7.

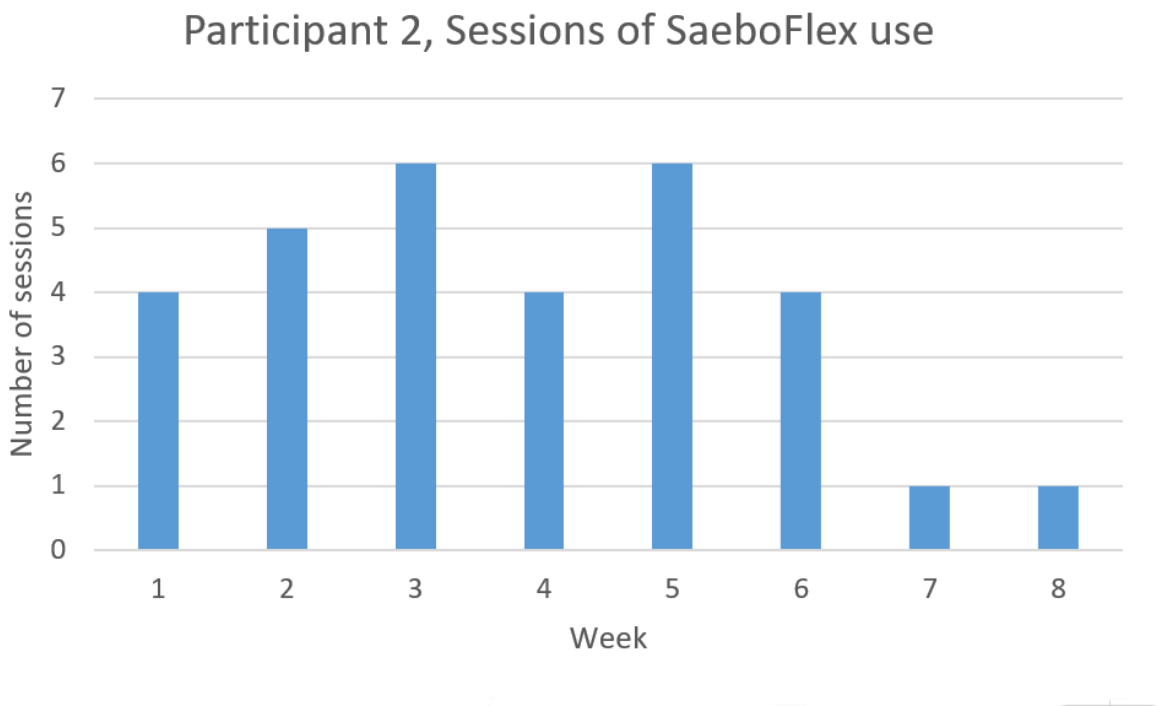

Figure 52: Sessions of SaeboFlex use for Participant 2

Participant 2 completed 31 sessions (recorded) with the SaeboFlex orthosis during the 8 weeks of the study. He completed the most sessions in weeks 3 and 5 (6 sessions) and the fewest sessions in weeks 7 and 8 (1 session).

OTHER TASKS COMPLETED AT HOME

Participant 2 attempted to use his paretic hand for continued practice of grasp and release tasks for 10 minutes after the SaeboFlex orthosis was removed each session, as well as for tasks or portions of tasks identified through baseline assessment with the COPM. Grasp-release tasks were attempted first in sitting, with a smaller therapy ball (on his lap), and progressed to standing after several sessions. In addition to the practice of tasks or partial tasks as identified in the COPM, Participant 2 also attempted to use his right arm/hand for other daily tasks such

as turning on the bathroom light switch, turning on the bathroom tap and attempting to eat snacks. Cylindrical foam was provided to increase the handle size of his cutlery and pen and dycem was wrapped around his plastic water bottle to facilitate practice of the OPI's identified on the COPM.

SUMMARY OF QUANTITATIVE DATA

As described above, celeration line analysis and two-standard deviation band analysis were completed for most of the outcomes measures used in this study. Median/interquartile range analysis was used for the MAS, as it is an ordinal scale. Visual analysis was also completed. Several of the data sets had variable data in the Pre-intervention A phase. Some data sets demonstrated greater variability than others in this first phase. The outcome measures that had variable data in the Pre-intervention A phase were the: ArmA (active and passive function subscales), SIS (Stroke Recovery subscale), grip strength, MAS (finger flexors) and SSEQ (activity and self-management subscales). Two standard deviation band analysis can be used with variable or fluctuating baseline data[127] and may provide a more accurate analysis of the data than celeration line analysis, when baseline data is variable. Comparison of change in mean scores between phases to established MCID/MDC/MIC values was also done.

During two-standard deviation band analysis, at least two consecutive data points fell outside the two-standard deviation range in several of the outcome measures: CAHAI-7, FMA-UE, ArmA (active and passive function subscales), SIS (Stroke Recovery subscale), grip strength and the SSEQ, Self-management scale, indicating that a statistically significant change had occurred between the Pre-intervention and Intervention/Post-intervention phases.[92,126-128]

Celeration line analysis of the two data sets with stable Pre-intervention phase data (CAHAI-7 and FMA-UE) indicated that a real change in observed behaviour occurred as all the data points were above the celeration line.[88,127] Celeration line analysis wasn't plausible with the following data sets due to variability in the baseline data: ArmA (active function subscale), grip strength and MAS (finger flexors).

Median/interquartile range analysis indicated that a meaningful change had occurred when evaluating the MAS data for the elbow, wrist and finger flexors, as the interquartile bands between phases did not overlap.[126]

Comparison of change in mean/median scores between phases is illustrated below in **Table 3**. Established MCID/MDC/MIC values are also shown, as in **Appendix K**.

Table 3: Change in Mean/Median Scores, Participant 2

Outcome Measure	**Change in mean scores between Pre-intervention A and Intervention B phases**	**Change in mean scores between Intervention B and Post-intervention A phases**	**Total change in mean scores between Pre-intervention A and Post-intervention A phases**	**MCID/MDC/MIC**
CAHAI-7	2.4	2.0	4.4	MDC=6.3 points for 13 point scale[99]
ArmA, active function subscale	-12.7	-4.0	-16.7	MIC=1.1[97]

Outcome Measure	Change in mean scores between Pre-intervention A and Intervention B phases	Change in mean scores between Intervention B and Post-intervention A phases	Total change in mean scores between Pre-intervention A and Post-intervention A phases	MCID/MDC/MIC
ArmA, passive function subscale	-5.0	-0.3	-5.3	MIC=2.5[97]
SIS, Stroke Recovery scale	0	16.7	16.7	Change of 10-15 points is clinically meaningful[102]
FMA-UE	10.0	7.0	17.0	MCID=9.0[18] MDC=5.2[107]
Grip strength	1.0 kg	3.1 kg	4.1 kg	MCID=5.0 kg for paretic dominant hand[117]
SSEQ, Activity subscale	-3.3	4.0	0.7	Not established
SSEQ, Self-management subscale	1.3	1.7	3.0	
COPM, Performance	4.8	0.6	5.4	2-point increase is considered

Outcome Measure	**Change in mean scores between Pre-intervention A and Intervention B phases**	**Change in mean scores between Intervention B and Post-intervention A phases**	**Total change in mean scores between Pre-intervention A and Post-intervention A phases**	**MCID/MDC/MIC**
COPM, Satisfaction	5.6	0.8	6.4	clinically significant[118]
Outcome Measure	**Change in median scores between Pre-Intervention A and Intervention B phases**	**Change in median scores between Intervention B and Post-intervention A phases**	**Total change in median scores between Pre-intervention A and Post-intervention A phases**	**MCID/MDC/MIC**
MAS, elbow flexors	0	-2.0	-2.0	1 point decrease is generally seen as a clinically important difference[112]
MAS, wrist flexors	0	-2.0	-2.0	
MAS, finger flexors	-2.0	0	-2.0	

Legend: MCID = minimal clinically important difference, MDC = minimal detectable change, MIC = minimal important change, CAHAI-7 = Chedoke Arm and Hand Activity Inventory-7, ArmA = Arm Activity Measure, SIS = Stroke Impact Scale, FMA-UE = Fugl-Meyer, Upper Extremity, MAS = Modified Ashworth Scale, SSEQ = Stroke Self-Efficacy Questionnaire, COPM = Canadian Occupational Performance Measure

QUALITATIVE DATA RESULTS

ANALYSIS OF INTERVIEW RESULTS

The importance of continued therapy with the SaeboFlex orthosis, after discharge from inpatient rehabilitation, was noted in both participants' post-intervention interviews. The participants communicated a strong need to not 'give up' and to work hard to reach their goal of improved arm and hand use. Improved functional use of the paretic arm and hand was a common goal, while improved function positively affected the participants' confidence to continue with the therapy program. Three 'person' themes emerged from the qualitative analysis of Participant 1 and Participant 2's post-intervention interview data; 'confidence from progress made and self-efficacy to continue with arm therapy,' 'decreased impairment, increased function' and 'cognitive processes' which were all found to be mutually reinforcing and in turn led to a fourth 'person' theme 'hope for continued arm recovery'. For Participant 1, the 'cognitive processes' theme was comprised of four subthemes, 'sense of control,' 'relates to previous knowledge,' 'active problem solving' and 'developing self-knowledge'. Although data emerged from both participants during the qualitative interviews that led to the 'cognitive processes' theme, this appeared to be a stronger theme for Participant 1, with several comments made during the interview itself as well as during the intervention sessions. These comments and quotes are further described below. In addition, a 'context' theme emerged from the qualitative data that formed the background for the four 'person' themes. This 'context' theme was derived from three subthemes, 'service delivery,' 'physical environment' and 'social supports'. Although 'context' was an important theme that emerged from both

participants' qualitative data, there were some definite differences between participants in the information that emerged in these areas, which will be further discussed in the following sections. The themes and subthemes are described in the sections below and are illustrated by quotes from the participants. **Figure 53** illustrates the relationships between themes and subthemes for Participants 1 and 2.

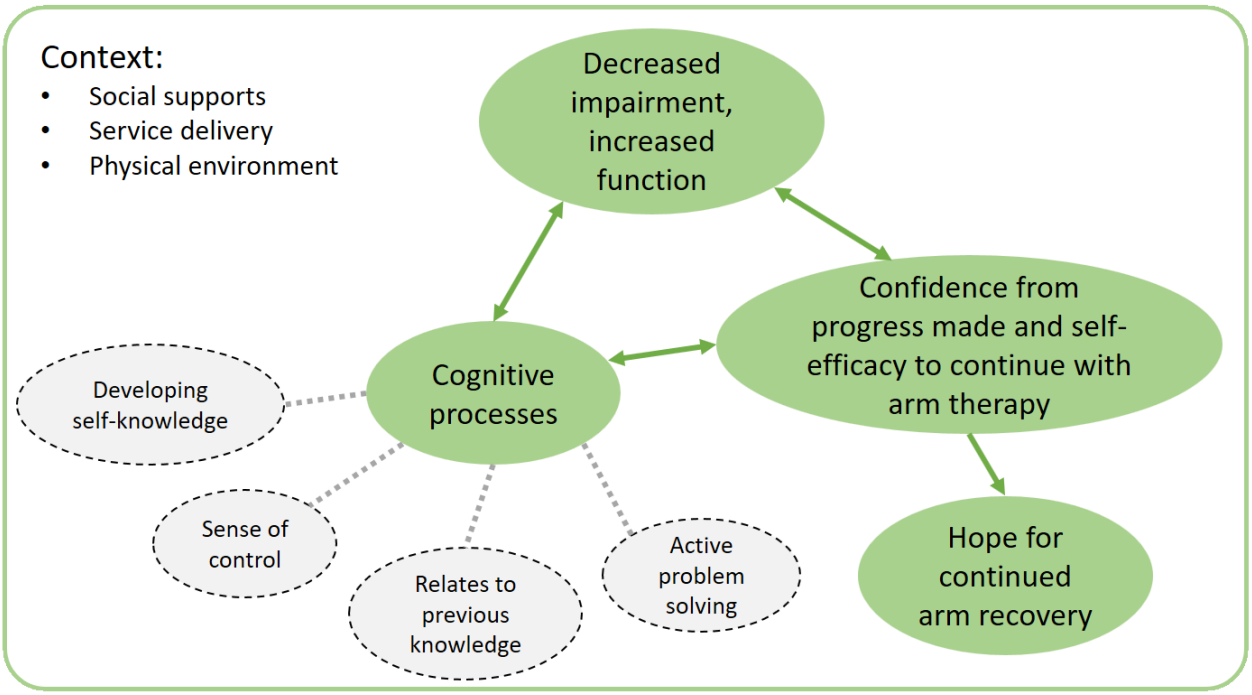

Figure 53: Relationships between themes and subthemes for Participants 1 and 2

PARTICIPANT 1

THEME: CONFIDENCE FROM PROGRESS MADE AND SELF-EFFICACY TO CONTINUE WITH ARM THERAPY

One of the themes, 'confidence from progress made and self-efficacy to continue with arm therapy' referred to the confidence derived from the observations of progress made in arm function as well as the self-efficacy to continue with therapy for the arm after the study was complete. These observations of progress and the participant's confidence were mutually reinforcing. For Participant 1, there was a strong emphasis on the continuous progress being made with his arm and hand movement, the awareness of which helped to improve his confidence. The fact that he could do more things with his paretic right arm appeared to increase his confidence and also motivated him to continue with the SaeboFlex program. This is well illustrated by several comments: "*I know for sure that it (arm) will improve because there's always improvements, like every week, there's something*" and "*it (right hand) gets stronger, like almost every day doing the exercise (with the SaeboFlex)*" and "*the fact I can do more I think that builds my confidence*" and "*(confidence for moving and using the arm) has definitely changed because I have much more movement in my shoulder and my grip like I mentioned is much stronger and I can straighten my fingers out, to a certain extent….*" This participant also described his motivation to continue with the SaeboFlex program in the future as well as his confidence that he will be able to continue with the program. This is illustrated by the following quote: "*I'm 100% confident (that can continue to use the SaeboFlex at home after the study). There's no issue with that at all*". This participant's perception of his recovery also appeared to affect how he felt about himself, "*the fact that I can do more things, just being*

able to accomplish specific tasks makes it, it's not as frustrating" and "*I'm very happy with the progress I've made…*".

THEME: DECREASED IMPAIRMENT, INCREASED FUNCTION

A second theme, 'decreased impairment, increased function' referred to the strength, tone and movement changes noticed by the participant in the paretic arm and hand after the therapy program with the SaeboFlex orthosis, which led to improved functioning in daily tasks. This improved functioning in daily tasks involved progress with the task itself as well as less dependence on others for help. Participant 1 especially described improvements in the strength, movement and muscle bulk of his paretic arm, which included his new ability to straighten out his elbow, "*I think (using the SaeboFlex) has improved my grip strength tremendously*" and "*The shoulder for sure has gotten stronger, in other words I can lift my arm much higher than I used to be able to*" and "*…the arm will straighten out very easily for that now (putting things lower down), which it couldn't do before*" and "…*the flexibility has improved I think in my wrist movement.*" This participant also described improvements in how his paretic hand opened, which he related to an improved ability to straighten his fingers, "*the more frequently I do it (use the SaeboFlex), the easier it is to keep the hand open without using the SaeboFlex, like when I'm doing other chores or things outside of the exercises*" and "*I can straighten my fingers better than I used to be able to*" which he also related to improved function, "*I have no problems putting a glove on anymore*". These improvements in arm movement and strength led to several improvements in how he could use his hand for daily activities, "*Just using my hand to hold things down, it's strong enough that it forces things into*

the cutting board and then I can cut with the left (dominant) hand" and "*I tried using a regular spoon and fork the other day to eat and I could actually lift the food up using my right hand*" and "*I have enough strength that I can use the right hand to hold the shower head under water pressure to spray my left side*" and "*I can pull the zipper up on my jackets very easily now*".

THEME: COGNITIVE PROCESSES

A third theme, 'cognitive processes' referred to the mental components of a person and included the processes of thinking and remembering as well as self-reflection and goal setting. As previously mentioned the 'cognitive processes' theme for Participant 1 was derived from four subthemes, 'sense of control,' 'relates to previous knowledge,' 'creative problem solving' and 'developing self-knowledge'.

SUBTHEME: SENSE OF CONTROL

One of the subthemes that led to the 'cognitive processes' theme was 'sense of control'. This subtheme referred to feelings of choice and empowerment over when and how the SaeboFlex therapy was completed. Participant 1 indicated that it was important to him to have the freedom and flexibility to do the SaeboFlex program at a time that worked for him. This was often late in the evening, which seemed to work well for his family's schedule, and is illustrated by the following quote, "*it allows me to do my exercises at my own pace and have the freedom to do it whenever I want to do it.*" Having a set program to follow was also identified as being helpful for this participant, "*I think it (SaeboFlex program) structures my exercises so that I can't really stray from them in the sense that it forces me to do things in a particular way.*"

SUBTHEME: RELATES TO PREVIOUS KNOWLEDGE

A second subtheme that led to the 'cognitive processes' theme was 'relates to previous knowledge'. This subtheme referred to strategies that this participant previously used, prior to his stroke, to think about and participate in physical activity, including following a set schedule and the need to work hard in order to see results, "*My goal would be to continue with it (using the SaeboFlex) at least three times a week and maybe one day on the week-end*" and "*steady, constant work (when using the SaeboFlex).*"

SUBTHEME: ACTIVE PROBLEM SOLVING

A third subtheme that led to the 'cognitive processes' theme was 'active problem solving' which referred to the idea of being able to independently look at ways to accomplish new tasks and solve challenges as they came up, including the ability to progress the therapy program as needed. This participant discussed the awareness of the need for increased time to accomplish new tasks and the importance of trying tasks on his own, even if they took more time, "*I think not overcompensating for a person, just giving them time to figure it out and not rushing them*" and "*There's nothing in the house that I can't do if I give myself enough time*." For this participant, this also involved not only being aware of the importance of increasing the difficulty of the SaeboFlex program but also having confidence in his ability to progress the program on his own, "*Because the way I use it (SaeboFlex) can be modified, in other words make it more difficult for myself, that doesn't seem to be, like right now I don't see any end in the process*."

SUBTHEME: DEVELOPING SELF-KNOWLEDGE

A fourth subtheme under 'cognitive processes' was 'developing self-knowledge' which referred to the participant's growing awareness of his own arm recovery including times when he noticed he had used his paretic right arm automatically for a task that he normally would have done with his left arm, "*The other day my right ear was itchy and I would usually use my left hand (to scratch it) but I was able to bring my right (hand up, to scratch it), even before I thought about it*." This awareness of his own arm recovery process also included some reflection on what time of day it was best to work on his arm training, *"…certain times of the day it's very easy to straighten the arm out and I have complete control straightening the fingers and other times, it depends on what I've done during the day or what time of day it is.*" This participant also indicated a desire to know the purpose of each exercise he worked on with the SaeboFlex orthosis, "*…if you understand that (the purpose) I think the exercise becomes more effective*; *if you don't really understand the purpose of what you're doing, it's not going to help.*" He also developed an awareness of how the frequency of using the SaeboFlex orthosis affected his arm, "*It seems like the more I use it (SaeboFlex) the better I get at things.*"

THEME: HOPE FOR CONTINUED ARM RECOVERY

A fourth theme 'hope for continued arm recovery' appeared to be derived from the other three 'person' themes and referred not only to feelings of pride in the progress made so far with his arm recovery but also to optimism about his future arm recovery. The participant noted how daily tasks were getting easier to do which gave him hope that his arm would continue to improve. "*I realize I can do things, I do, do them with it (right hand) and it does work…,*"

"*Something you've never done for say months and you don't think you can do it but then you try it and you say, you know I can do this*". The progress that this participant noted made him feel hopeful for more arm recovery, "*I'm very happy with the progress I've made and expect to make in the future.*"

THEME: CONTEXT

During the qualitative data analysis, three subthemes emerged that developed a 'context' theme. These 'context' subthemes together formed the background for the other four themes. Although not as predominant in the data obtained during the interviews as the 'person' themes, the 'context' subthemes were found to underlie the other 'person' themes and influence them. The three 'context' subthemes, 'service delivery,' 'physical environment' and 'social supports' will be described below and illustrated with quotes from the participant.

SUBTHEME: SERVICE DELIVERY

One of the 'context' subthemes that formed the background for the 'person' based themes was 'service delivery' which referred to the structure of the home therapy program itself, for users of the SaeboFlex orthosis after stroke. Participant 1 described the therapeutic relationship and the location of the therapy intervention itself, both which he found personally helpful, "*I think they (other SaeboFlex users) have to trust that the person training them knows what they're doing even though it (the program) may not feel comfortable at first*" and "*…the fact that you came to the house made it a thousand times easier than if I had to go somewhere*."

SUBTHEME: PHYSICAL ENVIRONMENT

A second 'context' subtheme that formed the background for the 'person' based themes was 'physical environment' which referred to the participant's view of his personal surroundings as well as characteristics of those surroundings, including the temperature, which affected how he was able to use his arm, "*Have your work space clear and uncluttered so you don't trip over anything, move everything out of the way*" and "*…if I'm subjected to really cold weather my arm will tighten up and I can't straighten that arm until I get back to a warm place*".

SUBTHEME: SOCIAL SUPPORTS

A third 'context' subtheme that formed the background for the 'person' based themes was 'social supports' which referred to the support required to assist with the SaeboFlex device itself as well as the support required to continue with a challenging therapy program. Participant 1 described how important it was to him for his family to allow him the time to practice things and figure things out on his own, as this allowed him to be more independent, "*…my family is very good for that (not rushing me)…realizing that it takes me longer to do things than it used to and they just wait and eventually if they give me enough time then I can do it"* and *"I tell her (his wife) don't do anything for me if you think I can do it."*

PARTICIPANT COMMENTS CAPTURED IN LOGBOOK

Participants were encouraged to write comments in their logbooks during the 8-week intervention. These comments, combined with comments made by the participant during the intervention sessions with the principal investigator and documented verbatim, are shown below.

Week 1: “hard to grip balls at first, hard to move arm with elbow at side” “easier if concentrate on relaxing the arm”

Week 2: “(have to) concentrate more for grip with the silver spring or else will drop the ball”

Week 3: “harder to let go (with silver spring), waited 10 seconds between balls to straighten fingers,” “I think it’s the silver springs that are helping, I have to concentrate so much more to let go,” “able to squeeze washcloth with more force (this week)”

Week 6: “My arm feels looser the day after I use the Saebo”

Week 7: “able to open fingers more now when letting go of things” “it’s easier to put my winter glove on now”

Week 8: “Thanks for helping me and allowing me to participate in this study, its been a great benefit to me.”

PARTICIPANT 2

THEME: CONFIDENCE FROM PROGRESS MADE AND SELF-EFFICACY TO CONTINUE WITH ARM THERAPY

This theme, as previously described for Participant 1, also emerged during the analysis of Participant 2’s interview data. For Participant 2, there was a strong emphasis on feeling a sense of accomplishment and pride that he was able to complete the 8 week SaeboFlex program, *“Especially (feeling good) when I finished the 8-week program.”* There was also an emphasis on feeling confident that he would continue to use his arm after the SaeboFlex intervention was complete as well as feelings of pride that his ability to move and use his arm had improved

during the course of the study intervention, *"I'm pretty sure I can (continue to use arm after study is over) because there's times when I have to…I practice"* and *"I have confidence (to do some of the things I couldn't do before)."*

THEME: DECREASED IMPAIRMENT, INCREASED FUNCTION

This theme, as previously described for Participant 1, also emerged from the interview data for Participant 2. Participant 2 noted that the strength of his hand had increased, as had his ability to move his arm, especially the shoulder and the hand. "*I have pretty good strong grip now, mostly in my hand*" and "*to hold on(to) something (has gotten easier). I have no problem to hold something"* and "*(I can) lift up my arm pretty high now. Before I couldn't, I couldn't move it*" and "*Helps, helps me a lot. Helps me move my hand good (and) my fingers*". Participant 2 also noted that his arm felt looser after using the SaeboFlex orthosis, "*It tends to loosen up my arm anyways. My elbow is looser (now) and I can put my arm straight now.*" He also noted that several of his daily tasks had gotten easier for him to do with his right hand, "*I can put my socks on now. Before I couldn't do it (put socks on)*" and "*Grabbing a towel or turning the tap on or using a fork…holding the fork right too, I'm able to do it*."

THEME: COGNITIVE PROCESSES

This theme, as previously described for Participant 1, referred to the mental components of a person and included the processes of thinking and remembering as well as self-reflection and goal setting. Although subthemes did not emerge to specifically support this theme, as they did for Participant 1, for Participant 2 the focus seemed to be more on attaining his goal of

continued arm recovery despite how challenging the SaeboFlex program was for him at times, "*Just keep on trying. My goal is to keep going*" and "*There's times I wanted to quit but I didn't want to…so that was the main goal, not to (quit). Just to keep on trying*." This participant also mentioned, during the post-intervention interview, that he would like to encourage others to work hard on their SaeboFlex therapy programs as well, "*just do the things, the homework. The homework was good.*" "*Never give up, that's the only thing, advice I can give them*."

THEME: HOPE FOR CONTINUED ARM RECOVERY

As for Participant 1, a fourth theme 'hope for continued arm recovery' appeared to be derived from the three mutually reinforcing 'person' themes. For Participant 2, this emerged as feelings of pride in the progress made so far as well as hope for continued arm recovery in the future, and included consideration of the time and patience he will need to continue working on his arm program, "*Well I know it's, it's going to get better (right arm) because it's able to do stuff on its own now*" and "*I came a long way, now I can do it (put on socks). Before it was tough for me,*" and "*I know it's just going to take time, sooner or later I'll get there; I just (need to) keep on practicing."*

THEME: CONTEXT

As for Participant 1, three 'context' subthemes emerged from the qualitative data analysis, which formed the background for the four 'person' themes. The three 'context' subthemes, 'service delivery,' 'physical environment' and 'social supports' will be described below and illustrated with quotes from the participant.

SUBTHEME: SERVICE DELIVERY

One of the 'context' subthemes that formed the background for the 'person' themes was 'service delivery' which related to the structure of the home therapy program itself, for users of the SaeboFlex orthosis after stroke. Participant 2 indicated that he found the set 8-week program helpful, even though he found it difficult to pick up the 4" therapy balls using the SaeboFlex at the start of the program, "*Especially (feeling good) when I finished the 8-week program*" and "*My first (time) it was hard. Was hard for me to grab on (to the ball) and eventually I got used to it and it worked*" and "*It's easy to grab on (to) something now*."

SUBTHEME: PHYSICAL ENVIRONMENT

As for Participant 1, a second 'context' theme emerged from the qualitative data that formed the background for the 'person' themes. The 'physical environment' subtheme emerged as being particularly important for Participant 2. As mentioned previously, Participant 2 stayed in three different hotel rooms during the study intervention period and was therefore not in his own home. The hotel rooms were all small and although each had a table to use for practicing grasp-release tasks as part of the study intervention, options/tasks for practicing using the hand after the SaeboFlex orthosis was removed were limited. Although not recorded in the post-intervention interview, Participant 2 mentioned to the principal investigator on several occasions during the study intervention that he often did not sleep well and that the bed was often uncomfortable and/or there was excessive noise in the hotel during the night. Several other environmental stressors were also not recorded during the post-intervention interview but involved issues that were mentioned frequently by Participant 2 and his wife at the

intervention visits. This included the stress of having to liaise frequently with a government agency regarding meal payments and transportation requests to various appointments that occurred concurrently during the intervention period. Although Participant 2's wife was primarily responsible for these phone calls and interactions, this appeared to be something that was stressful to both Participant 2 and his wife, during the time of the study intervention.

SUBTHEME: SOCIAL SUPPORTS

As for Participant 1, a third 'context' subtheme emerged and formed the background for the 'person' themes. This 'social supports' subtheme referred to the support required to assist with the SaeboFlex device itself as well as the support required to continue with a challenging therapy program. Participant 2 clearly identified that having his family around him helped him to stay motivated to complete his therapy program using the SaeboFlex orthosis, "*As long as my family's around me to (be there), that helps me a lot,*" and "*That's why I don't (quit), not allowed to try and quit.*" Participant 2 also accepted help from his wife to don the SaeboFlex orthosis each time he used it, which he saw as helpful, "*Mostly got help at first (from wife, to don SaeboFlex).*"

PARTICIPANT COMMENTS CAPTURED IN LOGBOOK

Participants were encouraged to write comments in their logbooks during the 8-week intervention however Participant 2 did not record any comments. Comments made by Participant 2 during the intervention sessions with the principal investigator were documented verbatim and are shown below.

Week 1: “not using right hand at all; I eat OK with my left hand now,” “couldn’t use SaeboFlex every day – shoulder was sore”

Week 2: “shoulder a bit sore – didn’t use SaeboFlex every day,” “my arm feels stronger,” wife: “we aren’t babying him as much anymore”

Week 3: “my thumb is starting to straighten”

Week 4: “not feeling great this week,” wife: “he’s improving”

Week 5: participant and wife: “did better on the assessments this time”

Week 6: “used the SaeboFlex every day last week” “eating some of my meals with my right hand now”

Week 8: wife: “he’s improving”

MIXED METHOD DATA RESULTS

PARTICIPANT 1

During the qualitative data analysis, four ‘person’ themes emerged, along with one ‘context’ theme that emerged from three subthemes, as outlined above. One of the themes ‘confidence from progress and self-efficacy to continue with arm therapy’ described the link between this participant’s confidence and his progress as well as the self-efficacy to continue with his arm therapy program after the study was complete. Several quotes from the participant suggested that he had noticed improvements in his arm recovery, such as, “*I know for sure that it will improve because there’s always improvements, like every week, there’s something*” and “*I’m*

very happy with the progress I've made…" which supports many of the quantitative outcomes that suggested there was steady improvement, especially considering the results of some of the outcome measures such as the CAHAI-7 and the FMA-UE, which both showed statistically significant improvement over the course of the 8-week intervention. This theme also indicated that the participant felt that his confidence had improved, saying, "*the fact I can do more I think that builds my confidence*" and "*(confidence for moving and using the arm) has definitely changed because I have much more movement in my shoulder and my grip like I mentioned is much stronger and I can straighten my fingers out, to a certain extent and the flexibility has improved I think in my wrist movement,*" which potentially more fully explains this participant's view of the changes in his confidence, and the link between his progress and his confidence, than the results from the SSEQ (Activity and Self-management subscales) where it appeared that his confidence started high and remained high.

The theme, 'decreased impairment, increased function' described the physical changes that the participant noticed in his upper extremity as the SaeboFlex intervention progressed, as well as how those physical changes affected the functional changes he noted in his upper extremity. Participant 1 indicated that he found that the strength of his grip had improved throughout the course of the SaeboFlex intervention stating, "*I think (using the SaeboFlex) has improved my grip strength tremendously*". Although the quantitative measure of this participant's grip strength improved, as shown by the two-standard deviation band analysis, it did not meet the criteria for MCID for somebody with a paretic non-dominant hand post stroke. Quotes from this participant also indicated that he found his paretic right hand to be looser and to open easier

stating, "*I can straighten my fingers better than I used to be able to*" and "*I have no problems putting a glove on anymore*". This supports the quantitative data obtained from the MAS (finger flexors) and the ArmA, active and passive function subscales, which all showed a significant change in hand spasticity and use of the hand despite spasticity, during the 8 weeks of the intervention. The qualitative analysis also indicated that the participant felt that movements of his paretic elbow and wrist were better, "*…the arm will straighten out very easily for that now (putting things lower down), which it couldn't do before*" and "..*and the flexibility has improved I think in my wrist movement,*" which supported scores obtained quantitatively on the MAS (elbow and wrist flexors) where a decrease in score on the MAS of greater than 1 point is generally accepted as a clinically important difference.[112] Participant comments from his logbook from weeks 6 and 7 also supported these changes in arm spasticity, "*My arm feels looser the day after I use the Saebo,*" "*able to open fingers more now when letting go of things*" and "*it's easier to put my winter glove on now*." Quotes described in this theme also indicated that the participant had noticed changes in the ability to use his paretic arm for daily functional tasks, such as, "*I have enough strength that I can use the right hand to hold the shower head under water pressure to spray my left side*" and "*I can pull the zipper up on my jackets very easily now.*" This supports what was found quantitatively with the CAHAI-7 and the ArmA, active function subscale, which were the two primary quantitative outcome measures for the study and also supports the significant improvement noted in COPM scores (both Performance and Satisfaction scores) between Pre-intervention and Intervention/Post-intervention assessment times.

The theme, 'cognitive processes' was composed of 4 subthemes, and included the mental processes of thinking, remembering, self-reflection and goal setting. In the second subtheme, 'relates to previous knowledge' Participant 1 drew upon his former knowledge of exercise training as indicated by, "*My goal would be to continue with it (using the SaeboFlex) at least three times a week and maybe one day on the week-end*". This aligns with the quantitative recording of 'Sessions of SaeboFlex use' which indicates that during the 8-week intervention the participant used the SaeboFlex orthosis at least three times a week in all but one of the weeks (week 5). In the third subtheme, 'active problem solving' the participant indicated that, "*There's nothing in the house that I can't do if I give myself enough time*" which supports the improved scores obtained quantitatively on the COPM, CAHAI-7 and SIS, Stroke Recovery scale, that look specifically at activity based tasks.

Comments from this participant's logbook for week 3, "*harder to let go (with silver spring), waited 10 seconds between balls to straighten fingers*" and "*I think it's the silver springs that are helping, I have to concentrate so much more to let go*" further explain the quantitative findings of the number of 'Repetitions of SaeboFlex use" where the number of repetitions completed in weeks 3 to 5 decreased more than the number of 'Sessions of SaeboFlex use' decreased during these same three weeks. As stated by the participant, this is perhaps due to the increased time required to let go of the 4" therapy balls when using the silver springs, as the silver springs encouraged a more active release of flexor tone and activation of the finger extensors than did the stiffer yellow, red or blue springs. These comments in the participant's logbook also indicate a greater degree of concentration when using the weaker silver springs,

which may link with the 'active problem solving' subtheme, indicating a greater need to 'focus' on the task.

With the qualitative analysis, we were able to gain more insight into some important aspects of Participant 1's upper extremity recovery than we could have with the quantitative analysis alone**.** In the theme, 'hope for continued arm recovery' we were able to gain more insight into how this participant perceived his upper extremity recovery as well as his hopes for the future, "*I realize I can do things, I do, do them with it (right hand) and it does work…*" and "*Something you've never done for say months and you don't think you can do it but then you try it and you say, you know I can do this*." These important insights, while not directly captured in the quantitative data, may help to explain the significant changes that occurred in this participant's COPM Performance and Satisfaction scores from the Pre-intervention to the Intervention/Post-intervention phases.

PARTICIPANT 2

During the qualitative data analysis, four 'person' themes and one 'context' theme with three subthemes emerged, as outlined above. One of the themes, 'confidence from progress made and self-efficacy to continue with arm therapy' described the link between this participant's confidence and his progress as well as the self-efficacy to continue using the affected arm after the study was complete. This participant suggested that he felt that his confidence had improved as a result of the SaeboFlex intervention, *"I have confidence (to do some of the things I couldn't do before)".* This participant's self-efficacy to continue using his arm after the study was completed was illustrated by the following quote, *"I'm pretty sure I can (continue to use*

arm after study is over) because there's times when I have to…I practice". Quantitatively, the SSEQ was used to measure changes in self-efficacy from the Pre-intervention to Intervention and Post-intervention phases. Although the data for the Activity scale of the SSEQ for Participant 2 indicated a potential drop in self-efficacy during the Intervention phase, the Self-management scale of the SSEQ indicated that an increase in self-efficacy for self-management behaviours may have occurred during the Intervention and Post-intervention phases, compared to the Pre-intervention phase.

The theme, 'decreased impairment, increased function' described the physical changes that the participant noticed in his upper extremity as the SaeboFlex program progressed, as well as how those physical changes affected the functional changes he noted in his upper extremity. Quotes from the participant indicated that he felt his grip strength had improved throughout the course of the SaeboFlex intervention stating, "*I have pretty good strong grip now, mostly in my hand*" and "*to hold on(to) something (has gotten easier). I have no problem to hold something.*" Although the quantitative measure of this participant's grip strength improved significantly, as measured by two-standard deviation band analysis, it did not meet the criteria for MCID for an individual with a paretic dominant hand post stroke. Quotes from this participant also indicated that he felt his arm movement had increased stating, "*(I can) lift up my arm pretty high now. Before I couldn't, I couldn't move it*" and "*Helps, helps me a lot. Helps me move my hand good (and) my fingers*". This self-observation supports the quantitative scores obtained from the FMA-UE, which improved significantly according to the two-standard deviation band analysis and also exceeded the established MCID value for this outcome measure. Quotes from this

participant also indicated that he felt that his arm, particularly the elbow, was looser, stating "*It tends to loosen up my arm anyways. My elbow is looser (now) and I can put my arm straight now.*" This supports the change noted in the quantitative MAS (elbow flexor) scores where a meaningful change was found to have occurred between phases of the study, according to the median/interquartile range analysis, a change which also exceeded the change value required to establish a clinically important difference for this outcome measure. This quote also may have helped explain statistically significant differences found between study phases in the ArmA (both active and passive function subscales). Quotes from the participant such as, "*I can put my socks on now. Before I couldn't do it (put socks on)*"and "*Grabbing a towel or turning the tap on or using a fork…holding the fork right too, I'm able to do it,*" illustrate improved functioning in daily tasks, which supports significant scores obtained on the CAHAI-7, the SIS, Stroke Recovery scale, as well as the ArmA (active function subscale) in addition to the clinically significant changes noted in the Performance and Satisfaction scores of the COPM between the Pre-intervention and Intervention/Post-intervention phases. Comments documented from the participant's wife, "he's improving" at 4 and 8 weeks of intervention also help explain the scores obtained on the quantitative measures listed above. Other comments, "we aren't babying him as much anymore" may also support quantitative changes noted on the activity-based outcome measures, as the participant was receiving less help from his family.

The theme 'cognitive processes' described the role of such mental components as thinking, remembering, self-reflection and goal setting. Quotes from this participant such as, "*Never give up, that's the only thing, advice I can give them*" and "*just do the things, the homework. The*

homework was good," supports the quantitative recording of 'Repetitions of SaeboFlex use' and 'Sessions of SaeboFlex use' which although show some inconsistencies during weeks 7 and 8 of the intervention, generally show persistence and dedication to the intervention by the number of sessions and repetitions completed. Despite having a bad chest cold during week 4 of the intervention, feeling unwell during weeks 7 and 8 of the intervention, being away from home, moving frequently and having limited room to practice tasks in his small hotel rooms, Participant 2 consistently worked hard on his prescribed SaeboFlex program.

With the qualitative analysis, we were able to gain more insight into some important aspects of Participant 2's recovery than we could have with the quantitative analysis alone. The theme, 'hope for continued arm recovery' helped us gain more insight into how this participant felt about his progress and his hopes for the future, with quotes such as, "*Well I know it's, it's going to get better (right arm) because it's able to do stuff on its own now*" and "*I know it's just going to take time, sooner or later I'll get there.*" These important insights, while not directly captured in the quantitative data, may help to explain the significant changes that occurred in this participant's COPM Performance and Satisfaction scores, as well as explain changes noted in the SSEQ, Self-management scale, from the Pre-intervention to the Intervention/Post-intervention phases.

PARTICIPANTS 1 AND 2

During the mixed method analysis of both participants' data, several similarities were noted. The mixed method data analysis showed that both participants had quantitative increases in arm movement, hand grip strength and functional use of the paretic arm and hand that were

supported by the qualitative data. Significant quantitative decreases in spasticity of the elbow flexors, was supported by the qualitative data for Participant 2 as were the elbow, wrist and finger flexors scores on the MAS for Participant 1. Grip strength scores improved significantly for both participants using two standard deviation band analysis, which although was supported by the qualitative data for both participants, did not meeting the MCID scores for either participant (for both a dominant paretic and non-dominant paretic hand). COPM scores improved significantly for both participants, with the greatest improvements noted between the Pre-intervention (baseline) and Intervention (4-week) assessment points.

During the qualitative analysis of both participants' post-intervention interview data, several common themes and subthemes emerged and were related to each other as outlined in the model previously described. Although one of the themes involved the participants' level of self-efficacy and confidence in continued arm recovery, one key difference also emerged. While the qualitative data from Participant 1's interview indicated that there was a relationship between his self-efficacy to continue with the arm therapy program (using the SaeboFlex orthosis), the data that emerged from Participant 2's interview indicated that there was a relationship between his self-efficacy and continued use of his paretic arm, not necessarily using the SaeboFlex orthosis. Participant 2 was seen to view the 8-week SaeboFlex intervention as time-limited and having an end point, so the focus was on completing the 8-week program but not necessarily using the SaeboFlex orthosis beyond that time. So, while the qualitative data indicated self-efficacy to continue therapy for his paretic arm, this may not have included ongoing use of the SaeboFlex orthosis to do that. When further comparing how the qualitative

results in this theme helped explain the quantitative results for both participants, it was noted that Participant 1 had high scores initially, which then persisted, on both the Activity and Self-management scales of the SSEQ, while Participant 2 had greater fluctuation of scores for both scales between phases of the study. Participant 2 showed significant improvement in the Self-management scale of the SSEQ over the 8-week intervention.

Another difference in the qualitative data between the two participants emerged in the area of 'cognitive processes' as outlined above. Four subthemes emerged from Participant 1's data in this area. These subthemes, as described above, included, 'sense of control,' 'relates to previous knowledge,' 'active problem solving' and 'developing self-knowledge'. These subthemes emerged to further clarify and define the 'cognitive processes' theme for Participant 1. Participant 1 appeared to be more self-reflective when it came to determining how to best understand the purpose and use of the intensive SaeboFlex intervention and frequently verbalized this during the post-intervention interview and also during the weekly intervention sessions with the principal investigator. Although Participant 2 set goals for himself related to the intervention itself, he did not often verbalize any thoughts related to self-reflection.

As mentioned, three 'context' subthemes also emerged from the data, for each participant, as a background for the four 'person' themes. Although these 'context' subthemes were described the same for each participant, the codes that made up these subthemes were different as was the impact of each subtheme on the four themes. For example, in the 'social supports' subtheme for Participant 1, there was an emphasis on doing things on his own, without help from anybody else. For Participant 2, the emphasis was more on the fact that support from the

family was not only helpful but necessary. This included support with donning the SaeboFlex orthosis as well as support to complete the intervention itself. Another 'context' subtheme, 'physical environment' was also described the same for each participant with the focus on the physical surroundings in which the intervention took place, but was very different for each participant. While this subtheme focused on environmental factors, such as temperature, for Participant 1, for Participant 2, this subtheme focused more on the environmental stressors that occurred during the time of the study intervention because this participant was not in his own home environment.

The mixed method data analysis showed that both participants shared the qualitative data outlined in the theme, 'Hope for continued arm recovery' which although not measured directly in the quantitative data, may have impacted the increase in scores noted quantitatively in the COPM and SIS, Stroke Recovery scale, for both participants and the increase seen in Participant 2's scores on the Self-management section of the SSEQ. This theme illustrated the link between awareness of progress already made in arm recovery and optimism about future recovery that both participants shared.

DISCUSSION

Early, intensive therapy that is progressed at a rate that is individually challenging is important for inducing neuroplasticity post stroke[15,17] and improving upper extremity outcomes.[19] This mixed methods study explored the effectiveness of the SaeboFlex orthosis in improving upper extremity recovery for those discharged from inpatient stroke rehabilitation and while waiting for outpatient occupational therapy. This study also explored the relationship between the

participants' level of self-efficacy and use of the SaeboFlex orthosis in the home environment as well as the participants' experience of use of the SaeboFlex orthosis in the home environment. Qualitative data analysis helped to explain and further clarify the quantitative results of this study.

QUANTITATIVE AND QUALITATIVE FINDINGS

Quantitatively, several of the outcome measures used in this study demonstrated significant change from the Pre-intervention to Post-intervention phases for both participants. Both participants' scores showed statistically significant improvements when evaluated with two-standard deviation band analysis on several of the outcomes measures: CAHAI-7, ArmA (active and passive function subscales), FMA-UE, SIS (Stroke Recovery scale) and grip strength. Both participants' scores also showed meaningful change on the MAS (elbow, wrist and finger flexors) when evaluated with median/interquartile range analysis. Both participants' scores for the COPM (Performance and Satisfaction) exceeded the 2-point increase considered to be clinically significant[118] with most of the change in score noted in the first 4 weeks of the study intervention for both participants.

When participants' scores were compared with established MCID/MDC/MIC scores, meaningful change was also noted. Both participants' SIS, Stroke Recovery scale scores exceeded 10-15 points which is considered to be clinically meaningful;[102] their FMA-UE scores exceeded the established MCID of 9.0[18] and their MAS (elbow, wrist and finger flexors) scores exceeded the generally accepted 1 point decrease said to be a clinically important difference.[112] Both participants' scores for the ArmA (active and passive function subscales) exceeded the

established MIC's for this assessment which are 1.1 and 2.5 respectively.[97] Although neither participants' change in grip strength exceeded the established MCID for a non-dominant or dominant paretic hand,[117] the authors of the MCID study admit that due to the small sample size, "the variability in change scores was large" indicating that they had subjects with "change scores less than the calculated MCID values who considered themselves 'much better'".[117] Perhaps more importantly, both participants indicated in the post intervention interview that they felt their grip strength had improved over the course of the intervention period. Although the MDC has not been determined for the CAHAI-7, the MDC is 6.3 points for the CAHAI-13[99] which has 6 more bilateral tasks than the CAHAI-7. It is assumed therefore that the MDC for the CAHAI-7 would be less than 6.3 points. Participant 1's change score on the CAHAI-7 was 21.7 points, indicating that a true change had likely occurred, while Participant 2's change score was 4.4 points.

For Participant 1, the greatest amount of change in the outcome measure scores occurred in the first 4 weeks of the study intervention, with the exception of changes in FMA-UE scores and grip strength. For Participant 2, the greatest amount of change occurred in the first 4 weeks for the following outcome measures: CAHAI-7, ArmA (active and passive function subscales), FMA-UE, MAS (finger flexors) and the SSEQ, self-management subscale, in addition to the COPM.

For the SSEQ, Participant 1 scored at the top end of both scales (activity and self-management) and showed only minimal change between study phases. Clinically meaningful changes to self-efficacy, as measured by this scale, may not have been possible due to a potential ceiling effect since self-efficacy for this participant started high and remained high. It is possible that the high

self-efficacy, as measured by the SSEQ, was linked to the positive results that this participant experienced using the SaeboFlex orthosis in this study.

It should be noted that there is not currently an established value for clinically meaningful change for the SSEQ and the activity scale has been criticized for not differentiating between the actual level of physical impairment resulting from the stroke and the lack of confidence the individual has in performing the specified task.[134] For example, Question 6, 'how confident are you that you can use both your hands for eating your food' may be difficult to answer for someone who is only able to use one hand to eat but still has confidence in his/her ability to perform the task of eating.[134] This confusion may have in fact contributed to Participant 2's variable responses in the activity scale of the SSEQ.

The self-management subscale of the SSEQ, dealing more with questions related to persevering with a home program, has not been criticized in this way and may offer some understanding of the relationship between self-efficacy and self-management. Participant 2 showed a statistically significant increase in this scale, with two-standard deviation band analysis, from the Pre-intervention to the Intervention/Post-intervention phases possibly indicating an increase in self-efficacy for self-management tasks.

Since the amount of time using the SaeboFlex orthosis was inconsistently recorded in the participants' logbooks, the number of sessions of use per week was captured instead. The number of SaeboFlex sessions per week met or exceeded the minimum suggested number of sessions (three times per week) in all but one week (week 5) for Participant 1 and in all but two

weeks (weeks 7 and 8) for Participant 2. Week 5 was a 'reassessment week' for Participant 1 (research assistant met with him three times in his home), which may have contributed to decreased use of the SaeboFlex orthosis that week. Weeks 7 and 8 were difficult for Participant 2 as he was ill and also changed hotels twice during that time period.

Repetitions of SaeboFlex use were also recorded. Participant 1 recorded 3865 more repetitions and one more session of use during the 8 weeks of the study intervention than did Participant 2. While Participant 1 stated that he "timed himself for 10 minutes a task" and recorded the number of reps completed during that time, Participant 2 was not initially timing himself, and instead stated he completed as many of each grasp-release task that he thought he could do. Participant 1 seemed to relate the SaeboFlex training program to other types of exercise training programs he had completed in the past, as was discussed in the 'cognitive processes' subtheme 'relates to previous knowledge,' and also noted that the more he used the SaeboFlex orthosis, the more improvements he observed with his arm recovery, as was discussed in the 'developing self-knowledge' subtheme. These 'cognitive processes' may have contributed to the greater number of repetitions that Participant 1 completed over the course of the intervention. As previously mentioned, some grasp-release tasks took longer to complete, resulting in fewer repetitions, especially if the task was graded up so the participant was using the least resistive silver spring. The participants therefore potentially took more time to release the 4" therapy ball, if using a silver spring, as it was a more challenging task. An increase in the number of repetitions completed may therefore not always be desired or be seen as 'progressing' the grasp-release activity.

Four ‘person’ themes and one ‘context’ theme emerged from the qualitative data, for both participants, which supported and further explained the quantitative data. The themes that emerged in this study aligned with results from a recent study that looked at patient and therapist experiences of the SaeboFlex orthosis, where patients (n=11) reported that they were able to achieve greater upper extremity function using the SaeboFlex orthosis and also experienced increased confidence and motivation.[135]

POTENTIAL INFLUENCE FROM OTHER VARIABLES ON STUDY FINDINGS

Both participants attended outpatient physiotherapy typically once or twice a week, starting the first week of the study intervention; however, Participant 1 did not attend physiotherapy during weeks two and three of the intervention due to cancelled physiotherapy appointments or conflicting medical appointments and Participant 2 missed some physiotherapy appointments due to illness. Both participants stated that the physiotherapy consisted mostly of work on balance and walking, as well as stretches for the shoulder. Both participants also mentioned having some shoulder soreness the day after physiotherapy, which they attributed to the shoulder stretching. This resolved quickly for Participant 1 and lasted somewhat longer for Participant 2, who also complained of shoulder pain related to the bed he was sleeping on in the hotel. While there is a possibility that the outpatient physiotherapy influenced the study results, the influence is likely negligible, especially since minimal homework related to active movement of the upper extremity was noted to be provided between physiotherapy appointments.

Both participants, being recently discharged from inpatient rehabilitation, had several medical appointments during the first few weeks of the study intervention. Despite this, both participants were able to do at least 3 sessions of grasp-release practice with the SaeboFlex orthosis during those first few weeks. Although fatigue from having multiple medical appointments within a short period of time may have affected the results of the study, this is thought to be the norm for many stroke survivors once discharged from inpatient rehabilitation and may make the results more generalizable.

As mentioned, Participant 2 stayed in a hotel with his wife for the duration of the study. This led to self-reported difficulties with sleep due to noise and an uncomfortable bed as well as limited options for progression of the SaeboFlex program due to only one table height and cramped space. Tasks completed after the SaeboFlex orthosis was removed were also somewhat limited as although there was access to a small bathroom, there was no access to a kitchen or other areas of a typical home in which to practice functional tasks. Participant 2 also suffered from illness during weeks 4, 7 and 8 which affected the number of sessions completed with the SaeboFlex orthosis, particularly in weeks 7 and 8, when he was feeling unwell and also changed hotels twice. The fact that Participant 2 had more limited opportunities for grading of his SaeboFlex program and for practice of functional tasks after the SaeboFlex orthosis was removed may have impacted on the results of the study. Certainly, the stress of being away from home may have affected the results of the study for Participant 2; however, it was noted by the principal investigator that despite being away from home and suffering from illness

during the study intervention, the participant was very motivated and carried out the prescribed SaeboFlex program as often as he was able to.

STUDY OBJECTIVES: WHAT WAS LEARNED?

This study had 3 main objectives as outlined in the Research Purpose and Objectives section. With respect to **Objective 1**, this study showed that use of the SaeboFlex orthosis did improve upper extremity function, strength, movement, spasticity and self-perceived occupational performance, with continued use immediately after discharge from inpatient stroke rehabilitation and while waiting for outpatient occupational therapy services. The mixed method data analysis showed that the qualitative data supported the improvements noted quantitatively as measured by several outcome measures in the areas of impairment, activity and participation.

With respect to **Objective 2**, the relationship between the participants' level of self-efficacy and use of the SaeboFlex orthosis in the home environment was explored. The SSEQ was used to evaluate self-efficacy at three time points throughout the study. Participant 1 scored high on both scales of the SSEQ at all three time points indicating that his self-efficacy started high and remained high throughout the study. While a ceiling effect may have been present, these high scores may also have been linked to the positive outcomes that Participant 1 experienced using the SaeboFlex orthosis at home during this study, since high self-efficacy has been linked with successful self-management behaviours post stroke.[63,69] In the post-intervention interview, Participant 1 indicated that his confidence had improved throughout the course of the study and was related to his ability to do more things with his paretic arm, improvements that were

not demonstrated in the SSEQ scores. Participant 2's data on the self-management scale of the SSEQ did increase significantly between study phases, as measured by two-standard deviation band analysis, indicating an increase in self-efficacy for self-management tasks. This was supported by data from the post-intervention interview where Participant 2 indicated that his confidence for moving and using his paretic arm had improved. Improvements in self-efficacy are possible and may be required before improvements in participation in daily activities can occur.[71]

With respect to **Objective 3**, participants' experience of use of the SaeboFlex orthosis in the home environment was explored. This was done through the post-intervention interviews carried out by the principal investigator after the study intervention was complete. Four 'person' themes and one 'context' theme emerged for each participant and a model was developed that described the relationship between the themes. Although each of the two participants completed the study in their 'home' environment, these two environments were very different from each other. Despite these differences, positive outcomes were described by both participants.

COMPARISON OF STUDY FINDINGS TO EXISTING LITERATURE

The results of this study add to and strengthen the literature supporting the use of the SaeboFlex orthosis early in the upper extremity recovery process post stroke. Although only a few studies have been completed with participants using the SaeboFlex orthosis in the early stages,[45,46,58] several similarities were noted between the current study and previous studies.

Similar to the current study, early studies showed significant improvements in impairment based outcome measures,[45,46] including the FMA-UE.[58] Although different outcome measures were used to measure changes in function or activity level, compared to those used in the current study, improvements were also noted.[45,46]

This study is the first to look at changes in spasticity, using the MAS, when the SaeboFlex orthosis is used in the early phases of stroke recovery, as well as the first to look at the effects of spasticity on passive and active movement goals using the ArmA. It is also the first study to measure participants' performance and satisfaction with individually identified occupational performance issues, by use of the COPM.

Similar to the current study, Stuck et al., observed variability in the number of grasp-release repetitions completed during their early interventional study and yet clinically significant improvements were still reported.[46] Although post intervention interviews were not completed in other early intervention studies, one study discussed the results of a post-intervention questionnaire which revealed that all participants felt the SaeboFlex training had improved their upper extremity outcomes[46] and another study noted that participants "felt empowered" using the SaeboFlex orthosis and reported improvements in self-management skills, however information on how these improvements were measured is not reported.[58]

Franck et al., in their study of 8 stroke patients, with a mean time of stroke onset of 9.3 weeks, which is similar to the mean time of stroke onset in the current study, noted that participants who showed little improvement in baseline assessments conducted once a week every second

week, over a 6 week period, improved more with use of the SaeboFlex orthosis than those who showed improvements initially on assessment.[45] Although the baseline assessments for the current study were different in that they occurred three times in one week, every second day, there may be some similarities, especially when looking at the demographic data from Participant 1, which indicated unchanged scores from admission to discharge from inpatient stroke rehabilitation on the CMSA-II, arm, hand and shoulder pain sections. Although these inpatient scores were unchanged, indicating no change in physical impairment of the paretic upper extremity during the course of this participant's inpatient rehabilitation, significant changes were later noted in upper extremity impairment and function with SaeboFlex use.

While recruitment for the current study was initially quick for the two participants, a third participant was not recruited. Lannin et al., in a recently published study that looked at the feasibility of using the SaeboFlex orthosis in a subacute setting with patients with little or no hand function, determined that training with the orthosis was feasible and "enabled massed UL practice", however slow recruitment was also identified as a limitation in that study, resulting in a study that was unfortunately underpowered.[136]

The theme of 'cognitive processes', which included codes related to the mental components of thinking, remembering and self-reflection, is similar to what was found in a study of eight chronic stroke survivors with upper extremity impairment who were interviewed while completing upper extremity tasks.[137] The participants in this study stated that "paying attention to and developing an awareness of the component movements of tasks" was more important

than just completing the task as it allowed them to repeat the movements when they performed other tasks as well.[137]

Three of the themes that emerged from the qualitative data analysis of the current study were similar to three themes reported in a recent pilot study by Andriske et al., that evaluated patient and therapist experiences using the SaeboFlex orthosis.[135] The theme 'hope for continued arm recovery' is also reflected in the pilot study, where the "sense of hope also encouraged further aspiration, as patients looked forward to achieving future goals as a result of their use of the SaeboFlex."[135] The theme 'confidence from progress made and self-efficacy to continue with arm therapy,' where the confidence and improvements made were mutually reinforcing, is also similar to that reported in the pilot study, where, "successful doing was a key factor in the building of confidence," as identified by 8 of the 11 study participants.[135] Several of the participants in the pilot study (10 out of 11), also reported having improvements in grip strength, movement, and control of their arm, which is similar to the 'decreased impairment, increased function' theme in the current study where physical and functional improvements were noted in the paretic upper extremity.[135] It should also be noted that therapists in this pilot study (n=5) found that use of the SaeboFlex orthosis helped to increase patient motivation, due to the "rapid improvements observed in patient function" and also enabled intense focus on the upper extremity during therapy sessions,[135] which although not recorded during the study intervention or post-intervention interviews, reflects the principal investigator's perception of use of the SaeboFlex orthosis during the study intervention. In addition, Soundy et al., linked task mastery to improved hope in those recovering from stroke[138] while the importance of

keeping hope alive was identified in a qualitative study by Barker et al., that looked at stroke survivors' perspective on upper extremity recovery (n=19).[139] The importance of drawing on support from others was also identified in this study, which is similar to the 'social supports' 'context' subtheme identified in the current study.[139]

LIMITATIONS

This study has several potential limitations. The main limitation of this study was that each participant was assessed only three times during each phase of the study. While this was done to facilitate the start of the intervention as soon as possible after discharge from inpatient rehabilitation, and to limit participant fatigue from the potentially lengthy assessments, celeration line analysis, which applies a line of best fit to the baseline data points and extends the line to the intervention phase,[124] may not have been appropriate for all of the outcome measures, given the instability of some of the baseline data. Baseline assessment should ideally continue until the data is stable.[89] This likely accounts for the inconsistent results when comparing the two-standard deviation band and celeration line analysis, for some of the outcome measures. Also, it was noted that for some of the outcome measures, the celeration line data was not plausible due to the variability of the baseline data. For example, the baseline data for the MAS (elbow flexors) for Participant 1 demonstrated a decelerating trend that is not plausible extending into the intervention phases. This type of trend could potentially have been improved with additional measurement points in the baseline phase. To ensure consideration of trends in the data, visual analysis should be used in conjunction with statistical analysis and the results of statistical analysis should not be overinterpreted.[127]

Another limitation of this study may have been related to the study design itself. The design included reassessment three times, two days apart, pre-intervention, after 4 weeks of intervention and post-intervention. The middle (4-week) assessment period therefore occurred during week 5 of the intervention. Having three visits from the research assistant during week 5 may have affected the number of sessions and repetitions the participants completed with the SaeboFlex orthosis that week. While this potentially affected the amount of use for Participant 1, it did not appear to be a factor for Participant 2 during that week. Also, because the intervention occurred in the sub-acute phase post stroke, improvements noted could arguably have been due to natural recovery however, upper extremity outcomes following stroke for moderately to severely impaired upper extremities are generally poor[5,6] and in this study, CMSA-II scores completed at the start and end of the inpatient rehabilitation stay (prior to recruitment) were unchanged for one of the two participants, indicating that little or no upper extremity recovery had occurred up to that point.

Another limitation of this study is that the research assistant hired to complete the outcome measures was an occupational therapy student with some knowledge of the outcome measures but limited experience actually administering them. Although she was trained in the use of the outcome measures by the principal investigator prior to the study and standardized training procedures were reviewed when available,[104] some of the outcome measures, particularly the MAS, have been criticized for lacking inter-rater and intra-rater reliability for some muscle groups[108] and therefore some inconsistency of scoring may have occurred. Also, due to

environmental and time constraints, the MAS was completed in a sitting position, instead of in supine as was indicated in **Appendix I.**

In addition, while the principal investigator incorporated the four main ways of improving self-efficacy[76] into the 1-hour intervention sessions, their frequency of use was not specifically recorded during the study, so the influence of self-efficacy enhancing interventions could not be established. Also, since the SSEQ, the quantitative outcome measure used in this study to assess self-efficacy, does not have an established level of clinically meaningful change, interpretation of these results should be done with caution.

Another limitation of the study is related to the post-intervention interview. The types of questions used to guide the individual interviews (see **Appendix O**) may have inadvertently affected the participants' responses. This is a common limitation when doing participant interviews and needs to be considered.[140]

The small number of study participants and the fact that both participants were male, of similar ages, and with intact sensation to their paretic upper extremities, prevents the results of this study from being generalizable to all individuals using the SaeboFlex orthosis post stroke. In addition, since this study only had two participants, one with a paretic dominant hand and one with a paretic non-dominant hand, we were unable to distinguish whether there was any effect of hand dominance on recovery of the upper extremity using the SaeboFlex orthosis,[93] as both participants improved. We also have no information on how the difference in the number of repetitions completed between the two participants affected their upper extremity outcomes.

Also, since no follow-up assessments occurred after the 8-week final assessment, we have no information on the lasting effects of the intervention.

CLINICAL AND RESEARCH IMPLICATIONS

CLINICAL IMPLICATIONS

Findings from this study suggest that early and continued use of the SaeboFlex orthosis, after discharge from inpatient stroke rehabilitation, may improve upper extremity outcomes for some people recovering from stroke. The first 8 weeks and especially the first 4 weeks after discharge from inpatient stroke rehabilitation may be especially important for upper extremity recovery using the SaeboFlex orthosis. Although this is a busy time for clients and their families, as they are settling into life at home after a stroke and often have many follow-up medical appointments, findings from this study suggest that intensive and continued use of the paretic upper extremity with assist from the SaeboFlex orthosis may be required to maximize upper extremity outcomes. Although the exact intensity of therapy required initially is not known, therapy provided more frequently in the first couple of weeks after discharge from inpatient rehabilitation may facilitate improved use of the SaeboFlex orthosis at home. While education on donning the SaeboFlex orthosis could be provided, independence with donning the orthosis does not seem to be a pre-requisite to using the orthosis if a supportive family member is available. Education on 'why' certain tasks are being assigned may also be helpful; one of the participants in the current study indicated that it helped him to focus more on the task if he knew why he was doing it.

Findings from this study suggest that prioritizing intensive and progressively challenging therapy using the SaeboFlex orthosis during this time, with extra visits initially to set up the program and make adjustments to the orthosis, may be required to facilitate early usage. Future visits should focus on reviewing and progressing the program so that tasks remain challenging, including modifications to the grasp-release tasks themselves and changing the springs as needed to grade the amount of assistance provided to open the fingers and thumb, related to the goals of the intervention. Those using the orthosis should be encouraged to 'think through' any challenges encountered with their program as a way to increase individual problem solving.[41] This is important because participating in 'just right challenge' tasks that require active problem solving, creates an adaptive neuroplastic response originating at the cellular and molecular level[11,18] which is important for ongoing upper extremity recovery post stroke.

While the number of grasp-release repetitions completed with the SaeboFlex is important, the results of this study showed that improvements can occur even when lower numbers of repetitions are completed, which was also noted by Stuck et al.[46] This may especially occur when a less resistive spring is used as part of the training program, where the goal is facilitation of active finger extension, as it may take longer and require more concentration for release of the 4" therapy ball when using a less resistive spring. This study intervention also included grading the grasp-release tasks themselves, such as practicing challenging tasks in sitting initially if upper extremity tolerance for certain movements was low, before progressing to standing, as well as using a mirror or window for visual feedback and using bilateral tasks to

promote symmetry. These environmental considerations were also considered when completing tasks after removal of the SaeboFlex orthosis, i.e., completing tasks or components of tasks in sitting if this allowed for more successful repetitions.

Specific to the objectives of this study, alternate ways of providing therapy to those using a SaeboFlex orthosis at discharge from inpatient rehabilitation should be considered to maximize service delivery and upper extremity outcomes. This may include brief intervention appointments by the outpatient occupational therapist, if possible, to progress individuals' SaeboFlex programs while they are still on the waiting list or brief follow-up appointments by the inpatient therapists after discharge from inpatient rehabilitation. While neither of the two participants were finished using the SaeboFlex orthosis after the 8-week intervention was complete, both had improved and had the potential to be progressed to a different type of orthosis once outpatient occupational therapy had started. With this in mind, therapists might also consider a process of 'loaning' the orthosis to the individual for a short time period when the intervention is started early, due to a potential shorter period of use.[58,135] A decision about whether to order the individual their own SaeboFlex orthosis could occur after a trial of a pre-determined length of time at home. Group sessions might be another option therapists can consider when looking at alternate ways of providing therapy to those soon after discharge from inpatient rehabilitation.

Findings from this study could also be used to evaluate the assessments therapists use to measure change pre-and post use of the SaeboFlex orthosis. While quantitatively measuring the amount of spasticity in specific muscle groups, using a scale such as the MAS, is important,

assessment of the effects of upper extremity spasticity on daily tasks is also important for therapists. Use of a questionnaire like the ArmA, which includes questions on both active use of the upper extremity as well as questions on ease of caring for the paretic arm, may improve the therapists' understanding of the effect of the spasticity on daily functioning and also help with setting spasticity-related upper extremity goals.

Qualitative findings suggest that therapists should consider the role of self-efficacy as it relates to continued use of the SaeboFlex orthosis at home. Measurements of self-efficacy should be considered as should the use of self-efficacy enhancing interventions, which may increase the confidence needed to maintain positive rehabilitation goals.[67] While the self-management scale of the SSEQ was used in this study to measure self-efficacy related to self-management, other options have also been used. Winstein et al., looked at self-efficacy as a key contributor to persistent use of the paretic upper extremity and instead evaluated self-efficacy related to each participant's meaningful goals on a 0-10 scale, ie. "How confident are you that you can…?".[141] This type of question could also be used in relation to the individual occupational performance issues identified on the COPM, as evaluating self-efficacy both before and after rehabilitation interventions could allow therapists to monitor responses to the intervention as well as help with understanding of both successes and lack of progress in therapy.[62] Therapists may also need to consider facilitating self-management skills post stroke. Self management programs, including skills training in the areas of problem solving, decision making, goal-setting and coping skills, have been found to improve not only quality of life but also self-efficacy post stroke,[142]

while improvements in self-efficacy may be required to maintain positive rehabilitation goals and participation in daily activities.[67,71]

RESEARCH IMPLICATIONS

Although findings from this study on the effectiveness of use of the SaeboFlex orthosis in early outpatient rehabilitation are promising, more research is required. Replication of the treatment intervention with a variety of participants is important to improve the generalizability of single subject design research.[128] A larger study, with additional assessment periods 3-6 months or longer after the intervention would be valuable to gain information on the lasting effects of the intervention. Including those with partially or completely impaired sensation would also be helpful as sensory impairment is common post stroke,[49] and may affect the amount of improvement attained with use of the SaeboFlex orthosis.[58] Since use of the SaeboFlex orthosis allows independent practice with grasp-release upper extremity tasks after the initial set-up of the program, requiring less individual therapy assistance,[45] a cost benefit analysis may be beneficial, which may have implications for staffing.[46,58] Cost benefit analysis could also be used to evaluate other factors potentially related to having to wait to receive upper extremity therapy post stroke, including the length of therapy required[58] and the role of soft tissue changes and patterns of learned non-use if therapy is started later.[56,79] Further information on the optimum dosage and frequency of SaeboFlex use is also required.

Further evaluation on the relationship between self-efficacy and arm recovery is also required, specific to use of the SaeboFlex orthosis. This study has shown that there may be a relationship between self-efficacy and use of the SaeboFlex orthosis. Further evaluation of the relationship

between arm recovery and the four main ways through which self-efficacy can be acquired or improved, as defined by A. Bandura,[76] would be useful for therapists who may wish to incorporate these principles into their daily practice. Since high self-efficacy has been linked to successful self-management behaviours post stroke,[63,69] self management approaches that would be helpful to those completing an intensive upper extremity therapy program should also be considered, to maximize independence and also prepare and guide stroke survivors through the physical and psychological demands of recovery.[139]

Evaluation of the link between upper extremity outcomes using the SaeboFlex orthosis and increased active problem solving should also be considered, as this has been evaluated in other upper extremity interventional studies.[141] This information would provide therapists with additional insights or tools to use when setting up SaeboFlex home programs.

CONCLUSIONS

While occupational therapists are often concerned with occupation-based interventions, many stroke survivors have upper extremity physical impairments that when reduced can lead to improved function for successful occupational performance.[143] Interventions such as the SaeboFlex "are the means to an occupational end"; a therapy tool that therapists can use to facilitate recovery which can lead to improved function in daily tasks.[143] In this study, the SaeboFlex orthosis was used with two participants early after stroke to determine its effectiveness in improving upper extremity outcomes. Despite using the SaeboFlex orthosis with both a dominant paretic upper extremity and a nondominant paretic upper extremity, both participants showed improvements at both the impairment and activity level in this study.

Qualitative outcomes indicated a relationship between decreased impairment and increased function as well as relationships between cognitive processes and self-efficacy to continue with the therapy program, which led to hope for continued arm recovery. Differences in the level of support required from family members as well as the physical environment in which the therapy intervention occurred were noted between participants and yet improvements occurred for both. Early continued intervention using a SaeboFlex orthosis, after discharge from inpatient rehabilitation and while waiting for outpatient occupational therapy, resulted in improved upper extremity function for both participants. Further research is needed to determine the effects of this intervention on a larger group of participants as well as a cost benefit analysis to determine the value of providing the intervention as early as possible as part of the upper extremity treatment program.

APPENDICES

APPENDIX A SCREENING CHECKLIST

Inclusion Criteria ("yes" for eligibility)	**Yes**	**No**
18 years of age or older		
First stroke within the past 6 months		
Admitted to Riverview Health Centre for inpatient stroke rehabilitation		
Being discharged to home location within the city of Winnipeg		
Premorbid fully functional upper extremity		
Able to speak and understand English		
Has been fit with and started using a SaeboFlex orthosis as an inpatient at Riverview Health Centre		
Referred to outpatient occupational therapy at the Health Sciences Centre, Winnipeg, for ongoing upper extremity rehabilitation using a SaeboFlex orthosis		
Able to commit to the time requirements of the study		
Able to follow multi-step commands and understand the purpose and required use of the SaeboFlex orthosis		
Have three times per week access to a caregiver to assist with donning the SaeboFlex orthosis in the home as required for the duration of the study		
Exclusion Criteria ("no" for eligibility)		
Chedoke McMaster Stroke Assessment (CMSA), Impairment Inventory, Shoulder Pain Section score of 1-3		
Modified Ashworth Scale score of 3 or more for the elbow, wrist and/or finger flexors of the paretic upper extremity		
Swan neck deformities or contractures of fingers or wrist of paretic upper extremity		
History of skin breakdown on the paretic upper extremity or score of less than 6 out of 12 on Sensation Section of Fugl-Meyer Upper Extremity Assessment		
Significant cognitive impairment as determined by a score of 21 or less on the Montreal Cognitive Assessment		
Able to fully extend fingers 10 times in a position of maximal shoulder flexion and elbow extension with a neutral wrist		

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Effectiveness of a dynamic wrist-hand orthosis in early outpatient rehabilitation of the upper extremity post stroke: a multiple single subject design evaluation

Protocol number: not applicable

Principal Investigator: *Brenda Semenko, R106-771 McDermot, Winnipeg*
Co-Investigators: *Ruth Barclay, R106-771 McDermot, Winnipeg*
Jacquie Ripat, R106-771 McDermot, Winnipeg
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Sponsor: *Health Sciences Centre Foundation (Allied Health Research Grant), PW112-700 William Avenue, Winnipeg, MB*
University of Manitoba (College of Rehabilitation Sciences Endowment Fund), R106-771 McDermot Avenue, Winnipeg, MB

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this research study and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. The study Principal Investigator is receiving financial support to conduct this study.

Purpose of Study

The purpose of this study is to explore the effectiveness of the SaeboFlex orthosis in improving arm function for people in the early phases of rehabilitation post stroke. You are being asked to take part in this study because you have started using a SaeboFlex orthosis with your inpatient therapist at Riverview Health Centre and are being discharged home with a SaeboFlex orthosis to wait for outpatient occupational therapy services at the Health Sciences Centre.

This research is being done because use of the SaeboFlex orthosis has not been well studied with those who are using the orthosis early on in their rehabilitation post stroke, particularly with those using the orthosis in their homes after discharge from inpatient stroke rehabilitation. Currently, there is a waiting list for outpatient occupational therapy services at the Health Sciences Centre, including therapy for using the SaeboFlex orthosis. A total of 3 participants will participate in this study.

Study procedures

If you take part in this study, you will have the following procedures:
You will be seen by the Principal Investigator, who is an occupational therapist, in your home for 1 hour, 3 times a week for 2 weeks and then for 1 hour, once a week for 6 weeks while you wait to get into outpatient occupational therapy at the Health Sciences Centre. The Principal Investigator will monitor and progress your upper extremity training program using the SaeboFlex orthosis for grasp and release activities and will leave homework for you to do with and without the SaeboFlex orthosis at least 3 times a week for 1 hour. A logbook will be provided to record homework tasks assigned and completed. The Principal Investigator will also complete a short interview with you during the first intervention session at your home and after 4 and 8 weeks of training with the SaeboFlex orthosis to help determine and monitor arm recovery goals that are important to you.

After the 8-week intervention is complete, the Principal Investigator will request to meet with you in your home for approximately 1 hour to ask you some questions about the effect of the SaeboFlex orthosis on your arm recovery and use of the SaeboFlex orthosis at home. These interviews will be audio-recorded and transcribed by a transcriptionist (who will have signed a pledge of confidentiality) for analysis purposes. The transcriptionist will not have access to any information that would identify you. The Principal Investigator's advisor and committee members may access paper copies of the interview transcripts without identifying information.

A research assistant will contact you to arrange for 3 assessment appointments to take place in your home (approximately every second day) soon after your discharge from Riverview Health Centre and prior to the start of the SaeboFlex training sessions with the Principal Investigator. The same research assistant will also see you in your home for 3 assessment appointments (approximately every second day) after 4 and 8 weeks of training. There will therefore be a total of 9 assessment appointments. Each assessment appointment will last for approximately 1½ - 2 hours.
The research assistant will use various assessments to determine how you can use your arm for daily tasks (such as wringing out a washcloth and picking up a small cup), your grip strength, as well as how much tightness you have in your arm as a result of the stroke. The research assistant will also get you to fill out 2 short questionnaires describing the amount of difficulty that you have experienced in the last 7 days doing specific tasks (such as putting your arm through a shirt sleeve and picking up a cup)

and how confident you are that you can do certain daily activities (such as completing your own exercise program).

Prior to starting the study, the Principal Investigator will meet with you to determine your eligibility for the study and may administer screening assessments of sensation, spasticity, shoulder pain and cognition. Once eligibility has been confirmed and the consent has been signed, your inpatient medical record will be reviewed to obtain information on your age, gender, the type of stroke you had, the date of your stroke, your dominant hand, your arm affected by the stroke and your assessment scores on the Montreal Cognitive Assessment and Chedoke McMaster Stroke Assessment which were taken by your therapists when you were an inpatient at Riverview Health Centre. This information will be recorded on a recording sheet. Your name will not be recorded on this sheet. Only the Principal Investigator and research assistant will have access to your name and contact information.

Participation in the study will be for 10 weeks (1 week of pre-assessment followed by 8 weeks of intervention and then 1 week of re-assessment and a post intervention interview).

The researcher may decide to take you off this study if you develop significant shoulder pain or hand edema (both of which are common post stroke) which prevents you from using the SaeboFlex orthosis. If you start to see outpatient occupational therapy at the Health Sciences Centre, the final assessments and interview will be completed and your participation in the study will come to an end.

If you request, the Principal Investigator can provide feedback to you about your own performance at any time during the study and can discuss the results of the study with you after the data has been analyzed.

You can stop participating in the study at any time. Should you wish to withdraw, please inform the Principal Investigator, Brenda Semenko, by e-mail at [redacted] or by calling [redacted]. There are no consequences to your withdrawal from this study.

Risks and Discomforts

Due to the repetitive nature of upper extremity rehabilitation post stroke, arm fatigue and discomfort may occur. This may be temporary as the arm gets stronger with repeated practicing. Participation in the post study interview may cause mild emotional discomfort associated with self-reflection. You may choose to not answer any question, and may choose how much you share with the researcher.

Benefits

By participating in this study, you will be providing information to the study team on the effects of use of the SaeboFlex orthosis in assisting with the recovery of arm function post stroke. There may or may not be direct benefit to you from participating in this study however it is hoped that there will be a benefit from having ongoing therapy with the SaeboFlex orthosis soon after discharge from inpatient rehabilitation.

We hope the information learned from this study will benefit others recovering from arm deficits post stroke in the future.

Costs

All the assessments and treatments, which will be performed as part of this study, are provided at no cost to you.

Payment for participation

You will receive no payment or reimbursement for any expenses related to taking part in this study.

Alternatives

You do not have to participate in this study to receive treatment for your condition. Please talk to your regular therapist about all your treatment options. Your participation in this study will not affect your regular therapy in any way.

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. All study documents related to you will contain only your assigned patient number. The matched names will be stored in a locked drawer accessible only to the Principal Investigator and research assistant.

Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

All data collected during the study will be kept in a locked secure area and only the Principal Investigator and research assistant will have access to this information. If any of your research records need to be copied to any of the above study staff, your name and all identifying information will not be included.

We will audiotape and transcribe the individual interviews that follow the 8-week intervention. Prior to the transcription, all identifying features of conversations, such as confidential information (e.g. names of participants, families) will be removed by the Principal Investigator. Recorded data will be stored on encrypted drives accessible only to the Principal Investigator. Paper copies of the transcripts may be provided to the Research Supervisor (advisor) and committee members as part of the research process. Audio recordings and interview transcripts will be permanently destroyed after seven years. The University of Manitoba Health Research Ethics Board may review research-related records for quality assurance purposes. However, these records will have no information that identifies you in any way.

Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care in any way.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the Principal Investigator: Brenda Semenko at [redacted] or at [redacted].

For questions about your rights as a research participant, you may contact: The University of Manitoba Health Research Ethics Board at [redacted].

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Brenda Semenko and/or the study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed.

I authorize the inspection of my study records by The University of Manitoba Health Research Ethics Board.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I agree to being contacted in relation to this study. Yes □ No □

Participant signature_____

Date _____(day/month/year)

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

Printed Name: _____

Date _____(day/month/year)

Signature: _____

Role in the study: _____ *(qualified member of the research team)*

APPENDIX C PARTICIPANT DEMOGRAPHICS

Participant Identification Code	
Age (years)	
Gender	
Time post stroke (weeks)	
Type of stroke	
Paretic side (left or right)	
Dominant side (left or right)	
MoCA score (at admission to Riverview)	
CMSA, Impairment Inventory score (at admission to Riverview):	
Arm	
Hand	
Shoulder Pain	
CMSA, Impairment Inventory score (at discharge from Riverview):	
Arm	
Hand	
Shoulder Pain	

APPENDIX D DATA CAPTURE SHEET

Baseline (pre-intervention)	**Day 1**	**Day 3**	**Day 5**
DATE:			
ArmA, active function subscale			
ArmA, passive function subscale			
CAHAI-7			
SIS (Stroke Recovery scale)			
FMA-UE			
MAS (elbow flexors)			
MAS (wrist flexors)			
MAS (finger flexors)			
Grip strength (average of 3 trials, in kg)			
SSEQ, activity scale			
SSEQ, self-management scale			
COPM, Performance Score			
COPM, Satisfaction Score			
After 4 weeks of intervention	**Day 1**	**Day 3**	**Day 5**
DATE:			
ArmA, active function subscale			
ArmA, passive function subscale			
CAHAI-7			
SIS (Stroke Recovery scale)			
FMA-UE			

Baseline (pre-intervention)	**Day 1**	**Day 3**	**Day 5**
MAS (elbow flexors)			
MAS (wrist flexors)			
MAS (finger flexors)			
Grip strength (average of 3 trials, in kg)			
SSEQ, activity scale			
SSEQ, self-management scale			
COPM, Performance Score			
COPM, Satisfaction Score			
After 8 weeks of intervention	**Day 1**	**Day 3**	**Day 5**
DATE:			
ArmA, active function subscale			
ArmA, passive function subscale			
CAHAI-7			
SIS (Stroke Recovery scale)			
FMA-UE			
MAS (elbow flexors)			
MAS (wrist flexors)			
MAS (finger flexors)			
Grip strength (average of 3 trials, in kg)			
SSEQ, activity scale			
SSEQ, self-management scale			
COPM, Performance Score			

Baseline (pre-intervention)	Day 1	Day 3	Day 5
COPM, Satisfaction Score			

Key: ArmA = Arm Activity Measure, CAHAI-7 = Chedoke Arm and Hand Activity Inventory-7, SIS = Stroke Impact Scale, FMA-UE = Fugl-Meyer Assessment-upper extremity section, MAS = Modified Ashworth Scale, SSEQ = Stroke Self-Efficacy Questionnaire, COPM = Canadian Occupational Performance Measure

In each column, please CIRCLE the amount of difficulty that you or your carer have experienced in doing the activity, over the last 7 days.

Activities (affected arm)	Difficulty 0 = no difficulty 1 = mild 2 = moderate 3 = severe difficulty 4 = Unable to do activity				
Section A Caring for your affected arm (not using it in tasks or activities)					
1. Cleaning the palm of the hand	**0**	**1**	**2**	**3**	**4**
2. Cutting finger nails	**0**	**1**	**2**	**3**	**4**
3. Cleaning the armpit	**0**	**1**	**2**	**3**	**4**
4. Cleaning the elbow crease	**0**	**1**	**2**	**3**	**4**
5. Positioning arm on a cushion or support in sitting (If never done circle 0)	**0**	**1**	**2**	**3**	**4**
6. Putting arm through a garment sleeve	**0**	**1**	**2**	**3**	**4**
7. Putting on a glove (If never done circle 0)	**0**	**1**	**2**	**3**	**4**
8. Putting on a splint (If never done circle 0)	**0**	**1**	**2**	**3**	**4**
Section B Independently completing tasks or activities using your affected arm					
1. Difficulty with balance when walking due to your arm	**0**	**1**	**2**	**3**	**4**
2. Hold an object still while using unaffected hand	**0**	**1**	**2**	**3**	**4**
3. Open (affected hand) a previously opened jar	**0**	**1**	**2**	**3**	**4**
4. Pick up a glass, bottle, or can	**0**	**1**	**2**	**3**	**4**
5. Drink from a cup or mug	**0**	**1**	**2**	**3**	**4**
6. Brush your teeth	**0**	**1**	**2**	**3**	**4**
7. Tuck in your shirt	**0**	**1**	**2**	**3**	**4**
8. Write on paper	**0**	**1**	**2**	**3**	**4**
9. Eat with a knife and fork	**0**	**1**	**2**	**3**	**4**
10. Dial a number on home phone	**0**	**1**	**2**	**3**	**4**
11. Do up buttons on clothing	**0**	**1**	**2**	**3**	**4**
12. Comb or brush your hair	**0**	**1**	**2**	**3**	**4**
13. Use a key to unlock the door	**0**	**1**	**2**	**3**	**4**
Total Score	Section A ☐☐ Section B ☐☐				

Totalling section A and B separately produces a total score for each sub-scale of the measure.
The sub-scales should not be combined.

APPENDIX F CHEDOKE ARM AND HAND ACTIVITY INVENTORY (CAHAI-7)

Chedoke Arm and Hand Activity Inventory: Score Form

CAHAI-7 Version

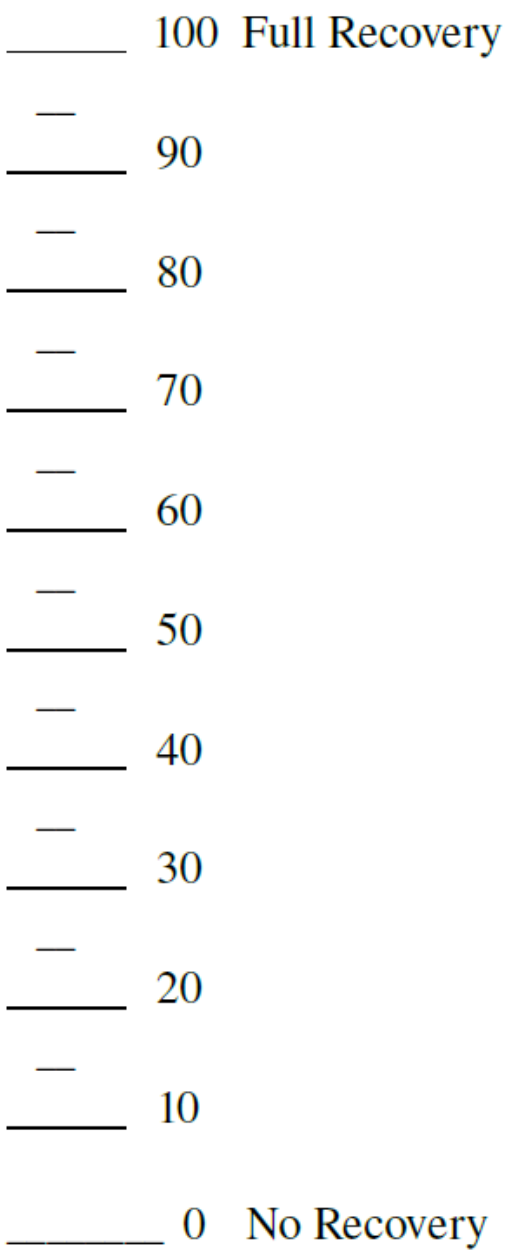
Name: **Date:**

Activity Scale			
1. total assist (weak U/L < 25%) 2. maximal assist (weak U/L = 25-49%) 3. moderate assist (weak U/L = 50-74%) 4. minimal assist (weak U/L > 75%)	5. supervision 6. modified independence (device) 7. complete independence (timely, safely)		
	Affected Limb:		Score
1. Open jar of coffee	☐ holds jar	☐ holds lid	
2. Call 911	☐ holds receiver	☐ dials phone	
3. Draw a line with a ruler	☐ holds ruler	☐ holds pen	
4. Pour a glass of water	☐ holds glass	☐ holds pitcher	
5. Wring out washcloth			
6. Do up five buttons			
7. Dry back with towel	☐ reachs for towel	☐ grasps towel end	
Total Score			/49
Comments			

Funded by The Ontario Ministry of Health and Long Term Care

APPENDIX G STROKE IMPACT SCALE (STROKE RECOVERY SCALE)

On a scale of 0 to 100, with 100 representing full recovery and 0 representing no recovery, how much have you recovered from your stroke?



Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT **ID:**
UPPER EXTREMITY (FMA-UE) **Date:**
Assessment of sensorimotor function **Examiner:**

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

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

Approved by Fugl-Meyer AR 2010 1

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

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

D. COORDINATION/SPEED after one trial with both arms, blind-folded, tip of the index finger from knee to nose, 5 times as fast as possible		**marked**	**slight**	**none**
Tremor		0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		> 5s	**2 - 5s**	**< 1s**
Time	more than 5 seconds slower than unaffected side 2-5 seconds slower than unaffected side maximum difference of1 second between sides	0	1	2
	Total D (max 6)			

TOTAL A-D (max 66)	

APPENDIX I MODIFIED ASHWORTH SCALE (MAS)

Modified Ashworth Scale Instructions

General Information (derived Bohannon and Smith, 1987):

- Place the patient in a supine position
- If testing a muscle that primarily flexes a joint, place the joint in a maximally flexed position and move to a position of maximal extension over one second (count "one thousand one")
- If testing a muscle that primarily extends a joint, place the joint in a maximally extended position and move to a position of maximal flexion over one second (count "one thousand one")
- Score based on the classification below

Scoring (taken from Bohannon and Smith, 1987):

0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part(s) rigid in flexion or extension

Modified Ashworth Scale Testing Form

Participant: _____ Date:_____

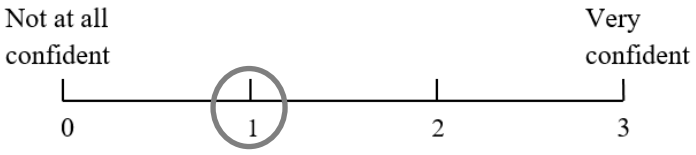
Muscle Tested	Score
Elbow Flexors	
Wrist Flexors	
Finger Flexors	

APPENDIX J STROKE SELF-EFFICACY QUESTIONNAIRE (SSEQ)

These questions are about your confidence that you can do some tasks that may have been difficult for you since your stroke.

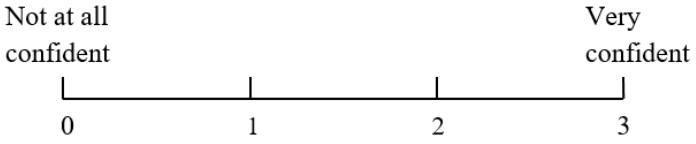
For each of the following tasks, please circle a point on the scale that shows how confident you are that you can do the tasks now in spite of your stroke.

Where 0 = *not at all confident* and 3 = *very confident*



How ***Confident*** are you ***now*** that you can

1. Get yourself comfortable in bed every night.



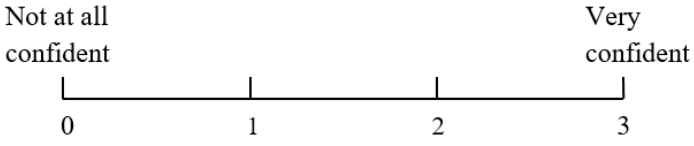
2. Get yourself out of bed on your own even when you feel tired.

3. Walk a few steps on your own on any surface inside your house.

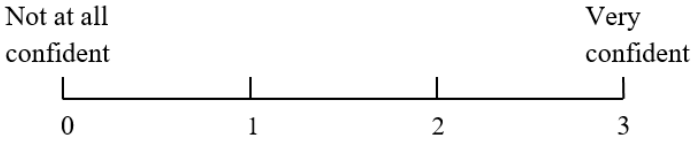
4. Walk about your house to do most things you want.

5. Walk safely outside on your own on any surface.

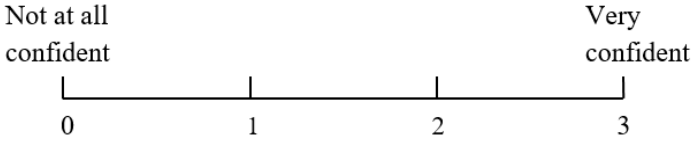
6. Use both your hands for eating your food.



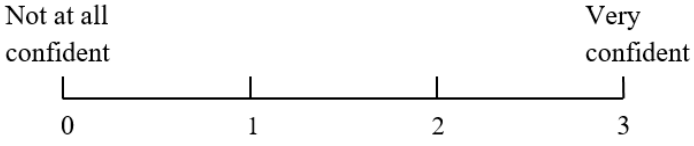
7. Dress and undress yourself even when you feel tired.



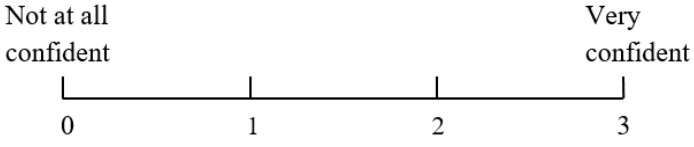
8. Prepare a meal you would like for yourself.



9. Persevere to make progress from your stroke after discharge from therapy.

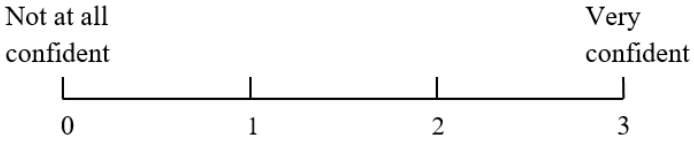


10. Do your own exercise programme every day.

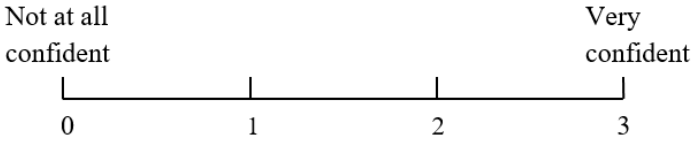


11. Cope with the frustration of not being able to do some things because of your stroke.

12. Continue to do most of the things you liked to do before your stroke.



13. Keep getting faster at the tasks that have been slow since your stroke.



APPENDIX K OUTCOME MEASURE PSYCHOMETRIC PROPERTIES

Measure	Type	Time to administer	Scaling	Scoring	Valid	Reliable	Floor/Ceiling Effects	Clinically Meaningful Change
Arm Activity Measure (ArmA)	Activity (self-report)	15 min.	5 point ordinal scale (0-4) 8 item passive function subscale, 13 item active function subscale	Passive function subscale: 0-32 Active function subscale: 0-52 Lower score = higher function	Internal consistency (Cronbach's alpha=0.85 passive subscale; 0.96 active subscale)[97] Construct validity with LASIS and DASH (rho 0.5-0.63)[97]	Test retest reliability 92-97.5% [97]	Passive subscale: scores distributed over the full range. Active subscale: ceiling effect for 37% of scores (ie. totally unable for all items)[97]	MIC = 2.5 on passive function subscale and 1.1 on active function subscale[97]
Chedoke Arm and Hand Activity Inventory (CAHAI-7)	Activity (7 bilateral functional tasks)	30 min.	7 point ordinal scale (1-7)	7-49 Higher score = higher function	Internal consistency (Cronbach's alpha=0.95)[100] Pearson correlation r=0.99 between CAHAI-7 and CAHAI-13; r=0.95 between CAHAI-7 and ARAT[100]	Interrater reliability ICC = 0.98 [99] Test retest ICC = 0.96 [100]	Not established	MDC = 6.3 points for 13 point scale; not established for shorter versions [99] MCID not established
Stroke Impact Scale version 3.0 (Stroke Recovery subscale)	Participation (self-report)	5 min.	100 point visual analog scale	0-100 0=no recovery 100=full recovery	Internal consistency (Cronbach's alpha=0.83-0.90)[102] Pearson correlation r=0.34-0.58 with other stroke measures [102]	Test retest reliability ICC 0.79 for Stroke Recovery subscale [103]	Floor effect: 3.1% Ceiling effect: 0.0%[103]	Changes of 10-15 points in an SIS domain are clinically meaningful[102]
Fugl-Meyer Upper Extremity (FMA-UE)	Impairment (33 tasks)	30 min.	3 point ordinal scale (0-2)	0-66 Higher score = less impairment	Internal consistency (Cronbach's alpha=0.94-0.98)[106] Spearman correlation 0.90-0.96 with other stroke measures[107]	Test retest reliability ICC=0.99[107] Interrater reliability ICC=0.96 [107]	Floor effect 1.9%, ceiling effect 17.0% 30 days post stroke[107]	MCID: 9.0 points[18] MDC: 5.2 points[107]

Measure	Type	Time to administer	Scaling	Scoring	Valid	Reliable	Floor/Ceiling Effects	Clinically Meaningful Change
Modified Ashworth Scale (MAS)	Impairment (elbow, wrist and finger flexors)	5 min.	6 point ordinal scale	0-4 for each muscle group (includes 1+) Lower score = less tone	Construct validity with FMA-UE (r=-0.94)[113]	Intrarater reliability 0.83 kw for elbow flexor spasticty[110] Interrater reliability 0.84-0.87 kw for elbow flexor spasticity[110,111]	Not established	1 point decrease is generally accepted as a clinically important difference[112]
Grip Strength	Impairment (mean of 3 trials)	5 min.	Ratio scale	Measured in kilograms Higher values = greater strength	Construct validity with FMA-UE (r = 0.84)[116]	Test retest reliability ICC=0.80-0.89[114] Intrarater reliability ICC>0.86-0.95[116]	Not established	MCID: 5.0 kg affected dominant, 6.2 kg affected non-dominant[117]
Canadian Occupational Performance Measure (COPM)	Participation (semi-structured interview)	30 min. initially 15 min. at 4 and 8 weeks	2, 10-point ordinal scales (1-10)	Sum each scale separately and divide by the number of OPI's Higher score=better perceived performance and satisfaction with performance	Discriminant validity confirmed by low correlation with five standardized performance measures (Spearman's correlation coefficients)[120]	Test retest reliability Spearman's correlation coefficient =0.89 for performance scores and =0.88 for satisfaction scores in people with stroke[120]	Not established	A change of 2 points is considered clinically significant[118]

Measure	Type	Time to administer	Scaling	Scoring	Valid	Reliable	Floor/Ceiling Effects	Clinically Meaningful Change
Stroke Self-Efficacy Questionnaire (SSEQ)	Self-efficacy (self- report) 13 items divided into 2 subscales (8 functional activities; 5 self-management tasks)	15 min.	4 point ordinal scale (0-3)	0-24 (functional activity subscale) 0-15 (self-management subscale) 0=not at all confident; 3=very confident Sum each subscale separately	Construct validity: Functional activity subscale 0.75 correlation with the FES[62] Self-management subscale -0.63 correlation with HADS[62]	Pearson Separation Index > 0.80 for both subscales[62]	Functional activity subscale: 0% floor effect, 1.7% ceiling effect[62] Self-management subscale: 0.8% floor effect, 7.6% ceiling effect[62]	Not established

ICC = intraclass correlation coefficient

MCID = minimal clinically important difference

MDC = minimal detectable change

MIC = minimal important change

LASIS=Leeds Adult Spasticity Impact Scale

DASH=Disabilities of Arm Shoulder and Hand

ARAT=Action Research Arm Test

FES=Falls Efficacy Scale

KW=Kappa weight

HADS=Hospital Anxiety and Depression Scale

APPENDIX L SCHEDULE OF EVENTS

While still at Riverview:

Recruitment and consent. Principal investigator evaluated the fit of the SaeboFlex orthosis once consent completed to ensure all adjustments were made prior to the start of the study, with referral back to the involved orthotist as needed. Donning the SaeboFlex orthosis was reviewed with the participant and caregiver as needed.

Week 0

Individual baseline assessments (3 series of baseline outcome measures taken 2 days apart) in participant's home by trained research assistant.

Weeks 1 and 2

Baseline assessment with the Canadian Occupational Performance Measure (COPM) was completed by the principal investigator, in the participant's home, at the first visit.

Participants were seen by the principal investigator three times per week for 1 hour; 5 grasp-release activities using the SaeboFlex orthosis x 10 minutes each, plus 10 minutes using the paretic upper extremity without the SaeboFlex orthosis for activities or portions of activities as identified as being individually important from baseline assessment with the COPM. Intervention included progression of SaeboFlex program in home environment and provision of logbook for participant to record repetitions completed during and between therapy appointments, time spent completing prescribed tasks and any additional comments. Although participants were expected to complete their SaeboFlex training a minimum of 3 times per week for 50 minutes, followed by 10 minutes of training without the orthosis, participants could choose to use the orthosis more frequently and were instructed to use the logbook to record any additional practice sessions. Logbooks were reviewed at the start of each session with the principal investigator and homework tasks were provided at the end of each session.

Weeks 3 and 4

Participants were seen by the principal investigator once a week for 1 hour; 5 grasp-release activities using the SaeboFlex orthosis x 10 minutes each, plus 10 minutes using the paretic upper extremity without the SaeboFlex orthosis for activities or portions of activities as identified as being individually important from baseline assessment with the COPM. Tasks completed with and without the SaeboFlex orthosis were progressed as the participant was able. Although participants were expected to complete their SaeboFlex training a minimum of 3 times per week for 50 minutes, followed by 10 minutes of training without the orthosis, participants could choose to use the orthosis more frequently and were instructed to use the logbook to record any additional practice sessions. Logbooks were reviewed at the start of each session with the principal investigator and homework tasks were provided at the end of each session.

Reassessment with the COPM was completed by the principal investigator, in the participant's home, at the 4-week appointment.

Week 5

Reassessment (3 series of outcome measures taken 2 days apart) in participant's home by trained research assistant.

Weeks 5-8

Intervention as for weeks 3 and 4.

Final assessment with the COPM was completed by the principal investigator, in the participant's home, at the 8-week (final) appointment.

Week 9

Final assessments (3 series of outcome measures taken 2 days apart) in participant's home by trained research assistant.

Week 10

Individual interviews by principal investigator in participants' homes.

APPENDIX M TASK PROGRESSION

Participants grasped the 4” therapy ball placed on the table (stabilized by a rubber wristband) at their midline (unless otherwise indicated) and released the ball according to the graded progression below (adapted from: Saebo Inc., certification course manual, 2013). Participants with increased tone were encouraged to bring their paretic hand back to their side between grasp-release repetitions to assist with relaxing the upper extremity. Tasks were attempted in standing first however if tolerance was low, were completed in sitting. If compensatory movements were noted, tasks were trialed bilaterally (progressing to unilaterally) and in front of a mirror if possible. Tasks were graded up (made harder) if able to complete 50 or more repetitions in 10 minutes and were graded down (made easier) if unable to complete 25 repetitions in 10 minutes.

1. Picked up ball on table at midline and placed in crate to right or left (depending on paretic side) (shoulder adduction/internal rotation)
    a. 4” tall crate
    b. 8” tall crate
    c. 12” tall crate
2. Picked up ball on table at midline and placed in crate to right or left (depending on paretic side) (shoulder abduction/external rotation)
    a. 4” tall crate
    b. 8” tall crate
    c. 12” tall crate
3. Picked up ball on table at midline and placed in crate to the front (shoulder flexion, attempting to keep elbow as straight as possible)
    a. 4” tall crate
    b. 8” tall crate
    c. 12” tall crate
4. Picked up ball on table at midline and with elbow tucked into side of chest, placed in crate on ipsilateral side (shoulder external rotation)
    a. 4” tall crate
    b. 8” tall crate
    c. 12” tall crate
5. Picked up ball on table at midline and dropped into crate placed (shoulder extension):
    a. 4” behind participant
    b. 8” behind participant
6. Picked up ball placed directly in front of paretic arm on table and placed in bowl positioned in front at midline (elbow flexion):
    a. 2” bowl

    b. 4” bowl
    c. 8” bowl
7. Picked up ball on table at midline and did combined movement as stated below:
    a. Touched chin and then released ball in crate to the ipsilateral side and on the floor (elbow flexion then extension)
    b. Picked up ball in position of elbow flexion (off of 4” or 8” upside down bowl) on table at midline and released ball in crate to the ipsilateral side and on the floor (elbow flexion then extension)
    c. External rotation movement of shoulder (as described in 4.) followed by release of ball to contralateral side in position of shoulder adduction and elbow extension
8. Functional activities with SaeboFlex orthosis, that were graded for optimal challenge:
    a. Grasped and released plastic water bottle (with/without water)
    b. Grasped water bottle, attempted to pour out water and placed back on table
    c. Grasped water bottle and moved to a shelf
    d. Lifted a plastic measuring cup (with a 4” therapy ball attached to the handle) and placed it over the sink to fill up with water/pour out water
    e. Grasped ball with fork inserted and attempted to hold into food while cutting with other hand
    f. Grasped a 4” diameter cup and brought up toward mouth
    g. Grasped ball with spoon inserted and used spoon to transfer cereal/beads from one bowl to another
    h. Grasped a hand-held brush and swept the table
    i. Grasped a 4” therapy ball with spatula inserted and attempted to lift/flip food on plate
    j. Loaded dishwasher with 4” therapy ball/plastic cups
    k. Turned water taps on/off (tap handle covered with a 4” therapy ball)
    l. Lifted a clothing hanger (with a 4” therapy ball attached to one corner of the hanger) and hung it on a clothing rack (didn’t do all of these)
9. Changed the spring resistance depending on the goal of the above grasp-release tasks. The red spring was trialed first. If the goal was **hand strengthening**:
    a. Silver spring (least resistive)
    b. Yellow spring
    c. Red spring
    d. Blue spring (most resistive)
10. Changed the spring resistance depending on the goal of the above grasp-release tasks. The red spring was trialed first. If the goal was independent **hand opening**:
    a. Blue spring (most help to open hand)
    b. Red spring
    c. Yellow spring
    d. Silver spring (least help to open hand)

APPENDIX N PARTICIPANT LOG

Date:				
Tasks with SaeboFlex including springs to be used (10 minutes each)	Time spent	Repetitions	Other upper extremity tasks completed	Comments
1.				
2.				
3.				
4.				
5.				
Tasks with SaeboFlex removed (10 minutes total)				
1.				
2.				
3.				

APPENDIX O INTERVIEW GUIDE

1. Usability:
    a. What are some good things about using the SaeboFlex orthosis at home?
    b. What are some challenging things about using the SaeboFlex orthosis at home?
    c. Do you plan to continue to use the SaeboFlex orthosis as part of the therapy you do for your arm at home?
    d. Do you have any suggestions or recommendations for others who are working on a SaeboFlex arm therapy program at home?
2. Body Function/Impairment:
    a. How has the SaeboFlex training completed over the past 8 weeks affected the strength of your weaker arm?
    b. How has the SaeboFlex training completed over the past 8 weeks affected the movement of your weaker arm?
    c. How has the SaeboFlex training completed over the past 8 weeks affected the tightness (or spasticity) of your weaker arm?
3. Activity/Participation/Occupational Performance:
    a. How has the SaeboFlex training completed over the past 8 weeks affected your ability to use your arm for daily tasks that are important to you?
    b. Can you describe which daily activities have gotten easier for you to do since using the SaeboFlex orthosis? How does this make you feel?
    c. Have any daily activities gotten more difficult for you to do since using the SaeboFlex orthosis? How does this make you feel?
4. Self-efficacy:
    a. Do you think your confidence for moving and using your arm has changed since the start of the study? How has it changed?
    b. How confident are you that your arm will continue to recover from the effects of the stroke?
    c. How confident are you that you can continue to move and use your weaker arm (with and without the SaeboFlex orthosis) when you are working alone on therapy tasks at home, now that the study is over?
    d. What kinds of things help you stay motivated to continue your therapy for your arm?
    e. What can others do to help you stay motivated as you continue to work on your arm recovery?

REFERENCES

1. Lindsay MP, Gubitz G, Bayley M, Hill MD, Phillips S, Smith EE. *Canadian stroke best practice recommendations: Overview and methodology*. Ottawa, ON: Heart and Stroke Foundation, Canada. 2014. Retrieved from http://www.strokebestpractices.ca/wp-content/uploads/2014/08/CSBPR2014_Overview_Methodology_ENG.pdf
2. Krueger H, Koot J, Hall R, O'Callaghan C, Bayley M, Corbett D. Prevalence of individuals experiencing the effects of stroke in Canada. *Stroke*. 2015;46:2226-2231.
3. Weaver L, Page S, Sheffler L, Chae J. Minimal depression: how does it relate to upper-extremity impairment and function in stroke? *Am J Occup Ther*. 2013;67(5):550-555.
4. Rosamond W, Flegal K, Friday G, et al. Heart Disease and Stroke Statistics – 2007 Update, A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2007;115:e69-e171.
5. Nakayama H, Jorgensen HS, Raaschou HO, Olsen TS. Compensation in recovery of upper extremity function after stroke: The Copenhagen stroke study. *Arch Phys Med Rehabil.* 1994;75(8):852-857.
6. Kwakkel G, Kollen BJ, Grond J, Prevo, AJH. Probability of regaining dexterity in the flaccid upper limb: impact of severity of paresis and time since onset in acute stroke. *Stroke*. 2003;34:2181-2186.
7. Hoffman HB, Blakey GL. New design of dynamic orthoses for neurological conditions. *Neurorehabilitation.* 2011;*28*(1):55-61.
8. International Classification of Functioning, Disability and Health: ICF. Geneva, Switzerland: World Health Organization. 2001.
9. Page S, Levine P, Hill V. Mental practice-triggered electrical stimulation in chronic, moderate, upper-extremity hemiparesis after stroke. *Am J Occup Ther*. 2015;69:6901290050p1-6901290050p8.
10. Mayo NE, Wood-Dauphinee S, Cote R, Durcan L, Carlton J. Activity, participation, and quality of life 6 months poststroke. *Arch Phys Med Rehabil*. 2002;83:1035-1042.
11. McCormack G. How occupational therapy influences neuroplasticity. *OT Pract*. 2009;14(17):CE-1-7.
12. Richards LG, Stewart KC, Woodbury ML, Senesac C, Cauraugh, JH. Movement-dependent stroke recovery: a systematic review and meta-analysis of TMS and fMRI evidence. *Neuropsychologia*. 2008b;46(1):3-11.
13. Gauthier LV, Taub E, Perkins C, Ortmann M, Mark V, Uswatte G. Remodeling the brain: plastic structural brain changes produced by different motor therapies after stroke. *Stroke*. 2008;39:1520-1525.
14. Pitts DG, O'Brien SP. Splinting the hand to enhance motor control and brain plasticity. *Top Stroke Rehabil*. 2008;15(5):456-467.
15. Nudo RJ, Plautz EJ, Frost SB. Role of adaptive plasticity in recovery of function after damage to motor cortex. *Muscle Nerve*. 2001;24(8):1000-1019.
16. Westlake KP, Byl NN. Neural plasticity and implications for hand rehabilitation after neurological insult. *J Hand Ther*. 2013;26(2):87-92.
17. Kleim JA, Jones TA. Principles of experience-dependent neural plasticity: implications for rehabilitation after brain damage. *J Speech Lang Hear Res*. 2008;51:S225-S239.
18. Arya KN, Pandian S, Verma R, Garg RK. Movement therapy induced neural reorganization and motor recovery in stroke: a review. *J Bodyw Mov Ther*. 2011;15:528-537.

19. Lang CE, Macdonald JR, Reisman DS, et al. Observation of amounts of movement practice provided during stroke rehabilitation. *Arch Phys Med Rehabil.* 2009;*90*(10):1692-1698. doi:10.1016/j.apmr.2009.04.005; 10.1016/j.apmr.2009.04.005

20. Winstein C, Lewthwaite R, Blanton S, Wolf LB, Wishart L. Infusing motor learning research into neurorehabilitation practice: a historical perspective with case exemplar from the accelerated skill acquisition program. *J Neurol Phys Ther*. 2014;38:1-11.

21. Lang C, Birkenmeier R. *Upper-extremity task-specific training after stroke or disability: A manual for occupational therapy and physical therapy*. Bethesda, MD: American Occupational Therapy Association Press; 2014.

22. Oujamaa L, Relave I, Froger J, Mottet D, Pelissier JY. Rehabilitation of arm function after stroke. Literature review. *Ann Phys Rehabil Med. 2009;52*(3):269-293. doi:10.1016/j.rehab.2008.10.003; 10.1016/j.rehab.2008.10.003

23. Thielman GT, Dean CM, Gentile AM. Rehabilitation of reaching after stroke: task-related training versus progressive resistive exercise. *Arch Phys Med Rehabil*. 2004;10:1613-1618.

24. Van Peppen RP, Kwakkel G, Wood-Dauphinee S, Hendriks HJ, Van der Wees PJ, Dekker J. The impact of physical therapy on functional outcomes after stroke: what's the evidence? *Clin Rehabil.* 2004;18(8):833-862.

25. Nelles G, Jentzen W, Jueptner M, Muller S, Diener HC. Arm training induced brain plasticity in stroke studied with serial positron emission tomography. *Neuroimage*. 2001;13:1146-1154.

26. Classen J, Liepert J, Wise SP, Hallett M, Cohen LG. Rapid plasticity of human cortical movement representation induced by practice. *J Neurophysiol.* 1998;79(2):1117-1123.

27. Hebert D, Lindsay MP, McIntyre A. et al. Canadian stroke best practice recommendations: Stroke rehabilitation practice guidelines, update 2015. *Int J Stroke.* 2016;11(4):459-484.

28. Nilsen D, Gillen G, Geller D, Hreha K, Osei E, Saleem GT. Effectiveness of interventions to improve occupational performance of people with motor impairments after stroke: an evidence-based review. *Am J Occup Ther*. 2015;69:6901180030p1-6901180030p9.

29. Chan DY, Chan CC, Au DK. Motor relearning programme for stroke patients: a randomized controlled trial. *Clin Rehabil*. 2006;20:191-202.

30. French B, Leathley M, Sutton C, et al. A systematic review of repetitive functional task practice with modeling of resource use, costs and effectiveness. *Health Technol Assess.* 2008;12(30):1-117.

31. French B, Thomas L, Leathley M, et al. Does repetitive task training improve functional activity after stroke? A Cochrane systematic review and meta-analysis. *J Rehabil Med*. 2010;42:9-14.

32. Yelnick AP, Le Breton F, Colle FM, et al. Rehabilitation of balance after stroke with multisensorial training: a single-blind randomized controlled study. *Neurorehabil Neural Repair*. 2008;22:468-476.

33. Birkenmeier RL, Prager EM, Lang CE. Translating animal doses of task-specific training to people with chronic stroke in 1-hour therapy sessions: A proof-of-concept study. *Neurorehabil Neural Repair, 2010;24*(7):620-635. doi: 10.1177/1545968310361957

34. Bernhardt J, Chan J, Nicola I, Collier JM. Little therapy, little physical activity: rehabilitation within the first 14 days of organized stroke unit care. *J Rehabil Med*. 2007;39:43-48.

35. Waddel KJ, Birkenmeier R, Moore JL, Hornby TG, Lang C. Feasibility of high-repetition, task-specific training for individuals with upper-extremity paresis. *Am J Occup Ther*. 2014;68: 444-453.

36. Lohse K, Lang C, Boyd L. Is more better? Using metadata to explore dose-response relationships in stroke rehabilitation. *Stroke*. 2014;45:2053-2058.

37. Shi YX, Tian JH, Yang KE, Zhao Y. Modified constraint-induced movement therapy versus traditional rehabilitation in patients with upper-extremity dysfunction after stroke: a systematic review and meta-analysis. *Arch Phys Med Rehabil.* 2011;92:972-982.

38. Wolf SL, Winstein CJ, Miller JP, et al. Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: the EXCITE randomized clinical trial. *JAMA*. 2006;296(17):2095-2104.

39. Page SJ, Levine P, Leonard AC. Modified constraint-induced therapy in acute stroke: A randomized controlled pilot study. *Neurorehabil Neural Repair*. 2005;19:27-32.

40. Taub E, Uswatte G, King DK, Morris D, Crago JE, Chatterjee A. A placebo-controlled trial of constraint-induced movement therapy for upper extremity after stroke. *Stroke*. 2006;37:1045-1049.

41. Taub E, Uswatte G, Bowman MH, et al. Constraint-induced movement therapy combined with conventional neurorehabilitation techniques in chronic stroke patients with plegic hands: a case series. *Arch Phys Med Rehabil*. 2013;94(1):86-94.

42. Page S, Murray C, Hermann V. Affected upper-extremity movement ability is retained 3 months after modified constraint-induced therapy. *Am J Occup Ther*. 2011;65:589-593.

43. Merzenich MM, Tallal B, Peterson B, Miller S, Jenkins WM. Some neurological principles relevant to the origin of cortical-plasticity. In J. Grafman & Y. Christen (Eds.), *Neuronal plasticity: Building a bridge from the laboratory to the clinic*. Berlin: Springer-Verlag. 1999:169-187.

44. Wolf SL. Revisiting constraint-induced movement therapy: are we too smitten with the mitten? Is all nonuse "learned"? and other quandaries. *Phys Ther*. 2007;87:1212-1223.

45. Franck JA, Timmermans AAA, Seelen HAM. Effects of a dynamic hand orthosis for functional use of the impaired upper limb in sub-acute stroke patients: A multiple single case experimental design study. *Technol Disabil.* 2013;*25*(3):177-187. doi:10.3233/TAD-130374

46. Stuck RA, Marshall LM, Sivakumar R. Feasibility of SaeboFlex upper-limb training in acute stroke rehabilitation: A clinical case series. *Occup Ther Int. 2014;*21(3):108-114. doi:10.1002/oti.1369; 10.1002/oti.1369

47. Farrell JF, Hoffman HB, Snyder JL, Giuliani CA, Bohannon RW. Orthotic aided training of the paretic upper limb in chronic stroke: Results of a phase 1 trial. *Neurorehabilitation, 2007;22*(2):99-103.

48. Allison R, Shenton L, Bamforth K, Kilbride C, Richards D. Incidence, time course and predictors of impairments relating to caring for the profoundly affected arm after stroke: a systematic review. *Physiother Res Int*. 2015;1-18. DOI: 10.1002/pri.1634

49. Broeks JG, Lankhorst GJ, Rumping K, Prevo, AJH. The long-term outcome of arm function after stroke: results of a follow-up study. *Disabil Rehabil*. 1999;21(8):357-364.

50. Graham L. Management of spasticity revisited. *Age Ageing*. 2013;42:435-441.

51. Thibaut A, Chatelle C, Ziegler E, Bruno M, Laureys S, Gosseries O. Spasticity after stroke: Physiology, assessment and treatment. *Brain Inj.* 2013;27(10):1093-1105.

52. Sahrmann SA, Norton BJ. The relationship of voluntary movement to spasticity in the upper motor neuron syndrome. *Ann Neurol*. 1977;2:460-465.

53. Butler A, Blanton S, Rowe V, Wolf S. Attempting to improve function and quality of life using the FTM protocol: Case report. *J Neurol Phys Ther.* 2006*;30*(3):148-156.

54. Hayward K, Barker R, Brauer S. Interventions to promote upper limb recovery in stroke survivors with severe paresis: a systematic review. *Disabil Rehabil*. 2010;32:1973-1986.

55. Rand D, Eng J. Disparity between functional recovery and daily use of the upper and lower extremities during subacute stroke rehabilitation. *Neurorehabil Neural Repair*. 2012;26(1):76-84.

56. Rand D, Eng J. Predicting daily use of the affected upper extremity 1 year after stroke. *J Stroke Cerebrovasc Dis*. 2015;24(2):274-283.

57. McCombe Waller S, Whitall J, Jenkins T. et al. Sequencing bilateral and unilateral task-oriented training versus task oriented training alone to improve arm function in individuals with chronic stroke. *BMC Neurol*. 2014;14:236.

58. Rickards N, Sharma A, Prosser M. Feasibility audit of SaeboFlex in stroke patients: impact on recovery across the patient pathway. *J Assoc Chart Phys Neurol.* 2015;9-13.

59. Hayward K, Neibling B, Barker R. Self-administered, home-based SMART (Sensorimotor Active Rehabilitation Training) arm training: A single-case report. *Am J Occup Ther*. 2015;69:6904210020p1-6904210020p8.

60. Bandura, A., (1997). Self-efficacy: the exercise of control. New York: WH Freeman and Co.

61. Lewin A, Jobges M, Werheid K. The influence of self-efficacy, pre-stroke depression and perceived social support on self-reported depressive symptoms during stroke rehabilitation. *Neuropsych Rehabil.* 2013;23(4):546-562.

62. Riazi A, Aspden T, Jones F. Stroke self-efficacy questionnaire: a Rasch-refined measure of confidence post stroke. *J Rehabil Med.* 2014;46:406-412.

63. Jones F, Riazi A. Self-efficacy and self-management after stroke: a systematic review. *Disabil Rehabil*. 2011;33(10):797-810.

64. Hellstrom K, Lindmark B, Wahlberg B, Fugl-Meyer A. Self-efficacy in relation to impairments and activities of daily living disability in elderly patients with stroke: a prospective investigation. *J Rehabil Med*. 2003;35:202-207.

65. Salbach N, Mayo N, Robichaud-Ekstrand S, Hanley J, Richards C, Wood-Dauphinee S. Balance self-efficacy and its relevance to physical function and perceived health status after stroke. *Arch Phys Med Rehabil*. 2006;87:364-370.

66. Schmid A, Van Puymbroeck M, Altenburger P. et al. Balance and balance self-efficacy are associated with activity and participation after stroke: a cross-sectional study in people with chronic stroke. *Arch Phys Med Rehabil*. 2012;93(6):1101-1107.

67. Robinson-Smith G, Johnston M, Allen J. Self-care self-efficacy, quality of life, and depression after stroke. *Arch Phys Med Rehabil.* 2000;81:460-464.

68. Stevens D, Anderson DI, O'Dwyer NJ, Williams AM. Does self-efficacy mediate transfer effects in the learning of easy and difficult motor skills? *Conscious Cogn*. 2012;21:1122-1128.

69. Boger EJ, Hankins M, Demain SH, Latter SM. Development and psychometric evaluation of a new patient-reported outcome measure for stroke self-management: The Southampton Stroke Self-Management Questionnaire (SSSMQ). *Health Qual Life Outcomes*. 2015;13:1-9.

70. Lennon S, McKenna S, Jones F. Self-management programmes for people post stroke: a systematic review. *Clin Rehabil*. 2013;27(10):867-878.

71. McEwen S, Polatajko H, Baum C. et al. Combined cognitive-strategy and task-specific training improve transfer to untrained activities in subacute stroke: an exploratory randomized controlled trial. *Neurorehabil Neural Repair*. 2015;29(6):526-536.

72. Kessler D, Egan M, Dubouloz C, Graham F, McEwen S. Occupational performance coaching for stroke survivors: A pilot randomized controlled trial protocol. *Can J Occup Ther*. 2014;81(5):279-288.

73. Chen S, Lewthwaite R, Schweighofer N, Winstein C. Discriminant validity of a new measure of self-efficacy for reaching movements after stroke-induced hemiparesis. *J Hand Ther*. 2013;26:116-123.

74. Korpershoek C, van der Bijl J, Hafsteinsdottir T. Self-efficacy and its influence on recovery of patients with stroke: a systematic review. *J Adv Nurs*. 2011;67(9):1876-1894.

75. Bandura A. The nature and structure of self-efficacy. In: Bandura A, ed. *Self-efficacy: the exercise of control.* New York,W.H. Freeman and Company; 2007:36-78.

76. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychological Review*. 1977;84(2):191-215.

77. Jeon HS, Woo YK, Yi CH, et al. Effect of intensive training with a spring-assisted hand orthosis on movement smoothness in upper extremity following stroke: A pilot clinical trial. *Top Stroke Rehabil.* 2012;19(4):320-328. doi:10.1310/tsr1904-320; 10.1310/tsr1904-320

78. Barry JG, Ross SA, Woehrle J. Therapy incorporating a dynamic wrist-hand orthosis versus manual assistance in chronic stroke: A pilot study. *J Neurol Phys Ther.* 2012;36(1):17-24. doi:10.1097/NPT.0b013e318246203e; 10.1097/NPT.0b013e318246203e

79. Davenport S. Recovery within grasp? A report on a preliminary study investigating the short and medium term effects of the SaeboFlex (functional tone management system) on chronic post stroke patients with residual upper limb deficit. *Synapse.* 2005;(Spring):12-15.

80. Woo Y, Jeon H, Hwang S, Choi B, Lee J. Kinematics variations after spring-assisted orthosis training in persons with stroke. *Prosthet Orthot Int.* 2013;37(4):311-316. doi:10.1177/0309364612461050; 10.1177/0309364612461050

81. Pooyania S, Semenko B. Botulinum toxin type-A (BoNTA) and dynamic wrist-hand orthoses versus orthoses alone for the treatment of spastic-paretic upper extremity in chronic stroke patients. *Open J Ther Rehabil*. 2014;2(1):12-18.

82. Chang WD, Lai PT. New design of home-based dynamic hand splint for hemplegic hands: a preliminary study. *J Phys Ther Sci*. 2015;27:829-831.

83. McCombe Waller S, Prettyman MG. Arm training in standing also improves postural control in participants with chronic stroke. *Gait Posture*. 2012;36:419-424.

84. Linder SM, Rosenfeldt AB, Bay RC, Sahu K, Wolf SL, Alberts JL. Improving quality of life and depression after stroke through telerehabilitation. *Am J Occup Ther*. 2015;69(2):6902290020p1-6902290020p10.

85. Legg L, Langhorne P. Rehabilitation therapy services for stroke patients living at home: systematic review of randomised trials. *Lancet*. 2004;363:352-356.

86. Rice D, Janzen S, McIntyre A, Vermeer J, Britt E, Teasell R. Comprehensive outpatient rehabilitation program: hospital-based stroke outpatient rehabilitation. *J Stroke Cerebrovasc Dis*. 2016;25(5):1158-1164.

87. Creswell JW. Chapter 10. Mixed Methods Procedures. *In: Research Design: Qualitative, quantitative, and mixed methods approaches (4th Ed).* Sage Publications, Inc.; 2014.

88. Portney LG, Watkins MP. Chapter 12. Single-subject designs. *In: Foundations of clinical research (3rd Ed).* Upper Saddle River, NJ: Pearson Prentice Hall; 2009.

89. Kazdin AE. Chapter 6. Introduction to single-case research and ABAB designs. *In: Single-Case Research Designs (2nd Ed).* Oxford University Press; 2011.

90. Ottenbacher KJ. Chapter 3. Introduction to single system evaluation strategies. *In: Evaluating Clinical Change: Strategies for Occupational and Physical Therapists*. Williams & Wilkins; 1986.

91. Hayner KA. Effectiveness of the California tri-pull taping method for shoulder subluxation poststroke: A single-subject ABA design. *Am J Occup Ther*. 2012;66:727-736.

92. Fetters L, Tilson J. Chapter 9, Appraising Studies with Alternative Designs. *In: Evidence Based Physical Therapy (1st Ed);* 2012*:*114-124.

93. Harris JE, Eng J. Individuals with the dominant hand affected following stroke demonstrate less impairment than those with the nondominant hand affected. *Neurorehabil Neural Repair*. 2006;20:380-389.

94. Gustafsson L, Walter A, Bower K, Slaughter A, Hoyle M. Single-case design evaluation of compression therapy for edema of the stroke-affected hand. *Am J Occup Ther*. 2014;68:203-211.

95. Gustafsson L, Lunnon J, Hoyle M, Marshall K, Bower K. Single-case design study of finger-to-axilla compression bandaging for edema of the hemiplegic upper limb. *Am J Occup Ther.* 2016;70:7002210010p1-7002210010p7.

96. Ashford S, Slade M, Turner-Stokes L. Conceptualization and development of the arm activity measure (ArmA) for assessment of activity in the hemiparetic arm. *Disabil Rehabil*. 2013;35(18);1513-1518.

97. Ashford S, Turner-Stokes L, Siegert R, Slade M. Initial psychometric evaluation of the Arm Activity Measure (ArmA): a measure of activity in the hemiparetic arm. *Clin Rehabil*. 2013;27(8):728-740.

98. Gustafsson LA, Turpin M, Dorman C. Clinical utility of the Chedoke Arm and Hand Activity Inventory for stroke rehabilitation. *Can J Occup Ther*. 2010;77(3):167-173.

99. Barreca SR, Stratford PW, Lambert CL, Masters LM, Streiner DL. Test-retest reliability, validity, and sensitivity of the chedoke arm and hand activity inventory: A new measure of upper-limb function for survivors of stroke. *Arch Phys Med Rehabil.* 2005;86(8):1616-1622.

100. Barreca SR, Stratford PW, Master M, Lambert CL, Griffiths J, McBay C. Validation of three shortened versions of the Chedoke Arm and Hand Activity Inventory. *Physiother Can*. 2006;58:148-156.

101. Lin K, Fu T, Wu C, et al. Minimal detectable change and clinically important difference of the stroke impact scale in stroke patients. *Neurorehabil Neural Repair*. 2010;24(5):486-492.

102. Duncan PW, Wallace D, Lai SM, Johnson D, Embretson S, Laster LJ. The Stroke Impact Scale version 2.0: Evaluation of reliability, validity, and sensitivity to change. *Stroke*. 1999;30:2131-2140.

103. Vellone E, Savini S, Fida R, et al. Psychometric evaluation of the stroke impact scale 3.0. *J Cardiovasc Nurs*. 2015;30(3):229-241.

104. Sullivan K, Tilson J, Cen SY, et al. Fugl-Meyer assessment of sensorimotor function after stroke: standardized training procedure for clinical practice and clinical trials. *Stroke*. 2011;42:427-432.

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

106. Lin JH, Hsueh IP, Sheu CF, Hsieh CL. Psychometric properties of the sensory scale of the Fugl-Meyer Assessment in stroke patients. *Clin Rehabil*. 2004;18:391-397.

107. Lin JH, Hsu MJ, Sheu CF, et al. Psychometric comparisons of 4 measures for assessing upper-extremity function in people with stroke. *Phys Ther*. 2009;89(8):840-850.

108. Thibaut A, Chatelle C, Ziegler E, Bruno M, Laureys S, Gosseries O. Spasticity after stroke: physiology, assessment and treatment. *Brain Inj*. 2013;27(10):1093-1105.

109. Bohannon RW, Smith MB. Interrater reliability of a modified ashworth scale of muscle spasticity. *Phys Ther*. 1987;67(2):206-207.

110. Gregson JM, Leathley M, Moore AP, Sharma AK, Smith TL, Watkins C.L. Reliability of the tone assessment scale and the modified Ashworth scale as clinical tools for assessing poststroke spasticity. *Arch Phys Med Rehabil*. 1999;80:1013-1016.

111. Kaya T, Karatepe AG, Gunaydin R, Koc A, Ercan UA. Inter-rater reliability of the Modified Ashworth Scale and modified Modified Ashworth Scale in assessing poststroke elbow flexor spasticity. *Int J Rehabil Res.* 2011;34(1):59-64.

112. Shaw L, Rodgers H, Price C, et al. BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. *Health Technol Assess*. 2010;14(26):1-141.

113. Katz RT, Rovai GP, Brait C, Rymer Z. Objective quantification of spastic hypertonia: correlation with clinical findings. *Arch Phys Med Rehabil*. 1992;73:339-347.

114. Bertrand AM, Mercier C, Bourbonnais D, Desrosiers J, Gravel D. Reliability of maximal static strength measurements of the arms in subjects with hemiparesis. *Arch Phys Med Rehabil*. 2007;21:248-257.

115. Mathiowetz V, Weber K, Volland G, Kashman N. Reliability and validity of grip and pinch strength evaluations. *J Hand Surg*. 1984;9:222-226.

116. Boissy P, Bourbonnais D, Carlotti MM, Gravel D, Arsenault BA. Maximal grip force in chronic stroke subjects and its relationship to global upper extremity function. *Clin Rehabil*. 1999;13(4):354-362.

117. Lang CE, Edwards DF, Birkenmeier RL, Dromerick AW. Estimating minimal clinically important differences of upper-extremity measures early after stroke. *Arch Phys Med Rehabil*. 2008;89:1693-1700.

118. Law M, Baptiste S, Carswell A, McColl MA, Polatajko H, Pollock N. *Canadian Occupational Performance Measure (5th ed.).* Ottawa, ON: CAOT Publications ACE; 2014.

119. Eyssen IC, Steultjens MP, Oud TA, Bolt EM, Maasdam A, Dekker J. Responsiveness of the Canadian Occupational Performance Measure. *J Rehabil Res Dev*. 2011;48(5): 517-528.

120. Cup EH, Scholte op Reimer W, Thijssen M, van Kuyk-Minis M. Reliability and validity of the Canadian Occupational Performance Measure in stroke patients. *Clin Rehabil*. 2003;17:402-409.

121. Saebo Inc. *Improving upper extremity motor recovery following neurological injury* [Certification course manual]. Charlotte, NC: Saebo, Inc.; 2013.

122. Thorne S. Chapter 8. Making Sense of Data. *In: Interpretive Description.* Walnut Creek, CA: Left Coast Press, Inc.; 2008.

123. Sugg K, Muller S, Winstein C, Hathorn D, Dempsey A. Does action observation training with immediate physical practice improve hemiparetic upper-limb function in chronic stroke? *Neurorehabil Neural Repair*. 2015;29(9):807-817.

124. Nourbakhsh MR, Ottenbacher KJ. The statistical analysis of single-subject data: a comparative examination. *Phys Ther*. 1994;74(8):768-776.

125. Ottenbacher KJ. Chapter 7. Visual Analysis of Single System Data. *In: Evaluating Clinical Change: Strategies for Occupational and Physical Therapists*. Williams & Wilkins; 1986.

126. Bloom M, Fischer J. *Evaluating practice: Guidelines for the accountable professional*. Englewood Cliffs, NJ: Prentice-Hall; 1982.

127. Ottenbacher KJ. Chapter 8. Statistical Analysis of Single System Data. *In: Evaluating Clinical Change: Strategies for Occupational and Physical Therapists*. Williams & Wilkins; 1986.

128. Graham JE, Karmarkar AM, Ottenbacher KJ. Small sample research designs for evidence-based rehabilitation: issues and methods. *Arch Phys Med Rehabil*. 2012;93(8 Suppl): S111-S116.

129. Ottenbacher KJ. Chapter 4. Measurement and Recording Procedures Associated with Single System Designs. *In: Evaluating Clinical Change: Strategies for Occupational and Physical Therapists*. Williams & Wilkins; 1986.

130. Hsieh H, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-1288.

131. Downe-Wamboldt B. Content analysis: method, applications, and issues. *Health Care Women Int*. 1992;13:313-321.

132. Thorne S, Reimer Kirkham S, O'Flynn-Magee, K. The analytic challenge in interpretive description. *International Journal of Qualitative Methods*. 2004;3(1):1-11.

133. Creswell JW, Plano Clark VL. Chapter 7. Analyzing Data in Mixed Methods Research. *In: Designing and Conducting Mixed Methods Research*. Sage Publications, Inc.; 2007.

134. Maujean A, Davis P, Kendall E, Casey L, Loxton N. The daily living self-efficacy scale: a new measure for assessing self-efficacy in stroke survivors. *Disability and Rehabilitation.* 2014;36(6):504-511.

135. Andriske L, Verikios D, Hitch D. Patient and therapist experiences of the SaeboFlex: A pilot study. *Occupational Therapy International*. 2017; Article ID 5462078:1-6.

136. Lannin NA, Cusick A, Hills C, Kinnear B, Vogel K, Matthews K, Bowring G. Upper limb motor training using a Saebo^{TM} orthosis is feasible for increasing task-specific practice in hospital after stroke. *Australian Occupational Therapy Journal*. 2016;63(6):364-372.

137. Sabini RC, Dijkers M, Raghavan P. Stroke survivors talk while doing: development of a therapeutic framework for continued rehabilitation of hand function post stroke. *Journal of Hand Therapy*. 2013;26:124-131.

138. Soundy A, Stubbs B, Freeman P, Coffee P, Roskell C. Factors influencing patients' hope in stroke and spinal cord injury: a narrative review. *International Journal of Therapy and Rehabilitation*. 2014;21(5):210-218.

139. Barker RN, Brauer SG. Upper limb recovery after stroke: the stroke survivors' perspective. *Disability and Rehabilitation.* 2005;27(20):1213-1223.

140. Letts L, Wilkins S, Law M, Stewart D, Bosch J, Westmorland, M. Appendix D: Guidelines for critical review form: Qualitative studies (Version 2.0). *In: Law M, MacDermid J. Evidence-based rehabilitation: A guide to practice (2nd edition)*. Thorofare, NJ: Slack, 2007.

141. Winstein C, Lewthwaite R, Blanton SR, Wolf LB, Wishart L. Infusing motor learning research into neurorehabilitation practice: a historical perspective with case exemplar from the accelerated skill acquisition program. *Journal of Neurological Physical Therapy*. 2014;38:190-200.

142. Fryer CE, Luker JA, McDonnell MN, Hillier SL. Self management programmes for quality of life in people with stroke. *Cochrane Database of Systematic Reviews.* 2016; Issue 8. Art. No.: CD010442. DOI: 10.1002/14651858.CD010442.pub2.

143. Doucet BM. Neurorehabilitation: Are we doing all that we can? *The American Journal of Occupational Therapy*. 2012;66(4):488-493.