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Ph.D. Program in Rehabilitation Science

The Effectiveness of Anti-Spastic Splint with Added Focal Muscle Vibration (FMV) in Decreasing Hand Spasticity and Improving Hand Functionality Among Individuals with Chronic Stroke: A Pilot Randomized Control Trial.

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Declaration

I declare that, except where explicit reference is made to the contribution of others, this dissertation is substantially my own work and has not been submitted for any other degree at the Arab American University or any other institution.

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Dedication

I dedicate this work to my beloved late mother and father, whose memory continues to inspire me every day. Your love, wisdom, and sacrifices laid the foundation for all my achievements. To my dear wife and children, whose unwavering love, patience, and understanding made this journey possible - your support has been my strength through every challenge. Finally, I dedicate this research to all stroke survivors who courageously face their daily battles with determination and hope, with the sincere wish that this work contributes to improving your quality of life and restoring your independence.

Amer Hashem Mohamad Jaroshy

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This thesis represents not only my individual effort but also the collective contribution of all these remarkable individuals who believed in this work and supported its realization.

The Effectiveness of Anti-Spastic Splint with Added Focal Muscle Vibration (FMV) in Decreasing Hand Spasticity and Improving Hand Functionality Among Individuals with Chronic Stroke: A Pilot Randomized Control Trial.

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Dissertation Committee:

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Abstract

Background: Spasticity affects approximately 30-40% of stroke survivors within the first year, significantly impairing upper limb function and activities of daily living. Traditional single-modality interventions have demonstrated limited effectiveness in achieving sustained functional improvements for individuals with chronic hand spasticity following stroke. This study investigated whether combining focal muscle vibration (FMV) with anti-spastic splinting could provide superior outcomes compared to either intervention alone.

Objective: The primary aim was to evaluate the feasibility and adherence of focal muscle vibration when added to anti-spastic splinting for people with spasticity after stroke. The secondary objective was to investigate the preliminary effectiveness of this combined intervention on reducing spasticity and improving hand functionality among chronic stroke survivors.

Methods: A pilot randomized controlled trial was conducted with 37 participants with chronic stroke (mean age 58.46 ± 10.73 years, 62.2% male) recruited from rehabilitation centers in Jenin region, Palestine. Participants were randomly allocated to three groups using

covariate-adaptive randomization: Group A (anti-spastic splint + FMV, n=12), Group B (FMV only, n=12), and Group C (anti-spastic splint only, n=13). The intervention protocol consisted of 12 sessions over 4 weeks. FMV was applied at 100 Hz frequency with 0.2-0.5 mm amplitude for 30 minutes per session. Anti-spastic splints were custom-fabricated volar static splints maintaining functional hand positioning. Primary outcome measures included the Modified Ashworth Scale (MAS) for spasticity, Fugl-Meyer Assessment Upper Extremity (FMA-UE) for motor function, Numeric Pain Rating Scale (NRS) for pain assessment, and range of motion measurements. Data were analyzed using paired t-tests for within-group changes and Analysis of Covariance (ANCOVA) for between-group comparisons, controlling for baseline values.

Results: Feasibility outcomes exceeded all predetermined benchmarks with 51.3% recruitment rate, 100% retention rate, 89.2% ± 8.7% overall adherence, and zero adverse events across 421 intervention sessions. Protocol fidelity was high, with FMV frequency accuracy at 97.3% and positioning accuracy at 91.7%. Significant between-group differences were observed for all primary outcomes ($p < 0.05$). Group A (combined intervention) demonstrated the largest improvements: MAS reduction of -1.25 ± 0.62 points ($p < 0.001$), FMA-UE improvement of +8.75 ± 3.91 points ($p < 0.001$), and pain reduction of -2.58 ± 1.44 points ($p < 0.001$). Group B (FMV only) showed moderate improvements: MAS reduction of -0.92 ± 0.51 points ($p < 0.001$), FMA-UE improvement of +6.33 ± 3.42 points ($p = 0.002$), and pain reduction of -2.08 ± 1.31 points ($p = 0.003$). Group C (splint only) demonstrated minimal, non-significant changes across all measures. ANCOVA results revealed large effect sizes for spasticity (partial $\eta^2 = 0.335$) and motor function (partial $\eta^2 = 0.289$), and medium effect size for pain reduction (partial $\eta^2 = 0.200$). Both Groups A and B exceeded the established minimal clinically important difference of 4.25 points for FMA-UE, with Group A showing nearly double this threshold.

Conclusions: This pilot randomized controlled trial provides compelling evidence that combining focal muscle vibration with anti-spastic splinting is feasible, safe, and preliminarily effective for managing hand spasticity in chronic stroke survivors. The combined intervention demonstrated superior outcomes compared to either modality alone, with evidence of synergistic rather than merely additive effects. The improvements achieved were clinically meaningful and comparable to more invasive interventions such as botulinum toxin injections, while maintaining excellent safety and tolerability profiles. These findings challenge traditional single-intervention approaches and support an emerging paradigm of

multimodal, systems-based rehabilitation. The strong feasibility outcomes, including exceptional retention and adherence rates, provide a robust foundation for designing larger-scale definitive trials. Future research should focus on conducting adequately powered randomized controlled trials with longer follow-up periods to establish the sustainability of these promising effects and optimize intervention parameters for clinical implementation.

Keywords: stroke rehabilitation, spasticity, focal muscle vibration, anti-spastic splinting, upper limb function.

Clinical Trial Registration: ClinicalTrials.gov ID NCT06358976

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List of Definitions of Abbreviations

Abbreviations	Title
AAUP	Arab American University Palestine
ADL	Activities of Daily Living
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
AROM	Active Range of Motion
BTX	Botulinum Toxin
CIMT	Constraint-Induced Movement Therapy
CNS	Central Nervous System
CONSORT	Consolidated Standards of Reporting Trials
DTI	Diffusion Tensor Imaging
EMG	Electromyography
FMA	Fugl-Meyer Assessment
FMA-UE	Fugl-Meyer Assessment Upper Extremity
FMV	Focal Muscle Vibration
GABA	Gamma-Aminobutyric Acid
Hz	Hertz
LTD	Long-Term Depression
LTP	Long-Term Potentiation
MAS	Modified Ashworth Scale
MCID	Minimal Clinically Important Difference
mm	Millimeter
NDT	Neurodevelopmental Treatment
NRS	Numeric Pain Rating Scale
PNF	Proprioceptive Neuromuscular Facilitation
RCT	Randomized Controlled Trial
ROM	Range of Motion
RUDAS	Rowland Universal Dementia Assessment Scale
SD	Standard Deviation
SE	Standard Error

TMS	Transcranial Magnetic Stimulation
WHO	World Health Organization

GLOSSARY OF TERMS

Term	Definition
Acetylcholine	Neurotransmitter released at neuromuscular junctions that triggers muscle contraction
Adaptation	Process by which the nervous system adjusts its responses to repeated or sustained stimuli
Afferent	Sensory nerve fiber that carries information from peripheral receptors toward the central nervous system
α-motoneurons (Alpha-motor neurons)	Lower motor neurons that directly innervate skeletal muscle fibers and control voluntary muscle contraction
Cerebellum	Brain region involved in motor coordination, balance, and motor learning
Cerebral cortex	Outer layer of the brain responsible for higher-order functions including voluntary movement and sensation
Constraint-Induced Movement Therapy (CIMT)	Rehabilitation technique that forces use of the affected limb by restraining the unaffected limb
Contracture	Permanent shortening of muscles, tendons, or ligaments causing joint deformity and limiting range of motion
Cortical	Relating to the cerebral cortex or outer layer of the brain
Corticospinal	Relating to neural pathways that connect the cerebral cortex to the spinal cord, crucial for voluntary movement
Damage	Injury or harm to neural tissue that can result in functional impairments
Depolarization	Change in cell membrane potential toward a more positive value, often triggering neural activity
Diffusion Tensor Imaging (DTI)	MRI technique that maps white matter tracts and neural connectivity in the brain
Dysfunction	Abnormal or impaired function of neural or muscular systems
Electromyography (EMG)	Technique for measuring electrical activity produced by skeletal muscles

Excitatory	Relating to neural signals that increase the likelihood of action potential generation
Excitotoxicity	Neuronal damage caused by excessive stimulation from excitatory neurotransmitters
Facilitation	Enhancement of neural transmission or muscle activation
Feedback loop	Neural circuit where output information is fed back to influence input, important for motor control
GABA (Gamma Aminobutyric Acid)	Primary inhibitory neurotransmitter in the central nervous system
Glutamate	Primary excitatory neurotransmitter in the central nervous system
H-reflex	Electrically elicited reflex used to assess the excitability of spinal motor neurons
Hemiparesis	Weakness or partial paralysis affecting one side of the body, commonly occurring after stroke
Hemiplegia	Complete paralysis of one side of the body
Hypertonicity	Abnormally increased muscle tone or tension, often associated with spasticity
Ia afferents	Primary sensory nerve fibers from muscle spindles that provide information about muscle length and velocity of stretch
Impairment	Loss or abnormality of physiological or anatomical structure or function
Inhibitory	Relating to neural signals that decrease the likelihood of action potential generation
Injury	Physical damage to neural or muscular tissue
Integration	Process by which the nervous system combines multiple inputs to produce coordinated responses
Interneuron	Neuron that connects sensory and motor neurons within neural circuits
Lesion	Area of tissue damage or abnormality, particularly in the nervous system

Long-Term Depression (LTD)	Persistent weakening of synaptic connections based on patterns of neural activity
Long-Term Potentiation (LTP)	Persistent strengthening of synaptic connections based on patterns of neural activity
Lower motor neuron	Motor neuron located in the spinal cord or brainstem that directly innervates skeletal muscle
Mechanoreceptor	Sensory receptor that responds to mechanical stimuli such as touch, pressure, or vibration
Meissner corpuscle	Cutaneous mechanoreceptor that responds to light touch and low-frequency vibration
Merkel disk	Cutaneous mechanoreceptor that responds to sustained light touch and texture
Microglia	Resident immune cells of the brain that respond to injury and inflammation
Motor cortex	Brain region in the frontal lobe responsible for planning and executing voluntary movements
Motor output	Neural signals sent from the central nervous system to muscles to produce movement
Motor unit	A motor neuron and all the muscle fibers it innervates
Motoneuron	Motor neuron; nerve cell that controls muscle contraction by transmitting signals from the CNS to muscles
Muscle spindle	Sensory receptor within muscles that detects changes in muscle length and contributes to proprioception
Neuromodulation	Therapeutic intervention that alters nerve activity through targeted delivery of stimuli
Neuroplasticity	The brain's ability to reorganize and form new neural connections throughout life
Pacinian corpuscle	Deep mechanoreceptor that responds to high-frequency vibration and deep pressure
Plasticity	Ability of neural tissue to change and adapt in response to experience or injury
Prefrontal cortex	Brain region involved in executive function, decision-making, and motor planning

Premotor cortex	Brain region involved in motor planning and preparation of movements
Presynaptic inhibition	Mechanism that reduces neurotransmitter release at synapses, modulating signal transmission
Proprioception	Sense of body position and movement in space, mediated by specialized receptors
Proprioceptor	Sensory receptor that provides information about body position and movement
Reciprocal inhibition	Neural mechanism where activation of one muscle group inhibits its antagonist muscles
Recovery	Process of regaining function following injury or disease
Reflex arc	Neural pathway that mediates a reflex action, typically involving sensory input and motor output
Reorganization	Process by which neural circuits restructure themselves, often following injury
Reticulospinal	Relating to neural pathways from the brainstem reticular formation to the spinal cord
Sensorimotor cortex	Brain region that integrates sensory and motor information for movement control
Sensory input	Information received by the nervous system from sensory receptors
Somatosensory	Relating to bodily sensations including touch, pressure, temperature, and proprioception
Spasticity	Neurological condition characterized by velocity-dependent increase in muscle tone and hyperactive reflexes
Spinal cord	Central nervous system structure that transmits signals between the brain and peripheral nervous system
Spinal reflex	Automatic response mediated by neural circuits within the spinal cord
Stretch reflex	Automatic muscle contraction in response to muscle stretch, mediated by muscle spindles
Subcortical	Relating to brain structures located beneath the cerebral cortex

Suppression	Reduction or inhibition of neural activity or responses
Supraspinal	Relating to neural structures and pathways above the level of the spinal cord
Synaptic plasticity	Ability of synapses to strengthen or weaken over time based on activity patterns
Tactile	Relating to the sense of touch
Thalamus	Brain region that relays sensory and motor information between different brain areas
Threshold	Minimum level of stimulation required to trigger a neural response
Transcranial Magnetic Stimulation (TMS)	Non-invasive brain stimulation technique using magnetic fields
Upper motor neuron	Motor neuron located in the brain that controls lower motor neurons in the spinal cord

Chapter 1: Introduction

1.1. Introduction

Stroke is a serious health problem of the 21st century that occurs in millions of people all over the world and leaves a considerable percentage to live with permanent neurological deficits that affect their quality of life and independence in activities of daily living (World Health Organization, 2025). One of the numerous complications that arise following a stroke, upper limb spasticity, is an extremely debilitating outcome that has traditionally proved refractory to management with standard treatment modalities (Burke et al., 2013). The complexity of post-stroke spasticity, characterized by velocity-dependent muscle tone increase, hyperreflexia, and subsequent functional limitations. These complications have necessitated the creation of new, multimodal rehabilitation approaches that simultaneously target biomechanical and neurophysiological aspects of this condition (Francisco & McGuire, 2012). The study was prompted by the recognition that traditional interventions with a single modality, though beneficial, have demonstrated limited effectiveness in achieving sustained functional improvements for those suffering from chronic hand spasticity following stroke (Lannin & Herbert, 2003). The research in this thesis examined the feasibility and preliminary effectiveness of simultaneous focal muscle vibration and anti-spastic splinting—a new treatment strategy that merged neuromodulation strategies with biomechanical support to deal with the complexity of post-stroke spasticity (Caliandro et al., 2012). This empirical investigation sought to enhance the developing knowledge regarding evidence-based rehabilitation interventions with the potential to adapt the rehabilitative setting for chronic stroke survivors with ongoing upper limb dysfunction (Buma et al., 2013).

1.2. Background and Rationale

Stroke is a leading cause of long-term disability worldwide. It has high rates of both morbidity and mortality and creates lasting disabilities in its survivors, impacting their

independence and overall quality of life. Over 15 million people suffer a stroke each year worldwide (WHO, 2025), with nearly two-thirds residing in low- and middle-income countries. About half of stroke survivors will suffer from long-term disabilities, such as spasticity or weakness (Toth et al., 2020) , thereby placing immense burden on healthcare resources and caregiving networks.

The financial burden of stroke is particularly high, including direct medical expenses, reduced productivity, and prolonged caregiver expenses. In 2016, the overall economic burden of stroke in the U.S. totaled an estimated $103.5 billion, including inpatient care, rehabilitation, and loss of earnings through disability. In many cases, unpaid family members serve as informal caregivers, with significant psychological and financial burden, in regions with little access to rehabilitation and high rehabilitation service costs. All these factors speak in strong terms for rehabilitation programs expansion, fair access to new therapies, and overall post-stroke rehabilitation and life improvement through policy reform.

Spasticity is a velocity-dependent rise in muscle resistance to passive stretching, that is coupled with hyperactive reflexes, which interrupt the performance of voluntary movement (Burke et al., 2013). It is a common stroke complication, with about 30% to 40% of post-stroke survivors developing spasticity in the first year, and a significant proportion of them developing it even later. Several factors, such as severity of the stroke, availability of rehabilitation interventions, and duration post-onset, affect spasticity development, with spasticity in upper limb proving particularly debilitating for fine motor function and overall independence (Francisco & McGuire, 2012).

Spasticity affecting the upper limb and hand profoundly hinders activity of daily living (ADLs) through restriction of voluntary motion, causing joint contractures and compromising dexterity. Grasping, releasing, handwriting, dressing, and use of utensils become increasingly difficult with increased muscle stiffness and hypertonicity interfering with coordinated motion (Kwakkel et al., 2008). Muscle shortening and deformity that arise with persistent spasticity worsen disability and lessen rehabilitation effectiveness. Inability to functionally use the hand necessitates use of the uninvolved limb, and through a mechanism of learned non-use, reduces neuroplastic potential for rehabilitation (Ballester et al., 2016).

Beyond the restrictions placed by physical impairment, upper limb impairment following a stroke creates considerable psychological and emotional consequences. Many survivors face feelings of frustration, anxiety, and depression stemming from an inability to carry out routine activities, subsequently lowering self-esteem and enhancing social isolation (Robinson & Jorge, 2016). The emotional distress surrounding spasticity is often compounded by ongoing pain and discomfort it creates, subsequently impacting mental well-being and overall wellness. In addition, caregiver dependency for routine daily living activities can develop feelings of helplessness and dependency, subsequently impairing motivation and rehabilitation program attendance (Gandolfi et al., 2021). To effectively address such complications, an overall approach must integrate physical rehabilitation with psychosocial intervention and specific interventions designed to enhance both motor rehabilitation and mental well-being.

2.2.1. Management Strategies for Spasticity

In contrast to significant advances in acute stroke management, long-term complications in predominantly upper limb dysfunctional and spasticity have continued to represent a significant challenge. Effective management of spasticity is a significant component of stroke rehabilitation, especially in those chronic spastic patients with a tendency to develop chronic disabilities despite intensive treatments. A substantial body of evidence indicates that the reduction of spasticity in the arm is intrinsically linked to significant enhancements in arm functionality, underscoring the critical interplay between spasticity management and functional recovery (Francis et al., 2004). Traditional methods of managing spasticity can be broadly divided into two main categories: pharmacological and non-pharmacological methods.

Pharmacological interventions, such as intramuscular injection of botulinum toxin, oral antispasmodics, and intrathecal administration of baclofen, have been extensively tried and tested in the treatment of hypertonicity. While these medications can successfully reduce muscle tone, they have some shortcomings. For instance, the effect of botulinum toxin is not sustainable and requires follow-up with repeated injections, which are invasive and not cost-effective. In the same way, drugs that are given via the oral route may be linked with systemic adverse effects such as drowsiness, muscle weakness, or fatigue, thus limiting their use over a long period (Nair & Marsden, 2014). Secondly, pharmaceutical care may be also limited within poor environments in terms of

resource and infrastructural deficiency, thus excluding numerous patients from accessing appropriate alternatives.

A variety of non-pharmacologic therapies, including stretching, splinting, proprioceptive neuromuscular facilitation (PNF), and neurodevelopmental treatment (NDT), are crucial for managing spasticity and improving motor function (Nair & Marsden, 2014). Through sensory-motor integration, NDT aimed to enable normal movement patterns. However, recent systematic reviews have found that there aren't enough empirical evidence to demonstrate the usefulness of NDT in reducing spasticity and improving functional performance following a stroke (Pathak et al., 2021).

Similarly, PNF is a therapeutic approached used with stroke patients to improve motor control, movement pattern, and range of motion. PNF is based on the principles of neuroplasticity, proprioception, and motor learning. It uses movement patterns that mimic natural functional movement to promote coordinated movement and inhibit reflexive activities after stroke. Despite the theoretical basis, current systematic reviews concluded the lack of quality evidence to support its effectiveness with spasticity after stroke (Alashram et al., 2021).

Hand splinting is largely popular nonpharmacological approach to manage spasticity in individuals with neurological conditions, such as stroke (Naro et al., 2017). The principle of splinting is mainly relied on providing a biomechanical support to the hand. This is achieved by keeping the hand in functional or neutral position, providing continues stretching of the spastic muscle. That may reduce hyper tone, decrease the probability of secondary complications such as contracture and/or muscle shortening. These complications are known to be prevalent in individuals with chronic stroke(Andringa et al., 2013). Also splinting found to reduce pain caused by spasticity and improve passive range of motion as well as hand positioning for functional activities (James & rehabilitation, 2001). However, splint effectiveness varies significantly based on the optimal design, material used, client education and commitment, which necessitates individualized treatment approaches (Lannin & Herbert, 2003).

2.2.2. Problem Statement:

Management of spasticity in the hand following stroke is a challenging clinical issue that demands novel, evidence-based solutions to yield concrete advances in function (Francisco & McGuire, 2012). Despite various presumed benefits of hand splinting,

effectiveness in the long-term concerning spasticity of the hand has been contentious, with systematic reviews indicating insufficient or variable evidence to establish its independent effect on hand rehabilitation and functional outcomes (Lannin & Herbert, 2003). The shortcomings of single-modality treatments were further accentuated by clinical observations and empirical study findings (Buma et al., 2013). Conventional methods, such as pharmacological and non-pharmacological strategies, could not effectively address the multifaceted nature of post-stroke spasticity that encompasses both biomechanical and neurophysiological characteristics (Burke et al., 2013). The multi-dimensional and complex nature of spasticity, as defined by alterations in muscle tone, motor function impairment, and resulting complications like contractures, demanded integrated strategies that had the capability to target multiple facets of the disorder concurrently (Francisco & McGuire, 2012). Current clinical guidelines have recommended the use of hand splinting in combination with other rehabilitation approaches, with the acknowledgment that splinting offers critical structural support and contracture prevention that can enhance total hand function when coupled with other treatments (Buma et al., 2013). This combined approach needs more research to establish whether it is beneficial in streamlining stroke rehabilitation outcomes and informing evidence-based practice recommendations in the therapeutic setting. There was a gap of empirical data on multimodal strategies to spasticity management specifically in the domain of integrating biomechanical interventions and neuromodulation techniques (Naro et al., 2017). Although isolated interventions have been the subject of intense investigation, the synergistic impacts that arise from the interaction of different therapeutic modalities have largely not been examined (Buma et al., 2013). This represented a significant limitation in the existing understanding of ideal rehabilitation strategies for persons suffering from chronic spasticity in the hand after stroke. Furthermore, the need for easily accessible and economically viable interventions was particularly urgent in low- and middle-income countries, where a high percentage of stroke survivors resided but had considerable difficulty accessing ever-costly pharmacological interventions or sophisticated rehabilitative devices (World Health Organization, 2025). The creation of evidence-based, integrated approaches that can be applied across various healthcare environments is a key priority for stroke rehabilitation globally.

1.3. The Research Aims

The primary aim of this pilot randomized controlled trial was to evaluate the feasibility and adherence of focal muscle vibration when added to anti-spastic splinting for people with spasticity after stroke. This feasibility assessment was crucial for determining the viability of conducting a larger-scale definitive trial and for identifying potential barriers to implementation in clinical practice. The feasibility evaluation encompassed multiple dimensions, including recruitment rates, retention rates, adherence to the intervention protocol, acceptability of the intervention to participants, and the practicality of outcome measurement procedures. These feasibility parameters were essential for informing the design and implementation of future larger-scale studies

The secondary objective of this trial was to investigate the preliminary effectiveness of focal muscle vibration when added to anti-spastic splinting on reducing spasticity and improving hand functionality among people with stroke. This preliminary effectiveness evaluation was designed to obtain estimates that could be used to design a future definitive trial, including effect size calculations and sample size determinations.

1.4. Significance of the Study

The present study is a significant contribution towards overcoming the challenge posed to persons with chronic stroke, particularly with spasticity and reduced hand function. As one of the first studies to explore the concurrent use of anti-spastic splinting and focal muscle vibration (FMV) in such a population, it fills an important gap in current literature and brings new insights into cutting-edge, multimodal rehabilitation techniques. The implications of this study will have significant impact on rehabilitation practice, and chronic stroke survivors.

This study will contribute to growing body of knowledge regarding effective spasticity management and improvement in hand function through an investigation of synergistic effects of combining biomechanical support (splinting) and neuromodulation techniques (FMV). Outcomes will extend the current understanding of potential in combining such interventions with current rehabilitation approaches, offering a new model for enhancing rehabilitation outcomes for chronic stroke survivors.

This research clarifies factors that impact hand function in persons with a history of chronic strokes, with an emphasis placed on the interrelationship between spasticity, motor control, and activity of daily living. By examining the impact of the proposed intervention on hand function, this study offers valuable insights regarding the specific needs of persons with a history of chronic strokes and identifies a critical role for individualized rehabilitation techniques.

The results of this pilot randomized controlled trial will provide a solid foundation for future large-scale studies and clinical trials. By demonstrating the feasibility and potential benefits of combining anti-spastic splinting with FMV, this research paves the way for further exploration of multimodal interventions in stroke rehabilitation. It also offers a possible structure for designing and implementing similar studies targeting hand function in chronic stroke survivors.

This study is focused on chronic stroke survivors, but its implications could extend to other groups with similar challenges, such as persons with traumatic brain injuries, spinal cord injuries, or neurological disease. In addition, the information gained through this study could contribute towards enhancing rehabilitation programs in general.

Chapter 2: Literature Review

2.1. Part 1: Stroke

2.1.1. Prevalence and Incidence of Stroke

Stroke remains one of the major public health concerns worldwide, its incidence steadily increasing due to the aging population and the growing burden of chronic diseases such as hypertension, diabetes, and obesity (Boehme et al., 2017). The World Health Organization reported that about 13 million persons yearly suffers from a stroke more than5 millions of them are fatal, and about 5 million sustain permanent disability. Also There are about 101 million people affected aby stroke worldwide. (World Health, 2022). These figures suggest that the amount of stress due to stoke on the health systems, families, and also societies is immense.

Low- and middle-income countries (LMICs) suffers more severe problem when compared to other countries. Nearly three-quarters of stroke-related deaths occur in these states. Strokes in LMICs have increased and are linked to poor management of complications such as high blood pressure, lack of access to care, and preventive options (Rahbar et al., 2022). In a matter of a few decades, it is predicted that overall cases of stroke will increase with an aging population and such complications becoming increasingly prevalent in such regions (Donkor, 2018).

The situation in high-income countries is different, the incidence of strokes has stabilized and even reduced in some cases. This is predominantly due to enhanced public health programs, increased management of modifiable risk factors, and rapid advanced intervention for acute strokes (Di Legge et al., 2012; Feigin, 2021). Despite such improvements, a lot of disabilities in high-income countries result from strokes. Most survivors require prolonged rehabilitation. The financial burden is very high, with medical expenses for strokes and loss of productivity costing billions of dollars annually in these nations (Di Legge et al., 2012).

Age is one of the most essential determinants of incidence and prevalence of stroke. Stroke risk doubles with each decade after the age of 55; thus, the older adults hold a

disproportionate share of both ischemic and hemorrhagic strokes (Feigin, 2021). However, increased incidence of stroke among young adults, aged between 18–45 years, is particularly alarming. The rise is attributed to several factors, which include uncontrolled hypertension, tobacco use, as well as an increasing incidence of metabolic disorders, especially diabetes and obesity (Sultan & Elkind, 2013). Younger patients with stroke have particular challenges, not only that they often need long-term rehabilitation and support, but also the socioeconomic impact due to stroke magnifies (Morris, 2011).

Gender differences in the incidence and consequences of stroke are well established in the literature. Men are statistically more likely to have a stroke than women, especially at younger ages; however, women suffer more severe consequences, including higher mortality and disability rates, especially among older cohorts (Petrea et al., 2009). Women also have a higher risk for complications, including atrial fibrillation and post-stroke depression, which worsen poor outcomes compared to their male counterparts. Furthermore, hormonal factors related to pregnancy and menopause greatly determine stroke risk among women, thus rendering imperative the need for more tailored approaches of stroke prevention and management, considering the gender dimension (Yoon & Bushnell, 2023).

Due to the lack of comprehensive national statistics in Palestine concerning prevalence and incidence, there cannot be an assessment of the overall magnitude of the problem of strokes. Nevertheless, studies from hospital settings have been indicating that strokes are becoming more frequent, particularly among young people, against the background of the rising prevalence of risk factors such as hypertension and diabetes (Sawalha, 2009). There are significant challenges to be faced by the healthcare infrastructure in Palestine in confronting the rising trend of stroke incidence, as services for stroke prevention, acute intervention, and rehabilitation are markedly limited, more so in rural and marginalized areas (Khatib et al., 2018).

Understanding the global and regional trends in stroke incidence and prevalence is critical to designing targeted public health interventions aimed at reducing the burden of stroke. High-income countries have shown great improvements in the prevention and treatment methods for stroke, while low- and middle-income countries show rising incidence rates with limited access to health services This thus provides a strong call for

action in the addressing risk factors that lead to stroke and in the improvement of health systems in resource-poor settings.

2.1.2. Pathophysiology of Stroke

The pathophysiological mechanisms underlying stroke represent a complex, multifactorial process characterized by the sudden interruption of cerebral blood flow, which leads to neuronal dysfunction and tissue injury. Stroke can be subclassified into two main types: ischemic stroke, accounting for approximately 87% of all cases, and hemorrhagic stroke, accounting for the rest 13%. The mechanisms of injury differ between these two groups; however, both result in significant neurologic dysfunction and long-term disability (Kuriakose & Xiao, 2020).

The circle of Willis manages the brain blood flow, it consisted of two carotids anteriorly another tow vertebral. Deficiency in blood flow to the brain causes ischemic stroke, which contributes to about 85% of stroke incidence. Ischemic stroke caused by thromboses or embolism in the brain. Atherosclerosis occurs due to plaque buildup in blood vessels, which narrows the vessels space and form a clot resulting in thrombotic stroke. (Musuka et al., 2015). In the event of embolic stroke, a clot migrates from a different source to block a brain artery. This blockage causes disruption of blood flow to the brain tissue causing necrosis. The embolism could migrate from the heart, or could be from venous or arterial origins (Ibrahim & Murr, 2020). Necrosis leads to plasma membrane damage cellular contents leak into the surrounding tissue, which leads to neuronal function loss (Broughton et al., 2009). Other major stroke consequences are, homeostasis loss, elevation in calcium levels, cytotoxicity, and excitotoxicity (Woodruff et al., 2011).

The penumbra, the region surrounding the central ischemic core, is the key to recovery after a stroke. Whereas the core dies rapidly and irreversibly in a few minutes, the penumbra consists of hypoperfused yet still viable tissue that can be rescued by timely intervention of reperfusion (Liu et al., 2010). Therapeutic strategies, such as thrombolysis with tissue plasminogen activator (tPA) or mechanical thrombectomy, aim at restoring perfusion to the penumbra and reducing the extent of cerebral damage (Gauberti et al., 2021). However, the time window for effective treatment is limited, typically within 4.5 hours for tPA and up to 24 hours for mechanical thrombectomy (Wechsler, 2014).

Hemorrhagic stroke results from rupture of a blood vessel, with bleeding confined either to within the brain parenchyma—defined here as intracerebral hemorrhage—or among the spaces in and around the brain, classified here as subarachnoid hemorrhage (Qureshi et al., 2001). The presence of blood outside of the vessels increases intracranial pressure while at the same time causing mechanical damage to cerebral tissue. The accumulation of blood in the brain sets off a cascade of downstream events, including neuroinflammation, oxidative stress, and compromise of the blood-brain barrier (Macellari et al., 2014).

In intracerebral hemorrhage (ICH), the mechanical effect of the hematoma compresses and displaces the surrounding brain structures, causing local tissue injury. Toxic by-products released from the breakdown of blood cells, including iron and heme, further contribute to neuronal injury. The inflammation following hemorrhage involves activation of microglia, the resident immune cells of the brain, and the release of pro-inflammatory cytokines, including IL-6 and TNF-α. All in all, this inflammatory response increases brain injury and promotes the development of perihematomal edema by increasing pressure on surrounding brain tissue, thereby worsening outcomes (Derry et al., 2020).

Subarachnoid hemorrhage (SAH) is normally caused due to a rupture of an aneurysm or the development of arteriovenous malformation causing bleeding into the brain surrounding, thus, mixing with the cerebrospinal fluid (CSF) (Edlow et al., 2008). It is most often preceded by severe painful headaches, and the likelihood of the following vasospasm, which is a potential cause of such ischemia. Vasospasm is generally caused by the breakdown products of blood, and in particular oxyhemoglobin, the result of which are the stimulation of blood vessels and consequent restriction. The contraction of the blood vessels decreases vasodilation to the brain thereby exposing an individual to the development of additional delayed ischemic deficits at a worse condition. Management of a subarachnoid hemorrhage often requires surveillance and requires the administration of calcium channel blockers, which potentially minimizes occurrence of secondary ischemia (Bernardini & Mayer, 1998; Siasios et al., 2013).

Long-term consequences of both ischemic and hemorrhagic stroke are based on the area and the size of the involved brain tissue. Neurological impairment typically entails unilateral weakness or hemiparesis, language impairment (aphasia), speech difficulty

(dysarthria), and defects in the fields of vision (Perna & Temple, 2015). Additional classic findings involve cognitive impairment especially in memory, attention, and executive function; which may impact the potential to return to normal activities (Elendu et al., 2023).

In both kinds of strokes, early intervention is very much important to reduce neuronal damage and improve functional outcomes. Over the past few years, with the advent of new imaging techniques such as MRI and CT angiography, clinicians can better identify the ischemic penumbra and hence guide appropriate treatment decisions. These neuroimaging modalities make the diagnosis more accurate and timely use of the reperfusion therapies improves the rate of recoveries (Nukovic et al., 2023).

Spasticity

Spasticity is a neurologic condition wherein there is an abnormal increase in muscle tone and involuntary muscle contraction, typically as a result of damage to the upper motor neuron. It often occurs after neurologic events such as strokes, with approximately 39% of stroke patients developing it in the initial year (Alashram et al., 2019).

Spasticity is defined by the Support Program for Assembly of a Database for Spasticity Measurement (SPASM) as “disordered sensory-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles” (Bhimani et al., 2014).

The importance of spasticity is evident in its potential to drastically limit mobility and activities of daily living, creating greater dependence on caregivers and a diminished quality of life for those affected (Bhimani et al., 2014).

Spasticity mechanisms are due to complex central nervous system and muscular system interactions. Implication of parts of the brain or spinal cord that are responsible for voluntary movement interferes with the control of muscle function, causing exaggerated reflexes and rigidity on stretching (Suputtitada, 2023).

This neurological deficit causes two primary mechanisms of spasticity: reflexively mediated mechanisms, with increased stretch reflexes due to a loss of inhibitory control, and non-reflexively mediated mechanisms, where maladaptive neural plasticity is the basis for abnormal excitatory patterns (Suputtitada, 2023).

It is essential to understand the mechanism and effects of spasticity to create personalized treatment regimens targeting both the muscular and neurological aspects of the condition. With proper management, functional independence can be regained and the quality of life improved by many, highlighting early intervention and the need for interdisciplinary medical care (Doquenia, 2023).

Mechanism of Spasticity

Spasticity is expressed by intermittent or persistent involuntary muscle contractions that are velocity-dependent, resulting in hypertonia and hyperactive reflex responses. The physiological mechanisms underlying spasticity are exemplified by complex interactions among the brain, spinal cord, and peripheral nervous system (Bhimani et al., 2014).

Neurological Basis

Development of spasticity is commonly associated with cerebral cortex damage, typically following events like stroke. The damage prevents normal communication between brain and muscle, leading to involuntary contraction of the muscle when it should be at rest (Bhimani et al., 2014). Destruction of the inhibitory control of the lower motor neurons results in hyperexcitability of the spinal motor neurons, leading to the features of spasticity, such as resistance to stretch on a velocity-dependent basis and hyperreflexia (Suputtitada, 2023).

Mechanisms of Action

Two primary mechanisms have been identified in the development of spasticity:

Reflexively Mediated Mechanisms: This phenomenon is an increase in stretch reflexes that occurs as a result of decreased supraspinal inhibition after injuries to upper motor neurons. The injured pathways are unable to inhibit the spinal reflex arcs, and this results in hyper-reflexive responses and spontaneous muscle contractions (Suputtitada, 2023).

Non-reflexively mediated mechanisms involve maladaptive plasticity, wherein the brain creates novel neural connections that can result in increased muscle stiffness. Such neural plasticity may result in the development of pathways that, although compensatory in nature, generate abnormal excitatory patterns that reinforce spasticity (Suputtitada, 2023).

Impact on Muscle Function

The accompanying physiological changes of spasticity may cause muscle contractures and alteration of muscle fiber composition, thereby aggravating the condition. As the classification and proportion of muscle fibers change, the biomechanical properties of affected muscles may decline, ultimately progressing to decreased function and greater stiffness over time (Duan et al., 2023). The alterations in spastic muscles are the mirror image of a multifaceted interaction between neurological injury and changed muscle physiology, which perpetuates the chronic characteristics of spasticity unless effectively treated (Rivelis et al., 2018). Understanding of the mechanisms of spasticity is of paramount importance to the development of effective therapy, as it provides the rationale for a personalized approach that would target both the neurological and muscular aspects of the disorder. Therapeutic interventions, such as physical reconditioning and pharmacologic therapies, seek to counteract these fundamental processes and maximize patient outcomes (Suputtitada et al., 2024).

2.1.3. Spasticity as a Stroke Complication

The clinical presentation of stroke survivors often includes impaired movement, often brought about by a combination of upper motor neuron syndromes such as spasticity, muscle weakness, loss of coordination, decreased dexterity, and prolonged muscle contractions. individuals with spasticity are often presented with functional impairment and a reduced quality of life. Abnormal postural patterns are usually present, which can be accounted for by an imbalance between agonist and antagonist muscle strength and the presence of hypertonia. Throughout the early stages of recovery of voluntary movement, the stroke patient will exhibit synergic patterns of mass muscle contractions. For the upper limb, this would involve adduction and internal rotation of the shoulder, elbow, wrist, and fingers flexion, and pronation of the forearm. For the lower limb, extensor synergy is commonly seen, involving adduction of the hip, extension of the hip and knee, and equinovarus position of the foot. As recovery continues, the synergistic patterns become attenuated; however, deficits in individual movements tend to remain (Sheffler & Chae, 2015).

Especially in the first year, spasticity usually causes disability and it worsens over time. Although some stroke survivors may not develop spasticity immediately post stroke but they may go on to develop it up to one year after stroke (Welmer et al., 2010). Recent

evidence, indicates an average onset period of approximately 34 days for spasticity among post-stroke survivors. Notably, a significant proportion of cases (50%) manifest spasticity within the initial month following stroke, with subsequent occurrences distributed over later time frames. Specifically, 25% of cases exhibit spasticity at two months post-stroke, and a smaller fraction (13%) presents symptoms after three months (Nam et al., 2019). These findings underscore the temporal dynamics of spasticity onset in this population, highlighting the need for clinical management of spasticity. Importantly 70% of post stroke survivors develop spasticity in the upper limb (Shiner et al., 2020).

It arises from upper motor neuron (UMN) damage in the corticospinal tract. This damage disrupts the balance between excitatory and inhibitory signals that control voluntary movement (Toth et al., 2020). In healthy individuals, the corticospinal tract carries motor signals from the brain to spinal neurons. These signals ensure precise control of voluntary movements. Stroke-related damage weakens inhibitory control over spinal reflexes. This leads to stretch reflex hyperexcitability, causing prolonged and excessive muscle contractions, even with minimal stimulation. This process results in resistance to passive movement, a defining feature of spasticity (Li & Francisco, 2015).

Spasticity manifests in various forms, each contributing to its complexity. Some individuals experience clonus, defined as rhythmic, involuntary muscle contractions often observed in the wrist or ankle. Others develop muscle stiffness or contractures, where sustained hypertonicity results in permanent muscle shortening and joint deformities (Trompetto et al., 2014). Contractures significantly limit range of motion, exacerbate pain, and elevate the risk of skin breakdown. These changes further restrict participation in rehabilitation activities (Harvey et al., 2017).

A key contributing factor of post-stroke pain development is increased muscle tone. Research has shown a strong association between spasticity and pain among stroke patients, with 72% of the spastic patients experiencing pain and 1.5% of the non-spastic patients. Spasticity has been linked with 60% of shoulder pain, 100% of elbow pain, and 33% of wrist pain; no consistent correlation between spasticity and lower limb pain has been determined (Wissel et al., 2010). Stretching of a shortened and spastic muscle can result in damage to the muscle fibers, and this can result in the release of substances that excite nociceptors within the muscle and cause nociceptive pain (Harrison & Field, 2015).

Individual's quality of life is usually affected by spasticity, far beyond its effects on motor function. Chronic pain, joint stiffness, and fatigue impede fundamental daily activities, such as dressing, personal care, and mobility (Bhimani et al., 2014). Long-term hypertonicity often leads to deformities, such as flexed wrists or equinovarus feet. These often require surgical intervention or long-term use of orthotic devices in order to preserve function and prevent complications (Pidgeon et al., 2015).

Emotional and social challenges often accompany spasticity. Most people with spasticity undergo major depression, anxiety, and social withdrawal. These secondary complications further increase the obstacles to regaining a normal life and reclaiming roles or positions they had before the stroke (Nair & Marsden, 2014). It is very important to address the combined physical and emotional problems that spasticity brings about. A multidisciplinary approach will help in enhancing function, improving quality of life, and aiding in meaningful recovery.

Healthcare professionals use standardized tools to assess and manage spasticity. The Modified Ashworth Scale (MAS) measures resistance to passive movement by using a numerical score that indicates the severity of spasticity; the higher the score, the more severe the impairment (Gregson et al., 1999). The Tardieu Scale, on the other hand, gives a more global assessment by measuring velocity-dependent catch angles during passive movements along with muscle tone measurement (Haugh et al., 2006). These tools give the necessary information to develop individualized treatment plans, catering to the special needs of each patient.

Managing spasticity requires a multidisciplinary approach. Early intervention reduces its impact and supports functional recovery. The cornerstone of treatment is rehabilitation intervention, which assists in maintaining mobility and preventing secondary complications. Pharmacological management with oral anti-spasticity medications provides further support. More advanced interventions include botulinum toxin injections and intrathecal baclofen pumps, which can more selectively reduce hypertonicity and improve function by targeting specific muscle groups. In severe cases, surgical procedures may address contractures and deformities to preserve range of motion and prevent long-term disability (Ward, 2002).

Effective management is based on understanding the complexity of spasticity and its impact on stroke survivors. Healthcare providers must consider its pathophysiological

mechanisms, diverse clinical presentations, and psychosocial consequences. This knowledge supports the creation of individual treatment plans, tailor-made for each patient's goals in rehabilitation and specific needs. Most importantly, addressing spasticity in a comprehensive manner will not only improve the quality of life but also enhance physical function. Effective care, through its ability to decrease dependency and increase independence, enables stroke survivors to reintegrate into their respective communities and makes recovery meaningful (Hesse & Werner, 2003).

Spasticity evaluation

Spasticity measurement involves a wide range of assessments aimed at establishing both the severity and effects of spasticity. Evaluation is critical since it dictates therapeutic intervention, measures the efficacy of treatment interventions, and how significantly it may influence the quality of life for patients. The diverse nature of assessment tools is obvious, which can be broadly categorized as subjective measures based on the clinician's judgment and objective measures with quantifiable outcomes, mirroring the intricate nature of spasticity and its presentation in diverse populations (Elovic & Publishing, 2015).

Commonly utilized assessment tools are the Modified Ashworth Scale (MAS) and Modified Tardieu Scale (MTS), both of which evaluate muscular resistance to passive movement. Other instruments, including the Resistance to Passive Movement Scale (REPAS) and various patient-reported outcome measures, provide more detailed information on the impact of the condition on the day-to-day lives and quality of life of patients (Mills et al., 2023). The reliability and validity of the measurement tools should be determined so that the severity of spasticity, as well as the effect of therapeutic treatment, can be properly quantified, which poses a continuous challenge to clinicians regarding the most appropriate method of spasticity measurement (Guo et al., 2022).

Advances in objective measurement of spasticity Electromyography and complex kinematic analysis are new instrumented measures that make measurements of spasticity more objective and open up new avenues to the comprehension of the complexity of muscle action and spasticity dynamics. However, the problem continues to exist, especially the inhomogeneity of the responses of the patients and the absence of consensus guidelines. Such challenges indicate the paramount need in the development of individualized assessment methods that consider specificities and comorbidities of the

patient and are in line with the overall clinical goals of improving patient care and achieving the best functionality outcomes (Rahimi et al., 2020).

In concomitance with the evolution of the discipline, ongoing studies are aimed at refining existing test instruments and creating new ones with the integration of technological and methodological innovations. These efforts play a major role in enhancing sensitivity and responsiveness in spasticity-related evaluations and ensuring their relevance in clinical contexts as well as facilitating the design of effective evidence-based therapeutic options (Gal et al., 2025; He et al., 2023).

Methods of Evaluation

The assessment of spasticity employs a combination of physical examination and outcome measures to establish the severity of the condition and its impact. These can be divided into two groups: subjective and objective measures with varying strengths and weaknesses. Subjective measures are frequently based on clinical judgment and are reliant on the examiner's subjective findings, whereas objective measures give quantifiable findings with less room for individual interpretation (Elovic & Publishing, 2015).

Commonly Used Assessment Tools

Modified Ashworth Scale (MAS)

The Ashworth Scale, originally described in 1964, remains one of the most widely utilized measures of spasticity, with scores from 0 (no increase in tone) to 4 (rigid limb). Despite having demonstrated good reliability for application in upper limbs, its application in lower limbs has been questioned. Revised versions, including the Modified Ashworth Scale and the Modified Modified Ashworth Scale, have been suggested to improving interrater reliability and precision in the measurement of muscle tone changes (Guo et al., 2022).

Modified Tardieu Scale (MTS)

MTS resembles MAS, as well as it uses the Likert scale to rate the muscular response; it also examines the speed of stretching, scoring the muscle resistance at slow and fast speeds (Guo et al., 2022).

Other assessment instruments of spasticity are the Resistance to Passive Movement Scale (REPAS) and the Spasm Frequency Scale (SFS) which provides an additional perspective of spasticity and related muscle tone (Mills et al., 2023). Used together with testing that involves observation, including visual movement analysis and gait evaluation, these represent an integral part of a proper understanding of the spasticity in an individual.

Instrumented Measurement Techniques

Instrumented measurement methods are essential in the assessment of spasticity as they allow clinicians and researchers to derive objective information that indicates muscle function and activity during a test. They are typically classified according to the type of physiological measures used and the environment of application. Four groups of physiological measurements have been recognized in the field of spasticity measurement: Kinematic measurements (KI), Muscle Activity (MA), Force/Torque (FT), and intrinsic Muscle Properties (MP) (Elovic & Publishing, 2015).

Kinematic measures (KI)

Kinematic measurements are utilized for quantifying the movement parameters, such as joint angles, velocity, and acceleration, in spastic patients. They give quantitative information about abnormal movement patterns, e.g., reduced range of movement or involuntary muscle contraction (Guo et al., 2022). Common techniques used in kinematic measurement include motion capture systems (e.g., Vicon, OptiTrack), electro-goniometry, and goniometers for joint angle measurement (Bartlett, 2014). In spasticity, kinematic measurements are of prime interest in measuring hypertonia, clonus, and deviations from normal motor control, thereby aiding in the discrimination between spastic and non-spastic movement impairment (Gracies, 2005).

Muscle Activity measures (MA)

Muscle activity measurements target neuromuscular activation through the assessment of electrical activity produced during muscle contraction. Muscle activity measurements are essential in identifying abnormal patterns of muscle activation, including over-co-contraction of antagonist muscle groups or over-reflex responses

(Merletti & Parker, 2004; Sanger et al., 2003). Electromyography (EMG), both surface and needle, is the chief method of measuring muscle activity and is complemented by functional electrical stimulation (FES) to quantify muscle response (Farina et al., 2014). In the assessment of spasticity, the measurements aid in the separation of voluntary from involuntary muscle activity, the recognition of excessive stretch reflexes, and in differentiating spasticity from other neuromuscular disorders, including rigidity (Gracies, 2005).

Force/Torque (FT)

Force and torque measurements are used to measure the resistance of muscles and joints to passive movement, giving information on the biomechanical properties of spasticity. These are most commonly done using isokinetic dynamometry, force sensors, strain gauges, and hand-held dynamometers (Stark et al., 2011). By quantifying muscle stiffness and resistance to an outside force, the measurements determine if the elevated muscle tone is velocity-dependent, the hallmark of spasticity. Furthermore, the measurements of force and torque differentiate between active versus passive force generation, critical to the optimization of therapies like pharmacological or non-pharmacological interventions (Balci, 2018; Gracies, 2005).

Muscle Properties (MP)

Intrinsic muscle properties are the structural and biomechanical muscle properties, such as stiffness, elasticity, and viscoelasticity. Intrinsic muscle properties contribute significantly to spasticity since chronic hypertonia will most likely cause muscle shortening, fibrosis, and changes in passive tissue mechanics (Gao et al., 2009; Lieber & Fridén, 2019). Some of the techniques used to evaluate intrinsic muscle properties include ultrasound elastography, magnetic resonance imaging (MRI), diffusion tensor imaging (DTI), and myotonometry, through which non-invasive muscle tone is quantified (Wang et al., 2023; Zúñiga et al., 2021). These characteristics need to be understood in order to distinguish neural contribution and mechanical stiffness so that interventions like botulinum toxin injections, surgery, and rehabilitation interventions can be guided in a manner that will optimize muscle function and prevent spasticity complications (Gracies, 2005; Sheean, 2002).

Patient-Reported Outcome Measures

Patient-reported outcome measures (PROMs) are vital instruments in the assessment of spasticity, offering first-hand information from the patients regarding their health state and quality of life. PROMs have the ability to detect subjective experiences of individuals with spasticity, offering insightful information that complements clinical evaluation and objective measures (Cella et al., 2007).

Importance of PROMs in Spasticity Evaluation

PROMs are important in defining the impact of spasticity on everyday activities, personal attitude, and overall quality of life of the patient. The involvement of PROMs in practice guarantees a more complete treatment and assessment since spasticity could have a significant effect to the mobility and independence. They are particularly suitable in those areas where objective assessment does not disclose the experience of a patient or the satisfaction with the treatment process. PROMs can support the determination of treatment effectiveness and patient satisfaction and therefore decisions in clinical opinions and healthcare resource distribution (Milinis et al., 2016).

Types of PROMs for Spasticity

There are several PROMs that are condition-specific to measure the effect of spasticity on quality of life. The Spasticity-related Quality of Life instrument (SQOL-6D): It takes an interest in the influence of spasticity on several aspects of life, such as pain, range of motion, active and passive function, mobility and balance (Turner-Stokes et al., 2021).

Visual Analog Scales (VAS): pain or discomfort caused by spasticity could be measured through these scales, the patients being able to define it along a continuum from "no pain" to "worst possible pain" (Gal et al., 2025).

Health-related Quality of Life Instruments: More generic measures, i.e., the SF-36 or EuroQol (EQ-5D), are often used to measure general health status and may include domains that are impacted specifically by spasticity (Milinis et al., 2016).

Challenges and Future Directions

In spite of usefulness, there are also problems with the use of PROMs in the evaluation of spasticity, i.e., variation among patients in their interpretation and requiring

standard protocols for administration. Additionally, PROMs should be culturally and linguistically sensitive to ensure validity across diverse populations.

Future studies would necessitate the prioritization of the creation of more sophisticated measures and the creation of novel PROMs that incorporate technological and methodological innovations, including telemedicine and digital health technologies. Through improved measurement of patient-reported outcomes, clinicians could be able to further tailor interventions to the individual needs of those with spasticity, with the ultimate goal of enhancing patient care and outcomes (Rikkert et al., 2018).

Individualized Approach to Evaluation

A single treatment option would be insufficient since spasticity has varying effects on patients. The goals of treatment should be realistic and significant and framed within each assessment, which is specific to the condition of the person and the current functioning as well as diagnosis and comorbidities. Clinicians should make priority both the objective results and report by the patient to determine the spasticity and how it impacts their lives in its entirety (Ganesh Bavikatte & Gaber, 2009).

Advances in Spasticity Measurement Techniques

Emerging technologies have called for more quantitative and objective measures for spasticity evaluation. Advances in biosensors, and robots, which enable real-time monitoring of muscle activity and movement patterns will hopefully augment the strengths of current assessment methods and offer novel insights into the pathophysiology of spasticity (He et al., 2023). Emerging technologies like shear wave ultrasound elastography are being investigated to assess their potential to quantify muscle stiffness in stroke survivors and show great promise for clinical application and research in the future (Wu et al., 2017).

2.2. Part 2: Hand Function and Spasticity Management

2.2.1. Hand Dysfunction in Post-Stroke Individuals

Hand dysfunction is a common and disabling sequela of stroke, especially for those patients that the spasticity affecting the upper limb. The hand plays a vital role in performing most ADLs, such as eating, dressing, and maintaining personal hygiene. Stroke-related impairments in fine motor function, grasp strength, and dexterity disrupt these daily tasks, reducing independence and overall quality of life (Raghavan & Clinics, 2015). Addressing hand dysfunction is important in post-stroke recovery for the regain of function and improvement of outcomes.

Spasticity in the upper limb is a major impediment to rehabilitation. The flexor muscles, especially those responsible for finger and wrist flexion, are usually affected. This, in turn, leads to abnormal postures, for instance, a clenched fist, due to flexor synergy patterns. These patterns dramatically limit the voluntary extension of the hand and hence impair the persons' ability to extend their fingers, grip objects, or release them (Sommerfeld et al., 2004). The inability to perform these basic movements makes bimanual activities difficult, such as tying shoelaces or fastening buttons.

Stroke survivors also lose fine motor skills, which include precision grip and coordination—skills imperative for any activity that involves pinching or manipulating small objects, such as writing with or handling utensils. Their loss significantly reduces independence in daily life. The resulting frustration often diminishes motivation, creating additional barriers to effective rehabilitation. Restoration of these skills is important for the improvement of functional outcomes and support of long-term recovery (Luker et al., 2015).

Secondary spasticity complications, including contractures, joint stiffness, and muscle atrophy, are significant barriers to the recovery of hand function. They often occur because the affected hand tends to remain in fixed positions for extended periods (Gracies, 2005). Contractures, which are irreversible shortenings of muscles, also further limit the hand's range of motion and make rehabilitation efforts more challenging while less effective. Early intervention using appropriate therapeutic methods that reduce spasticity and facilitate active movement is important to prevent such complications and help functional recovery (Katalinic et al., 2011).

The psychosocial impact of hand dysfunction must also be addressed. Many individuals experience emotional distress and social isolation as they struggle to perform

previously routine tasks. Rehabilitation programs that emphasize patient-centered goals and gradual, measurable progress help rebuild confidence and promote independence. These tailored approaches not only improve hand function but also contribute to an enhanced quality of life by fostering a sense of achievement and personal control (Purton et al., 2021).

2.2.2. Current Interventions for Spasticity

Multidisciplinary management of hand spasticity in stroke survivors is-important. The basis of intervention includes pharmacological and non-pharmacological approaches. The main goals are to reduce muscle tone, improve motor control, and restore functional use of the hand. Since the hand function is vital in performing most daily activities, interventions for upper limb spasticity are one of the main goals in post-stroke rehabilitation (Chen et al., 2025).

2.2.3. Pharmacological Treatments

Pharmacological interventions are required for the management of spasticity especially when it interferes with rehabilitation or causes pain and discomfort. Medications such as Baclofen, Tizanidine, Benzodiazapines, Dantrolene, Gabapentin decrease muscle tone by inhibiting excitatory neurotransmission in the central nervous system. These treatments target motor neurons to decrease hyperexcitability and alleviate spasticity (Stevenson, 2010).

Oral antispastic agents often cause multiple side effects like drowsiness, sedation, lethargy, dizziness, muscle weakness, and sometimes psychosis. Thus, limiting their use in long-term management. These agents are more appropriate with generalized spasticity requiring systemic treatment. In focal spasticity affecting specific groups of muscles, for example, muscles in the hand or the upper limb, intervention with injections of botulinum toxin type A provides localized relief with few significant systemic effects (Kuo & Hu, 2018; Montané et al., 2004).

Botulinum toxin (BT) blocks acetylcholine release at the neuromuscular junction. This action temporarily paralyzes spastic muscles, reducing muscle tone. BT treatment may result in decreasing muscle tone among spastic stroke patients and may improve passive range of motion (Yang, 2020). However, evidence suggested that changes are not transferred to improved functional abilities. Davis (2000) reports that functional

improvements after BT treatment were rated none or mild by most people with spasticity. Furthermore, BT is not covered by medical insurance; it is expensive and lasts only for a brief period of time.

Phenol is yet another method of controlling spasticity it is a neurolytic drug used in the control of spasticity, injected with the purpose of denaturing proteins and destroying nerves, eliminating muscle spasticity temporarily or permanently by disrupting motor and sensory nerve impulse transmission (Kocabas et al., 2010). The effect of phenol is dose-dependent, with higher strengths of solution inducing greater neural damage. However, administration of this drug is also associated with grave risks, such as prolonged motor paralysis due to nerve or vascular injury, and bowel, bladder, and sexual dysfunction. Phenol is conjugated and oxidized in the liver and subsequently excreted by the kidneys; hence, it is contraindicated in advanced liver disease and has been associated with renal toxicity, dermatologic disease, and gastrointestinal symptoms. The systemic side effects of vomiting, nausea, central nervous system stimulation, and cardiovascular depression limit its clinical use (D'Souza & Warner, 2023).

Another pharmacological intervention to manage spasticity is Intrathecal Baclofen Therapy, which involves implanting a pump surgically that releases Baclofen into the intrathecal space. It is used as an alternative to other methods such as BT treatment, it showed to be effective in the treatment of post stroke spasticity in some cases especially for the lower limbs, however it is an invasive procedure including surgical risks, pump malfunction, or catheter interruption (Francisco & McGuire, 2012). A recent review study indicated that current evidence is limited to support Intrathecal Baclofen Therapy use in spasticity management among post stroke survivors (Suputtitada et al., 2024).

2.2.4. Non-Pharmacological Interventions

Stretching is a highly frequent physical intervention used in the management of spasticity since it plays a critical role in the maintenance of muscle flexibility and prevention of contracture development. Sustained stretching exercises on a regular basis help alleviate sarcomere shortening, thus enabling maintenance or enhancement of muscle length and overall musculoskeletal function. However, in a randomized controlled trial, Coroian et al. (2018) did not find any significant benefit when comparing strengthening and passive mobilization in facilitation of upper limb improvement in chronic stroke patients.

Neurodevelopmental Treatment (NDT) or Bobath concept is another non-Pharmacological intervention to manage spasticity. It is a widely accepted approach to neurorehabilitation for clients with neurological dysfunction, such as stroke. NDT utilizes the science of motor learning and neuroplasticity to optimize functional movement and control by targeting abnormal tone and movement patterns. NDT intervention involves active facilitation techniques that enable patients to develop enhanced and functional movement patterns and, at the same time, inhibit maladaptive reflexes. Recent systematic reviews report a lack of strong evidence supporting NDT efficacy in spasticity following a stroke (Pathak et al., 2021).(Pathak et al., 2021).

Proprioceptive Neuromuscular Facilitation (PNF) is a highly common technique in neurorehabilitation, its emphasis is on enhancing neuromuscular control through stimulation of the sensory-motor system. Application of PNF is based on use of functional movement patterns, most often with a diagonal and spiral orientation, for enhancing coordination, strengthening, and flexibility. Resistance, tactile contact, and verbal cues are utilized in this technique to stimulate proprioceptors and enable achievement of desired movement patterns(Yeole et al., 2017).

A systematic review conducted by Alashram et al. (2021) evaluated the impact of Proprioceptive Neuromuscular Facilitation interventions for spasticity and motor performance. According to the findings, PNF seemed to have a positive impact on specific factors, including range of motion and gait.A high level of variation in terms of study methodological quality included in the review existed. Authors emphasized that a lack of long-term follow-up studies and discrepancies in uniform protocols posed important weaknesses in current evidence base.

Neuromuscular electrical stimulation is well-known to effectively manage spasticity, and its function is predominantly to modulate neuromuscular activity and promote functional motion. When Neuromuscular electrical stimulation is applied to an agonistic muscle, spasticity in an antagonistic muscle temporarily reduces. Nonetheless, even with its positive impact, its benefits are often transient, and therefore its use cannot serve as a sole long-term therapeutic intervention(Bethoux & Clinics, 2015).

Constraint-Induced Movement Therapy (CIMT) is a well-established non-pharmacological intervention for treating spasticity in upper limbs. CIMT is a rehabilitation method that induces use of the involved limb through constraint of use of

the uninvolved limb. In treating maladaptive behavior, CIMT utilizes neuroplasticity. Through repetitive use of the involved limb, it creates new neural circuits in the brain. Using this method, restoration of function and motor control is maximized in the long run. (Siebers et al., 2010).

CIMT demonstrated effectiveness in managing hand spasticity and improve functionality after stroke. However, lack of methodological consistency, long and varied therapy duration, and variation in intensity may cause inconsistency in the outcomes. These issues may lead to reduced feasibility of CIMT in daily therapy (Reiss et al., 2012; Siebers et al., 2010).

Another commonly utilized noninvasive technique for controlling spasticity in hands is splinting. It is not infrequent for resting splints to maintain the resting position of the hand at night, preventing contractures and allowing for a prolonged stretch of the involved muscles. In contrast, dynamic splints allow for a range of motion with a resistive force over spastic muscles, and they are worn during the daytime to assist with functional activity. Most patients use splinting in combination with other therapies, such as physical therapy and occupational therapy. (Katalinic et al., 2011).

2.2.5. Role of Splinting in Spasticity Management

Splinting stands out as a frequently utilized intervention in spasticity management in hands, particularly in cases of significant stiffness of the muscles and joint contractures in an individual. The important aims of splinting are to keep the hand in a functional position, avoid any deformity, and reduce muscle tension by prolonged tension of the spastic muscles. By stretching over a long period using splinting, one stands a chance to reduce hypertonia and eventually maximize the range of motion in the hand. (Kerr et al., 2020).

Various splints have been applied in the treatment of spasticity, the most prevalent ones being the static splinting and dynamic splinting. Static splinting (known also as resting splint) is designed so that the hand is placed in a resting position. Its purpose is to avoid the formation of contractures and at the same time maintain good posture of joints, which is why it is worn during the night and sometimes throughout the day, during long periods of time. It is most helpful to patients with severe spasticity, which exposes the patient to the greater risk of shortening of the muscles and the emergence of irreversible contractures. (Kerr et al., 2020).

Dynamic splints are designed to allow a range of motion and at the same time resist spastic muscles. Unlike static splints, they promote functional activity, such as opening and closing hands, and therefore can best be utilized during daytime use. For instance, a dynamic wrist splint can stabilize the wrist in a position of neutrality, allowing limited motion for both flexion and extension. (Yang et al., 2021).

Dynamic splints could be most useful for persons with low-grade spasticity. Patients with such spasticity have a level of voluntary motion, but require assistance in preventing aberrant postures and maintaining proper positioning. By supporting functional use of the hand, dynamic splints could have an important function in improving motor control and overall performance of a task. (C et al., 2018).

Despite its widespread application, splinting is not free of several restrictions. Stroke survivors report feelings of tension when restricted in a splint for extended periods, particularly when excessive tension placed on spastic muscles. Such tension can discourage compliance with scheduled splinting regimens, in the long run, undermining its therapeutic value. In addition, extended immobilization in a splint can cause stiffness in joints and loss of muscle strength, particularly when active exercise is not incorporated in overall care planning. (Yang et al., 2021).

2.2.6. Emerging Interventions: Focal Muscle Vibration (FMV)

Focal muscle vibration (FMV) is a novel and promising therapy for the management of spasticity in stroke survivors with great potential to induce motor recovery and enhance quality of life. Spasticity, or abnormal hypertonicity of muscles, interferes with motor functions and causes functional deficits that decrease autonomy and general well-being (Giorgi et al., 2024; Niazi et al., 2024). FMV is the application of mechanical oscillations (30–150 Hz) on selected muscle groups or tendons through equipment generating high-frequency vibrations. It is an intervention that is marked by the ability to attenuate spasticity through neurophysiological mechanisms, for instance, by controlling spinal reflexes, cortical reorganization, and remodeling of tissue (Fattorini et al., 2023; Filippi et al., 2023).

Through exciting muscle spindles, FMV maintains the firing of Ia afferents to stimulate both spinal and supraspinal pathways modulating muscle tone and facilitating motor control (Niazi et al., 2024). Specifically, FMV induces presynaptic inhibition in Ia terminals, which results in decreased release of glutamate onto α-motoneurons and a

corresponding decrease in their depolarization potential, with the overall effect being decreased muscle stiffness and improved motor performance (Shen et al., 2023). Furthermore, extended FMV (≥10 minutes) promotes long-term depression (LTD)-like plasticity of Ia-motoneuron synapses, which leads to residual inhibition 24–72 hours after the intervention (Giorgi et al., 2024). Such mechanisms point to FMV's twofold function in modulating peripheral and central factors of spasticity.

The extensive application of FMV in clinical settings is due to the fact that it is non-invasive, simple to apply, and there is an increasing body of evidence regarding its efficacy in alleviating spasticity, improving motor function, and promoting better rehabilitation outcomes (Aprile et al., 2020). Most recent research, for instance, that of Lu et al. (2024), proves that FMV effectively decreases spasticity and enhances upper extremity function in stroke patients. Aside from spasticity control, FMV has also been proven to exert effects such as gait performance improvement, muscle strength enhancement, and pain alleviation in stroke patients (Alashram et al., 2019; Chen et al., 2023). Its uses range from sports medicine to post-surgical rehabilitation, demonstrating its worth as a versatile rehabilitation instrument (Giorgi et al., 2024).

The efficacy of FMV could differ based on the patient-specific factors like the nature of the stroke (e.g., cortical vs. subcortical lesion), age, comorbidity, and pre-stroke levels of spasticity (Celletti et al., 2020; Lu et al., 2024). For instance, Filippi et al. (2023) note that the efficacy of FMV is optimized when used in conjunction with other interventions like neuromuscular electrical stimulation (NMES) or robot-assisted training, which indicates its utility within multimodal rehabilitative strategies. Conversely, Fattorini et al. (2023) point to FMV's promise in healthy populations, where it enhances muscle strength and decreases fatigue, suggesting applications beyond neurological rehabilitation.

In spite of its potential, there are limitations in the standardization of FMV protocols in terms of frequency, amplitude, and duration. Variability in these parameters hinders comparison across studies and generalizability (Viganò et al., 2023). To maximally exploit the therapeutic potential of FMV in contemporary rehabilitation, efforts should be made to transcend these limitations by conducting large multicenter studies with standardized protocols.

2.2.7. Mechanisms of FMV in Spasticity Management

2.2.7.1. Peripheral Mechanisms

FMV exerts its anti-spastic effect via multimodal neuromodulation of both spinal reflex arcs and peripheral muscle physiology. FMV inhibits hyperactive muscle tone by stimulation of sensory receptors within muscles, primarily through reciprocal inhibition and presynaptic inhibition of Ia afferents (Shen et al., 2023). These mechanisms involve proprioceptive feedback transmission to the central nervous system, relaxation of the muscles, and reduction of passive movement resistance, a main characteristic of spasticity. FMV generates mechanical oscillations between 30 and 150 Hz, leading to muscle spindle afferent firing rate synchronization, which causes persistent activation of Ia afferents (Niazi et al., 2024). This activation reinforces GABAergic presynaptic inhibition on Ia terminals, reducing the release of glutamate onto α-motoneurons and decreasing their ability to depolarize. Moreover, prolonged FMV induces LTD-like plasticity at Ia-motoneuron synapses, resulting in residual inhibition of 24–72 hours after intervention (Giorgi et al., 2024).

FMV also interferes with fibrotic cross-links of spastic muscles by facilitating collagen breakdown and realigning longitudinal extracellular matrix, which further reduces muscle stiffness (Niazi et al., 2024). Collectively, these peripheral mechanisms play a significant role in modulating muscle tone and improving functional outcomes in spastic patients.

Lu et al. (2024) observes that FMV enhances cortico-spinal excitability, especially in stroke patients in the subacute phase, where profound neuroplastic changes have occurred. Although this effect directly relates to central processes, it also supports the necessity of timing FMV interventions according to the patient's level of recovery. In patients with chronic stroke, in whom the neuroplastic effects may be less pronounced, the peripheral effects of FMV—e.g., minimizing muscle stiffness and disrupting fibrotic cross-links—may have a more central role in enhancing functionality. Furthermore, Lu et al. (2024) points out that FMV's effect on modulating muscle tone is contingent on patient-specific variables, including the location of lesions and baseline spasticity levels. Such heterogeneity echoes the call for individualized FMV protocols, especially in the chronically stroke population, where heterogeneity in motor deficits and spasticity severity is far greater.

- **Presynaptic Inhibition of Ia Afferents:**

FMV induces a high-frequency barrage of Ia afferent activity by activating muscle spindles, thus increasing GABAergic presynaptic inhibition at Ia terminals. This inhibits the release of glutamate onto α-motoneurons, decreasing their depolarizing capacity. Experiments demonstrate the reduction in H-reflex amplitude with FMV stimulation, which indicates decreased excitability of the motoneuron pool (Niazi et al., 2024; Shen et al., 2023). Prolonged vibration (≥10 minutes) induces long-term depression (LTD) of Ia-motoneuron synapses with 24–72 hours residual inhibition following intervention (Giorgi et al., 2024).

According to Filippi et al. (2023), FMV not only regulates spinal reflex pathways but also induces multisite neuroplastic changes through the modulation of motoneuron excitability in the spinal cord. The combined impact on both the cortical and the spinal levels can be the cause of the remarkable reductions in spasticity reported in some studies. Filippi et al. (2023) elaborate that FMV's capacity to recalibrate spinal cord inhibitory-excitatory networks is key to the normalization of reflex excitability and the reduction of co-contraction, both of which are impaired in stroke survivors.

- **Muscle Spindle Desensitization:**

Prolonged FMV (>15 minutes) induces spindle adaptation through thixotropic mechanisms, such as interference with actin-myosin cross-bridge formation in intrafusal fibers and opening of calcium-dependent potassium channels, hyperpolarizing bag2 fibers and reducing dynamic sensitivity. These adaptations reduce resting spindle discharge rates by 31%, attenuating baseline afferent input (Giorgi et al., 2024).

Fattorini et al. (2023) study indicates that FMV increases the rate of force development and reduces neuromuscular fatigue due to better muscle spindle activation and subsequent motor unit recruitment. Though more relevant to healthy subjects, this finding suggests that FMV might also improve muscle performance in stroke patients with spasticity through the optimization of spindle function and the removal of inappropriate afferent signaling.

- **Viscoelastic Tissue Remodeling:**

FMV disrupts fibrotic cross-linking of spastic muscles by increasing collagen breakdown, suppressing fibrotic signaling, and longitudinal extracellular matrix

alignment. Ultrasound imaging reveals a 23% reduction in muscle stiffness following 20 sessions of FMV (Niazi et al., 2024).

Lu et al. (2024) validate the research on viscoelastic tissue remodeling, observing that FMV's impacts on muscle stiffness are persistent. Their meta-analysis of 30 RCTs validates that FMV has a significant effect in lowering muscle tone and enhancing upper limb function among stroke survivors. They further observe that FMV's therapeutic effects are enhanced when combined with other treatment interventions, such as physiotherapy, and that this is especially true for spasticity reduction and motor recovery.

2.2.7.2. Central Mechanisms

Focal muscle vibration (FMV) promotes neuroplasticity in the central nervous systems. It increases the excitability of the motor cortex, which is usually compromised following cerebrovascular incidents, and strengthens inhibitory circuits known as "vibration-induced inhibition" (Caliandro et al., 2012; Giorgi et al., 2024; Toscano et al., 2019). The synergism lowers the amplitude of the stretch reflex and enhances motor control.

Lu et al. (2024) illustrates that FMV substantially increases cortico-spinal excitability, even at the subacute stage of stroke rehabilitation, which is marked by heightened neuroplasticity. Though the results underscore the importance of programming FMV interventions during peak neuroplasticity periods, they also present pressing implications for its application in post-stroke patients with chronic strokes. In chronic stroke, where neuroplasticity is reduced, FMV's peripheral mechanisms—i.e., reducing muscle stiffness and breaking up fibrotic cross-links—may have a greater role in enabling function. Additionally, their meta-analysis confirms that FMV significantly improves the function of the upper limbs and inhibits spasticity by altering cortical excitability and promoting reorganization of the motor pathways. These findings suggest that FMV may still be beneficial for chronic stroke patients, though potentially through other mechanisms or with different effectiveness depending on the severity of long-standing impairments.

- **Reticulospinal Tract Modulation:**

While focal muscle vibration (FMV) has been shown to influence spinal reflex pathways and induce neuroplastic changes, the specific mechanisms implicated within the

reticulospinal tract are not as comprehensively discussed in the current literature. Giorgi et al. (2024) highlight the modulation of cortico-spinal excitability in addition to spinal circuits that might indirectly recruit reticulospinal pathways. Similarly, Shen et al. (2023) point toward FMV-induced cortical activation within regions including the sensorimotor cortex, suggesting broader effects on the reorganization of the central nervous system.

According to Filippi et al. (2023), FMV ability to reset spinal cord inhibitory-excitatory networks could, indirectly, influence descending reticulospinal pathways. Reticulospinal pathways are essential for postural adjustment and motor control and contribute significantly to impaired voluntary movement after stroke. Indirect evidence is limited; however, neuroimaging procedures such as diffusion tensor imaging (DTI) could further explain the influence of FMV on microstructural changes in reticulospinal tracts with resulting improvement.

- **Cortical Reorganization and Neuroplasticity:**

FMV induces neuroplasticity changes within the central nervous system, more so in the motor cortex. Research indicates that FMV enhances cortical excitability, a condition usually compromised following cerebrovascular strokes (Giorgi et al., 2024). Elevated excitability promotes the reorganization of motor pathways, thereby improving the recuperation of motor functions among patients who have experienced strokes. FMV also influences inhibitory mechanisms, commonly termed "vibration-induced inhibition," that decreases the amplitude of stretch reflexes and enhances motor control (Caliandro et al., 2012; Toscano et al., 2019).

Lu et al. (2024) confirm these results, noting that the neuroplastic effects of FMV are not confined to the motor cortex alone but also involve a multisite reorganization. Their meta-analysis, for instance, reveals noteworthy motor function improvement and reduction in spasticity, which can be accounted for by FMV's potential to facilitate communication between the primary motor cortex and supplementary motor areas. These observations are consistent with general principles of neuroplasticity, as FMV promotes descending inhibitory pathways from the brain to help reduce spasticity and improve motor outcomes.

- **Cerebellar Activation:**

Shen et al. (2023) functional near-infrared spectroscopy (fNIRS) study proves that focal muscle vibration (FMV) considerably increases cortical activity in the key brain areas that are in charge of motor function and sensory processing. More precisely, FMV stimulation of the forearm flexor muscles participating in post-stroke individuals revealed elevated oxygenated hemoglobin (Hbo) in the bilateral sensorimotor cortex (SMC), prefrontal cortex (PFC), and occipital cortex (OC). The greatest activation was seen in the left sensorimotor cortex (LSMC), where the concentration of hemoglobin was increased by a mean of 0.0275 ± 0.0312 during the task condition as compared to the resting condition ($p < 0.001$). Equally, great activation was also seen in the right sensorimotor cortex (RSMC) and the left prefrontal cortex (LPFC) with p-values of <0.001 and <0.01, respectively. These findings suggest that FMV induces functional compensation through the stimulation of the involved hemisphere and interhemispheric networks, as supported by the cortical activation-clinical improvement correlations in muscle strength, decrease in spasticity, and upper limb function.

Fattorini et al. (2023) provide additional proof of FMV's promotion of cortical excitability and neuromuscular function. Although they conduct their studies with healthy populations, it is clear through their work that FMV's ability to enhance muscle spindle activation and resultant motor unit recruitment could also benefit stroke patients. By optimizing spindle functioning and limiting the excess afferent input, FMV is able to enhance the accuracy of motor command of the cerebellum and sensorimotor cortex, once more affirming its clinical merit for stroke recovery.

2.2.8. Clinical Efficacy of FMV in Stroke Rehabilitation

2.2.8.1. Reduction in Spasticity

FMV is shown to be effective in reducing spasticity across numerous studies, but results are variable depending on protocols and sample type. Giorgi et al. (2024), for example, reported significant reductions in spasticity for post-stroke patients, particularly in the upper limbs, as measured by the Modified Ashworth Scale (MAS). Not all research demonstrates equivalent effects, however. Caliandro et al. (2012) described improved upper limb functionality but found no difference among MAS scores of spastic reduction and control individuals. Study differences may be due to different parameters of vibration (e.g., frequency, amplitude) and muscle groups activated (Caliandro et al., 2012; Viganò et al., 2023). The double mechanism of FMV—cortical excitability modulation and

induction of peripheral plasticity within the spinal cord—is the basis for its dramatic action on spasticity (Viganò et al., 2023).

Lu et al. (2024) study validates that FMV decreases spasticity, and also improve the function of upper limb among stroke survivors. To gain maximum recovery benefits, they emphasized that FMV should be implemented during the subacute period, that is because neuroplasticity would be in its highest. On the other hand, the study findings also have significant implications for FMV use in chronic stroke patients. These patients usually experience ongoing spasticity and long-lasting motor deficits. Neuroplasticity is usually less robust in chronic stroke patients. In such case, FMV's peripheral effects may assume a more imperative role in functional improvement by reducing muscle stiffness, interfering with fibrotic cross-links, and increasing proprioceptive feedback. Besides, it is noted that the response of FMV is patient-specific and regulated by personal variables such as the site of the lesion and the baseline level of spasticity (Lu et al., 2024). This variability shows the need to have specific protocols that are individual and particularly in the stroke subjects who have chronicity where more heterogeneity is posed in the extent of spasticity and motor impairment.

2.2.8.2. Improvement in Motor Function

FMV plays a significant part in enhancing the recovery of motor function if combined with conventional therapy methods. Research has demonstrated that there are enhancements in the gait characteristics, including step length and toe-off velocity, particularly in stroke patients with intense motor deficits (Toscano et al., 2019). Further, Zeng et al. (2023) indicated a moderate recovery of motor function, particularly when FMV was added to task-specific rehabilitation strategies. These findings show the potential of FMV as an adjunct treatment to enhance motor recovery and functional outcomes in stroke survivors.

Filippi et al. (2023) present more findings indicating that FMV causes long-term neuroplastic modifications in the brain, thereby enhancing motor planning, execution, and kinematics. These effects persist following the conclusion of treatment, demonstrating that FMV facilitates prolonged neuroplasticity (Viganò et al., 2023).

Fattorini et al. (2023) research points to FMV's capacity to enhance muscular strength and diminish neuromuscular fatigue, which is probably the result of increased activation of muscle spindles and ensuing motor unit recruitment. Although they primarily

discuss healthy subjects, this finding indicates that FMV can potentially boost motor function in stroke survivors by optimizing spindle function and minimizing excessive afferent signaling.

2.2.8.3. Pain Management

FMV alleviates pain caused by post-stroke spasticity. Zeng et al. (2023) and Avvantaggiato et al. (2021) stated that FMV reduced distress due to spasm and muscle rigidity. Alashram et al. (2019) also indicated pain alleviation as a secondary effect, where patients had a reduction in distress caused by increased muscle contractions. Viganò et al. (2023) also demonstrated that FMV adjusts descending regulation of spinal interneurons, and this reduces hypersensitive muscle response.

Lu et al. (2024) corroborate these results, adding that FMV's analgesic effect is enhanced when combined with other therapeutic modalities like physiotherapy or electrical stimulation. This multimodal strategy targets the sensory and motor dimensions of spasticity, hence providing stroke patients with extensive pain treatment alternatives.

2.2.8.4. Functional Outcomes and Activities of Daily Living (ADLs)

In occupational performance, FMV enhances the performance of daily activities such as dressing, eating, and personal hygiene. Alashram et al. (2019) reported upper limb function improvements, which translated to increased independence in activities of daily living (ADLs). Filippi et al. (2023) demonstrated that FMV enhances fine motor control, which is required for daily activities involving object grasping and manipulation. Such benefits were particularly evident when FMV was applied as part of holistic rehabilitation plans (Viganò et al., 2023).

Filippi et al. (2023) are of the opinion that FMV's capacity to reset spinal cord inhibitory-excitatory networks is key to enhancing functional outcomes. By means of restoring reflex excitability and minimizing co-contraction, FMV facilitates the ease and efficiency of performing ADLs among stroke survivors. Furthermore, Lu et al. (2024) states that the therapeutic effects of FMV are increased when it is used together with task-specific training, especially in promoting motor recovery and functional independence.

2.2.8.5. Historical Development of FMV

Focal muscle vibration (FMV) evolution has been shaped by the development of scientific evidence, technological advancements, and evolving therapeutic paradigms. Historically, there have been reports of vibration therapy dating back to the late 19th century when Jean-Martin Charcot outlined "vibration therapeutics" as a treatment option for diseases of the nervous system (Viganò et al., 2023). Yet, systematic investigation of the influence of localized muscle vibration on the excitability of motor neurons commenced only in the mid-20th century, especially with pilot research conducted by Hagbarth and Bishop that constituted the foundation for describing its neurophysiological mechanisms (Celletti et al., 2020; Viganò et al., 2023). It was discovered that the potential of activation of muscle spindles to affect motor neuron excitability paved the way to modern-day applications of focal muscle vibration in rehabilitation practice.

- **Technological Advancements and Evolution of FMV Devices**

Technology has played a significant role in developing FMV. Previously, equipment was stationary with restricted capacity to target specific muscle groups or address the needs of particular patients. More recent FMV devices incorporate wearable technology, enabling mobility and ease of incorporation into daily routines (Filippi et al., 2023). This evolution is a demonstration of greater recognition of the multidimensional nature of FMV as a strategy for rehabilitation and performance enhancement. Fattorini et al. (2023) illustrate that recent advance in FMV devices allow for very precise calibration of parameters, i.e., frequency (30–150 Hz), amplitude, and duration, to maximize therapeutic effects. These advances are in line with current rehabilitation paradigms focused on individualized, multimodal intervention, where FMV is typically administered in combination with other interventions, i.e., electrical stimulation, physiotherapy, and occupational therapy (Lu et al., 2024).

- **Neurophysiological Insights and Broader Applications**

Traditionally FMV research has dealt mainly with its effect on motor neuron excitability and the reduction of spasticity. The peripheral effects on the CNS included that it inhibited presynaptic Ia afferents and altered activity in spinal reflex pathways (Caliandro et al., 2012; Toscano et al., 2019). Nevertheless, the most recent researches have shifted this emphasis to simpler mechanisms, including cortical reorganization, and multisite neuroplasticity (Filippi et al., 2023; Giorgi et al., 2024). To illustrate one of the above-stated examples, Lu et al. (2024) noted that FMV increases cortico-spinal

excitability especially during the subacute stage of stroke rehabilitation where neuroplasticity is most abundant. In the context of having the reduced capacity of neuroplasticity provided, the peripheral effects of FMV, i.e., eliminating muscle-stiffness, breaking down of fibrotic cross-links, and enhancing proprioceptive feedback may become even more critical in driving functional recovery in case of chronic stroke (Giorgi et al., 2024; Niazi et al., 2024). These findings highlight the effect of FMV on the peripheral and central nervous systems, and thus indicate its worth as an evolving treatment plan to cure the complex deficit of chronic stroke.

- **Comparison of Early vs. Modern FMV Practices**

Historically, and currently, FMV has been applied differently in terms of how widely it is applied. Historically, FMV was mainly applied to treat spasticity and hypertonia within neurological disorders (Marconi et al., 2011), however current studies focus on a much wider application of FMV treatment from pain reduction, enhancement of motor functions and even improvement of performance in otherwise healthy individuals (Fattorini et al., 2023; Giorgi et al., 2024). While FMV originally was used in isolation, it is now being used in conjunction with fairly broad rehabilitation protocols that optimizes how it works treatment-wise, with the FMV being just one component of the holistic rehabilitation protocol. Giorgi et al. (2024) even identify that combining FMV with traditional interventions like motor relearning or robot-assisted therapy provides synergistic effects, specifically referring to stroke patients.

- **Challenges and Future Directions**

Despite the encouraging potentials, there are diverse challenges to standardizing FMV protocols and obtaining reproducible result. The outcomes may be affected by variations in protocols in terms of vibration, individual attributes of the patients, and baseline spasticity (Lu et al., 2024; Viganò et al., 2023). Additionally, new imaging methods, such as diffusion tensor imaging (DTI) enhance our understanding of the involvement of FMV in the reticulospinal pathway and the associated microstructural changes; however, future studies should confirm them (Rodríguez-Pérez et al., 2022; Shen et al., 2023). To integrate FMV effectively into the modern rehabilitation practice, these limitations should be addressed by substantial multicenter studies.

2.2.9. Optimization of FMV Parameters

2.2.9.1 Frequency and Intensity

The frequency modulation appears to be an important feature that enhances the positive effect of focal muscle vibration (FMV) on reduction of spasticity in upper limbs and increase of motor activities in stroke patients. It has been established that lower frequency bands (30-50 Hz) exert their effect on spasticity through reflex pathways and reciprocal inhibition (Wang et al., 2020). The frequencies are best suited in subacute stage in stroke recovery when neuroplasticity is at its highest. On the other hand, frequencies of 80-150 Hz and more specifically 100 Hz are more suitable to accommodate the demands of the chronic stroke patients. The improvement of voluntary motor control (which is witnessed in the state of chronic spasticity) is attributed to the stimulation of sensory perception, the facilitation of cortical remapping, and the relaxation of muscles that is caused by high frequencies(Casale et al., 2014; Lu et al., 2024). Therefore, the use of 100 Hz FMV is shown to be very successful to reduce the hypertonicity of the upper limb flexor muscles and to improve the functional activities such as grasping and reaching.

Lu et al. (2024) meta-analysis stresses the need to optimize frequency parameters both to the recovery stage and based on the individual patient requirements. In chronic stroke patients, many of whom show a plateau in motor recovery, the application of 100 Hz FMV has emerged as a very promising intervention. The effects of this intervention are supposed to be mediated by mechanisms such as long-term potentiation (LTP) and metaplasticity (Giorgi et al., 2024; Viganò et al., 2023). That FMV is dual-action—both decreasing spasticity and enhancing motor control—puts it firmly in the perspective of being a comprehensive therapeutic approach to managing the multifaceted impairments that occur following chronic stroke. Through its effects on both neural and mechanical components of spasticity, FMV can be a target for upper-limb rehabilitation in this group.

The intensity of the vibration is an important factor that determines the effectiveness of FMV on the rehabilitation of upper limb impairment in chronic stroke patients. The best intensity (0.2–0.5 mm amplitude) would maximally activate and relax the muscle and lead to the best functional results (Viganò et al., 2023; Wang et al., 2020). An intensity that is too high would be irritating or overstimulating and thus, work against the desired impact of FMV (Filippi et al., 2023). In particular, chronic stroke subjects would be considered as being more sensitive to pain thus the choice for moderate intensity

plays a major role for the design of the treatment regimen. For instance, Fattorini et al. (2023) noted that low level intensity decreases in spasticity are additionally accompanied by increasing muscle strength and resistance to fatigue, probably as a result of a better spindle function and decrease of abnormal afferent signals. Therefore, FMV of moderate intensity may be particularly beneficial in chronic stroke, potentially leading to upper limb motor improvements and spasticity reduction.

Nevertheless, research support the need of conducting the vibration on the base of individualization according to patient specific condition as degree of initial spasticity, the site of lesion and the stage of recovery (Celletti et al., 2020; Niazi et al., 2024). In chronic stroke patients (showing long-standing disability and a strong patient-to-patient heterogeneity), personalized approaches are often considered as an essential factor for fostering the beneficial effects of stroke treatments. However, some studies have implemented standardized protocols (e.g., 100 Hz for the frequency and the amplitude across all participants) which aims as providing a reference about the overall effectiveness s of FMV (Casale et al., 2014; Giorgi et al., 2024). This approach allows the standardization of intervention, as well as the possibility to analyze the total efficacy of a specific FMV parameters (e.g., 100 Hz) for decreasing spasticity and improving upper limb function in chronic stroke patients. Moreover the combination of FMV with other treatments such as traditional physiotherapy or task-oriented training has been proposed as a strategy to improve therapeutic outcomes by involving both mechanical and neural aspects of spasticity (Alashram et al., 2019; Celletti et al., 2020).

2.2.9.2. FMV in Multimodal Rehabilitation Approaches

Adding FMV to stroke rehabilitation improves cortical reorganization. It is a main factor in stroke recovery at the cortical level. Stimulating the affected muscles using FMV promotes motor cortex reorganization, which is seen in chronic stroke patient (Noma et al., 2009). Cortical reorganization is based on neuroplastic mechanisms especially long-term potentiation (LTP) and metaplasticity, which enhance synaptic activity (Giorgi et al., 2024; Viganò et al., 2023).

As it was pointed out by Lu et al. (2024), combining FMV with other interventions (robot-assisted training or neuromuscular electrical stimulation) results in better outcomes. Also, it was noted that, FMV implementation was more effective when applied at the most optimal times of neuroplasticity. Furthermore, Lu et al. (2024) argues that

FMV is a multimodal rehabilitation tool due to its ability to positively affect peripheral and central nervous systems.

Traditional rehabilitation approaches, which is usually effective in motor and independency improvement, are often negatively affected by spasticity. FMV does not have this disadvantage because it induces muscle relaxation and neural excitability adjusts due to its presynaptic inhibition of the Ia afferents and reciprocal inhibition (Alashram et al., 2019; Giorgi et al., 2024). The research implies that FMV provides more flexibility of muscles, allows decreasing spasticity and enhances the involvement of the patient in treatment as a result of which the long-term outcomes are better (Celletti et al., 2020; Toscano et al., 2019). It has been mentioned that great positive effects on motor recovery scale including the Fugl-Meyer Assessment and Motricity Index have been reported when using FMV and traditional therapy (Toscano et al., 2019).

The proposal of Filippi et al. (2023) is that FMV action to recalibrate the inhibitory-excitatory networks in the spinal cord play key roles in the amplification of the benefits of multi-therapeutic interventions. By normalizing the reflex excitability and co-contraction, FMV helps an individual carry out the occupational performance like ADL easily and achieves more efficacy. Moreover, Fattorini et al. (2023) observed that FMV helps in muscle strength and endurance improvement, which is most likely achieved with a higher activation of muscle spindles and motor unit recruitment. These results confirm that FMV can also enhance motor performance in stroke by enhancing spindle status, as well as by cutting off the wrong signals by afferent reflexes.

FMV combination with other therapies is recommended to be explored, since it may alleviate the effectiveness of traditional approaches when used simultaneously. It is compatible with interprofessional rehabilitation by combining it with other forms of therapy, such as robotic, electrical stimulation, occupational and physiotherapy (Celletti et al., 2020). Enhancing FMV effectiveness is possible through individualization of its parameters such as frequency, amplitude, and duration, depending on patient specific factors including spasticity severity and stroke rehabilitation phase (Alashram et al., 2019; Celletti et al., 2020). Task-specific training proven to improve motor recovery and functional independency, yet its outcome could be enhanced when combined with FMV (Viganò et al., 2023) incorporation of FMV into comprehensive rehabilitation programs,

may further enhance the outcomes by addressing motor and non-motor deficits in stroke survivors. (Lu et al., 2024)

Recent studies have been leaning towards the prospects of multimodal neurorehabilitation strategies, especially use of FMV and robot-aided therapy, to improve recovery after stroke. Calabro et al. (2017) presented a pilot randomized controlled trial to define the effect of the integration of FMV with the Armeo-Power robotic system, which is designed to offer active movement-based training of upper limbs using task-specific activities. Age-matched chronic subjects of post stroke with upper limb spasticity were treated using either robotic therapy or robotic therapy with FMV on antagonist spastic muscles e.g., triceps brachii, supraspinatus, and deltoid, in this study. The findings indicated that the combination group showed an increased improvement in clinical spasticity (Modified Ashworth Scale) scores, motor cortex inhibition (short-interval intracortical inhibition, SICI) as well as H-reflex modulation indicating increased sensorimotor executive and cortical exercise.

The results of these studies suggest that focal muscle vibration can be a useful addition to the robot rehab as it will enhance the neurophysiological benefit thereof. The mechanism that is proposed is associated with the given mechanism transfer through proprioception optimization through FMV that in turn may precondition the motor cortex system and the spinal circuitry, thus the phenomenon of higher sensitivity of the task-specific training transmitted through dynamic robotic complexes may occur. In addition, it was shown that the gains in the combination group did not decline within a month of follow-up, showing the possibility of such long-term functional improvements under the condition of combining FMV as an intervention with structured, multimodal rehabilitation schemes. These findings complement on the rising numbers of studies which indicate that a combination of sensory stimulation methods, such as FMV, with other modern technologies, including robotics, may produce more efficient and long-lasting results in post-stroke treatment.

Table 2.1: Studies Combining FMV with Other Interventions in Post-Stroke Patients

Author/Year	Study Design	Intervention Group (FMV + Other Therapy)	Control Group	FMV Parameters	Combined Intervention	Outcome Measures	Key Results
Marconi et al., 2011	RCT	Physiotherapy alone	Physiotherapy alone	Frequency: 100 Hz Amplitude: 0.2–0.5mm Duration: 3 consecutive days	3×/day for 10 min	TMS (RMT, MEP map area/volume), SICI, ICF	Significant reduction in resting motor threshold. Increased motor map areas in vibrated muscles (only in the intervention group)
Caliandro et al., 2012	RCT	Standard physiotherapy alone	Standard physiotherapy alone	Frequency: 100 Hz Amplitude: 0.2–0.5mm Duration: 3 consecutive days	Daily physiotherapy including stretching and strengthening	WMFT-FAS, MAS	Significant improvement in WMFT. Functional Ability Scale scores in the FMV+PT group
Noma et al., 2012	Pilot study	Rest & stretch groups	Rest & stretch groups	Frequency: 91 Hz Amplitude: 1.0 mm Duration: 5 min	No specific additional therapy	MAS, F-wave analysis	Reduction in F-wave amplitude and persistence; improved spasticity scores
Tavernese et al., 2013	RCT	General physical therapy alone	General physical therapy alone	Frequency: 120 Hz Amplitude: 10 mm Duration: 30 min × 2/day for 2 weeks	Physical therapy focused on reaching movements	Kinematic analysis of reaching movement	Significant improvements in normalized jerk, linear/angular velocity, and movement duration in the FMV+PT group
Casale et al., 2014	Double-blind RCT	Sham vibration	Sham vibration	Frequency: 100 Amplitude: 2 mm	No additional structured therapy	MAS, robot-assisted motor tasks	Significant improvement in MAS scores and trajectory

				Duration: 30 min/day for 5 days			parameters in the FMV group
Costantino et al., 2017	RCT	Sham treatment	Sham treatment	Frequency: 300 Hz Amplitude: 2 mm Duration: 30 min	3×/week for 4 weeks	Hand grip strength, MAS, DASH, JTT, VNRS	Improvement in grip strength, reduced spasticity, pain, and disability
Celletti et al., 2017	Pilot study	Conventional therapy alone	Conventional therapy alone	Frequency: 100 Hz Amplitude: 0.2–0.5mm Duration: 3 consecutive days	Neurokinetic facilitation-based rehab program	MAS, WMFT, Motricity Index	Improved upper limb motor function in the FMV+rebalancing rehab group
(Calabro et al., 2017)	Pilot RCT	Armeo-Power robotic training alone	Armeo-Power robotic training alone	Frequency: 100 Hz Amplitude: calculated based on peak acceleration formula (2πf). Duration: 40 daily sessions (1 hour/ session)	5 sessions/ week for 8 weeks	Modified Ashworth Scale (MAS), Short Intracortical Inhibition (SICI), Hmax/Mmax ratio (HMR)	Significant decrease in MAS and HMR. Increase in SICI (cortical inhibition). Enhanced and prolonged aftereffects of Armeo-Power when combined with FMV

2.2.9.3. Limitations and Future Directions

Some limitations were noted in the literature about FMV. First, Generalizability of results is limited due to small sample sizes and demographic homogeneity (Alashram et al., 2019; Viganò et al., 2023). Second, is the methodological diversity between protocols. Studies used different frequencies (30–150 Hz), amplitude (0.2–0.5 mm), and therapy duration (10–30 minutes). These discrepancies generate inconsistencies, making it challenging to reach a conclusion. Third , there are no longitudinal studies to confirm the durability of FMV therapeutic effects and risk of rebound spasticity after treatment cessation (Niazi et al., 2024; Viganò et al., 2023).

The meta-analysis of Lu et al. (2024) suggests that variations in the FMV parameters significantly influence the results and even more when used in different stages of stroke recovery. For instance, lower frequencies (30–50 Hz) are preferred in the subacute phase and higher frequencies (80–150 Hz) might be optimal in individuals with chronic stroke. These results demonstrate the importance of standardized protocols according to patient characteristics, including lesion location and initial spasticity degree.

The exact mechanisms of action of FMV are still not well elucidated. There is little published data regarding its neurophysiological response on spinal and supraspinal pathways. Although some studies have suggested FMV might be involved with the cortical excitability and inhibitory pathways. The whole mechanisms of FMV still should be elucidated (Giorgi et al., 2024; Shen et al., 2023).

Filippi et al. (2023) suggest that the effect of FMV is based on its effect to re-calibrate inhibitory-excitatory networks in the spinal cord. By adjusting the reflex excitability and by inhibiting co-contraction, FMV facilitate motor recovery for stroke survivors. Further studies are necessary to confirm these results and to examine long-term motor recovery.

The integration of FMV with other treatment modalities (physiotherapy, occupational therapy, and new technologies such as robotics and virtual reality), has to be focused upon in the future research. Thus, enhancing multimodal therapeutic interventions.(Celletti et al., 2020; Giorgi et al., 2024). Overcoming these limitations is essential to reveal the clinical efficacy of FMV. This can be achieved through large-scale, multicenter research with standardized methods, and extended follow-up periods.

Fattorini et al. (2023) research shed the light on the effects of FMV in healthy individuals. It showed the positive effect of FMV on muscle strength and muscle endurance. Although their main focus was in sport performance. Such results may indicate that FMV may also improve muscle strength in stroke survivors. This dual application necessitates the FMV protocol to be compatible with patient's needs.

2.2.9.4. Clinical Implications

Focal muscle vibration (FMV) offers large potential in stroke rehabilitation. It reduces spasticity and improve motor performance. This is achieved by stimulating the process of neuromuscular modulation and motor recovery through adjusting the spinal

and cortical excitability (Alashram et al., 2019; Giorgi et al., 2024).). However, additional studies are necessary to achieve protocol optimization, mechanism clarification, and concede patient variability. Literature indicates that the effectiveness of FMV might be stroke- and patient-specific (e.g., cortical versus sub-cortical lesions), age- and comorbidity-mediated, and affected by baseline spasticity as well (Celletti et al., 2020; Niazi et al., 2024).

The meta-analysis by the research group led by Lu et al. (2024) underlines that FMV therapeutic effects are increased when combined with other interventions, such as the use of electrical stimulation or robot treatment. Combined therapy targets peripheral and central points of spasticity; therefore, it provides a more holistic intervention for stroke rehabilitation.

This requires the cooperation multiple disciples such as, allied health professionals, biomechanics, and technologists. FMV when applied with additional treatment, such as robotic-aided training or virtual reality, would improve treatment outcome (Filippi et al., 2023; Viganò et al., 2023). It needs standardized procedure-based large clinical trials to know the effectiveness of FMV. These trials should take place in other patient categories and long-term outcomes to determine not only short-term advantages but long-term benefits too (Niazi et al., 2024; Viganò et al., 2023).

The role of neuroplasticity in stroke recovery explains why there is a need to carry out longitudinal study comparing long-term effects of FMV on spasticity and function. These benefits could also be improved by starting therapy at the subacute stage when neuroplasticity is raised (Giorgi et al., 2024).

Rehabilitation center, educational institutes and their industrial partners can also improve integration of FMV into clinical settings due to networked collaborative research of the stakeholders. These types of networks aid in interprofessional transfer of knowledge and promote ideation of new, multimodal rehabilitation interventions.

Fattorini et al. (2023) explain that wearable FMV devices are opening up a world of new opportunities in increasing the connectivity of focal muscle vibration with everyday routine. The ability to move and be easily operated makes them acceptable in-home rehabilitation program particularly among those who have inadequate access to clinical setting. This shift, complies with the modern philosophies of rehabilitation, whereby

active involvement of the patients in the process of rehabilitation is made possible through the use of technology-based treatments.

FMV has a potential to develop post-stroke rehabilitation and have interprofessional practice and multidisciplinary innovation. The domain can synthesize the evidence to create evidence across disciplines to demonstrate the multifaceted benefits of FMV as used by different patient populations and established it as a core component of modern rehabilitation programs.

2.2.10. Combination Therapies: FMV and Splinting

Anti-spastic splinting combined with Focal Muscle Vibration (FMV) is a potentially usable strategy of tackling spasticity of patients with stroke. Unlike splinting, which provides the biomechanical assistance to the involved spastic muscles, FMV has been reported to exert an effect on the spinal reflex pathways and reportedly increases the cortical plasticity (Alashram et al., 2019; Giorgi et al., 2024; Jia Ty, 2024). The effects of all these therapeutic interventions combine to tackle the neural and mechanical components of the spasticity and thus may be a complete solution to patients with chronic spasticity.

The studies of FMV and splinting as isolated therapeutic procedures show that the mechanism of action of both interventions probably acts synergistically contributing to the improvement of the influence of each other in combination at the same period. FMV reduces the muscular tone, but doing so by means of activating presynaptic inhibition of Ia afferents and allowing reciprocal inhibition at the spinal level (Alashram et al., 2019; Giorgi et al., 2024; Jia Ty, 2024). On the other hand, the effect of anti-spastic splinting is to reduce the occurrence of joint contractures and muscle shortening that is common complications of spasticity (Celletti et al., 2020; Toscano et al., 2019). Theoretically, the effects of the two interventions by combining yield further enhanced results as compared to employing each of the interventions separately.

To the best of our knowledge, there are no studies that have specifically examined the use of FMV with anti-spastic splinting to control spasticity. However, recent reviews such as Jia Ty (2024) emphasize the importance of multimodal rehabilitation strategies, and it is conceivable that FMV plus adjunctive therapies—such as splinting—would enhance therapeutic effects. For example, Lu et al. (2024) point out that the efficacy of Functional Movement Variability (FMV) is enhanced when combined with other

therapeutic interventions, like robotic-assisted training or neuromuscular electrical stimulation. Likewise, Filippi et al. (2023) point out FMV's potential to re-tune inhibitory-excitatory networks within the spinal cord, maybe complementing the long mechanical stretch induced by anti-spastic splints to attenuate hypertonicity and allow for improved motor control.

while the combined use of FMV and anti-spastic splinting holds much promise, there is a need to further refine protocols and establish its efficacy. This lack will be remedied by the carrying out of large clinical trials with the aim of optimizing the use of this multimodal treatment for stroke rehabilitation.

2.3. Part 3: Study Context

2.3.1. Rehabilitation for Stroke Patients in Palestine

Rehabilitation for Palestinian stroke patients is confronted with significant challenges. There is a critical demand for overall rehabilitation programs to address impairments including spasticity and upper limb impairment. In Palestine, nevertheless, restricted access to sophisticated interventions impedes effective rehabilitation(Khatib et al., 2018).

Rehabilitation services cannot be reached in all locations. Most rehabilitation centers can be found in major cities such as Nablus and Ramallah. Rural communities lack enough rehabilitation centers and trained professionals. Inadequate access to rehabilitation creates delays, which may cause complication such as spasticity and contractures to worsen(Khatib et al., 2018). Political factors, including restrictions in traveling, complicate access to such services. Patients in Gaza face significant challenges due to the blockade, which restricts medical tools and training (Heaney, 2023).

As timely intervention is critical. Early intervention may help in reducing major complications. Delays in accessing care often lead to permanent neurological damage and entrenched impairments, increasing caregiver burden and reducing quality of life (Lacy et al., 2001). Without early intervention programs, many patients fail to achieve optimal recovery.

2.3.1.1. Availability of Advanced Spasticity Treatments in Palestine

Spasticity intervention in Palestine are mainly the routine management practices, like oral antispasmodics (e.g., baclofen, tizanidine), being one of the common interventions used. Physical therapy and occupational therapy are also widespread aspects of routine treatment (Amin et al., 2024). More advanced therapeutic choices, however, are rarely accessible, with injection of BT being performed on a very limited scale because of high costs. Intrathecal baclofen (ITB) treatment is still far from being accessible, primarily due to the lack of specialized facilities and well-trained professionals. In addition, a lack of access to specialized multidisciplinary teams and post-operative departments substantially restricts the use and implementation of these advanced therapeutic methods. (EssamaSuzanne, 2016).

2.3.1.2. Barriers to Access

In Palestine, the accessibility of new treatments for spasticity is greatly hampered by large barriers, most of which are financial, infrastructure-related, and due to inadequate specialized training (International, 2024). The elevated expense of interventions such as ITB and BT, and the rarity of health insurance, effectively restricts access to these therapeutic interventions. Logistical and political factors, such as restrictions in medical device importation, further contribute to a lack of accessible resources. As a result, physical and occupational therapy and oral antispasmodics become the dominant forms of management, and therefore, accessible and affordable alternatives become a matter of urgency.

2.3.1.3. The Role of Focal Muscle Vibration (FMV)

Non-invasive and low-tech interventions gain growing acceptance in environments with restricted access to infrastructure and funding. Techniques such as focal muscle vibration (FMV) have potential benefits. It requires neither sophisticated infrastructure nor prolonged training. It can be added to existing rehabilitation protocols. It can reduce spasticity and promote function in stroke patients (Avvantaggiato et al., 2021). As such, it stands out as a feasible alternative for regions with restricted access to high-tech therapies. By prioritizing new and accessible interventions, the critical demand for practical interventions in disadvantaged areas can be met.

2.3.2. Gaps in the Current Knowledge and Rationale for the Study

There are several current studies that support the use of FMV to manage upper limb spasticity with this population, and recommend the integration of FMV into the rehabilitation programs to achieve maximum benefit (Aprile et al., 2020). However, a systematic search of the literature was performed in the following databases: MEDLINE, EMBASE, CINAHL, PsycINFO, AMED, and Web of Sciences using MeSH terms and free text search keywords available (Appendix 1), no study was found combining FMV and static hand splint to manage hand spasticity after stroke. Therefore, due to the strength of evidence supporting the effectiveness of FMV approaches, the prevalence of hand splinting for this population in clinics, this proposed study aims to examine the effectiveness of FMV therapy combined with anti-spasticity static hand splint in improving hand function and reducing spasticity for stroke survivors with spastic hand.

This study is particularly relevant in the Palestinian context, where structural barriers, including financial limitations, political instability, and inadequate healthcare infrastructure, complicate the introduction of sophisticated rehabilitation technology. By exploring the feasibility and preliminary effectiveness of incorporating FMV and anti spastic static hand splint in this setting, the study may not only guide clinical practice in Palestine but also add to the literature regarding how new treatments can be tailored in LMICs, also it paves the way for more equitable and effective rehabilitation strategies worldwide.

Chapter 3: Methodology

3.1. Introduction

This pilot randomized controlled trial employed a rigorous methodological framework to test the feasibility and preliminary effectiveness of focal muscle vibration (FMV) integrated with anti-spastic splinting on upper limb spasticity among survivors of stroke. Guided by the CONSORT extension on pilot and feasibility trials, the study was designed to address the key feasibility objectives, such as recruitment rates, rates of adherence to the intervention, the appropriateness of outcome measurement, and safety. Stratified randomization procedure predetermined the balance of the key variables between the groups, and efforts to blind outcome assessors and maintain assessment reliability through standardized training protocols enhanced data validity. The standardization of intervention protocol ensured reproducibility, with detailed documentation of delivery methods, and compliance monitoring to support future scalability.

The study adopted a mixed methods approach to capture both quantitative and qualitative insights. By integrating robust methodological safeguards with flexibility to capture contextual challenges, this study establishes a strong foundation for advancing research on non-pharmacological spasticity management post-stroke.

3.2. Study Design and Rationale

A pilot randomized controlled trial (RCT) design was used to determine the feasibility of integrating focal muscle vibration (FMV) therapy with an anti-spastic static hand splint for managing hand spasticity in chronic stroke survivors. This design is particularly appropriate because it addresses feasibility, preliminary effectiveness, and safety key considerations in early-phase clinical trials (Arain et al., 2010; Lancaster et al., 2004; Thabane et al., 2010).

Assessment of the possibility to ascend the study is a pilot to the RCT. Considering that spasticity is a complex condition in chronic stroke patients, and that the combination of FMV and the anti-spastic splints is experimental in nature, the case is being studied based on recruitment feasibility, adherence to the intervention protocol, safe implementation of the interventions, and quality reliable outcomes assessment.

The assignment to the intervention and control groups could also be achieved through randomization, which reduced the contribution of confounding variables and guaranteed high levels of internal validity (Schulz et al., 2010). This is essential in dealing with stroke populations as the latter are variable in the severity of a stroke, prognosis and the level of spasticity. Randomization guarantees a lasting cause-effect conclusion due to the possibility to attribute perceived changes in spasticity decrease and functional improvement to the intervention (Jadad & Enkin, 2007).

As the complement to quantitative data, the embedded exploratory mixed-methods design was chosen (Plano Clark, 2017). This design will unite qualitative information about participants experiences and perceptions and will give more detailed knowledge about clinical efficiency and acceptability of the intervention. Although the quantitative component has objective evidence of the feasibility and effectiveness, the integrated qualitative component examines contextual factors that determine the outcomes, which will help in optimization of the intervention, as well as, a future large-scale trial design.

3.3. Study Aims and Feasibility Objectives

3.3.1 Primary Aim

The primary aim of this pilot randomized control trial is to evaluate the feasibility and adherence of focal muscle vibration when added to anti-spastic splint for people with spasticity after stroke. Additionally, we plan to understand participant perceptions about the focal muscle vibration in terms of acceptability and satisfaction.

3.3.2 Secondary Objectives

The secondary objectives of this trial were to investigate the preliminary effectiveness of focal muscle vibration when added to anti-spastic splint on reducing

spasticity and improving hand functionality among people with stroke and obtain estimates that can be used to design a future definitive trial.

3.3.3 Feasibility Assessment Framework

Along with the main goal to determine the effect of an intervention, one of the main functions of a pilot study is to establish the viability of the larger, fully powered, randomized controlled trial (RCT) (Chen et al., 2025). In this feasibility determination, various critical dimensions have been pinpointed namely recruitment, intervention code adherence, implementation feasibility, and protocols of outcome assessment.

3.3.4. Recruitment Feasibility

Tight inclusion criteria, patient preferences, and the health status of the potential participants are often listed as one of the greatest challenges to recruitment when conducting rehabilitation studies (Lancaster et al., 2004). The index of a successful recruitment in this pilot study was attainment of the desired size of the sample within the stipulated period of recruitment, the feasibility of the estimated rate of recruitment, and confirming to the inclusion criteria of the population with diversity resembling the larger population of the chronic stroke survivors. The dropout rate in the recruitment process was low as one of the elements of success (Stewart et al., 2020). Findings of this pilot research will be used to decide the need to modify the recruitment strategy in the main trial.

3.3.5. Intervention Adherence Assessment

The success of the intervention depends on following the focal muscle vibration (FMV) and anti-spastic splinting regime. The pilot study confirmed whether or not the participants adhered to the protocol throughout the study and which factors affected adherence to the protocol, including comfort, ease in using the protocol and motivation. A larger RCT may be under threat when there is a high dropout rates or interventions may not have the same level of application (Thabane et al., 2010).

3.3.6. Implementation Feasibility

The question of whether or not the intervention can be successfully integrated into clinical practice was another important question of this pilot RCT. the research tested the possibility of the subjects using the anti-spastic splint and vibration problem free and

following the combined therapy planning. The findings are critical in finding ways of how the intervention may be applied in practice in actual settings of rehabilitation.

Moreover, the pilot randomized controlled trial additionally discussed the logistic issues, that is, whether it is possible to introduce FMV into the everyday life of the participants and whether the instructions given out would be easy to follow at home. The data received by the respondents on usability and comfort of both splint and vibration device aided in the further development of intervention protocols. The present pilot study will guide the design of comprehensive educational programs to health care professionals and will pave the way to further application of the combination treatment in future studies.

3.3.7. Outcome Assessment Protocol Feasibility

Valid and reliable outcome measures must be used to quantify difference in spasticity and hand function. The pilot study concluded the possibility of using several standardized tests, i.e., the Modified Ashworth Scale (MAS) to evaluate spasticity levels; Fugl-Meyer Assessment of the Upper Extremity (FMA-UE) to assess the efficiency of the hand function; Numeric Pain Rating Scale (NRS) to estimate the degree of pain; and Range of Motion (ROM) values. In addition, logistic issues that surrounded the administration of these measures were also realized and sought. As one can see, consistency of administration of the MAS, avoid participant fatigue during the tests, a quiet place to take an accurate measurement of the FMA-UE were major considerations. Such initiatives are consistent with clinical trial protocols, data integrity and trial success are dependent on clear and well documented processes (Prasanna et al., 2024).

3.3.8. Safety Assessment

The safety profile of the intervention is an imperative area of concern of this pilot randomized controlled trial. Given that focal muscle vibration (FMV) is a relatively new method of spasticity treatment, it is necessary to monitor negative consequences or unintended effects to guarantee the safety of participants (Julliand et al., 2024). This is specifically necessary in case of chronic stroke survivors as, they might be more susceptible due to comorbidities or condition being chronic. Thanks to the pilot study, it was possible to monitor the adverse events continuously, which gives the valuable information about the combination of FMV with anti-spastic splints associated risks.

The safety was guaranteed by systematic observation of adverse events in all involved groups. Resting on constant communication with patients, self-reported data regarding adverse event and tolerability of treatment could be obtained. Moreover, interim evaluations were carried out in order to determine possible risks of intervention. Stopping rules were well formulated in order to discontinue the intervention when serious adverse effects occur including hospitalization, significant change in spasticity and pain, and some loss in range of motion or functionality. The stopping criteria could also be initiated by recommendations of the ethics committee. These has facilitated ethical soundness of the experiment and the intervention to be safe in a full-scale RCT (Thabane et al., 2010).

3.4. Study Setting

The experiment was achieved in several outpatient rehabilitation centers in Jenin region such as the Arab American University Palestine (AAUP) Rehabilitation Center, the Spine Rehabilitation Center, rehabilitation society of Aljalil, and Consultant Center of Occupational Therapy Rehabilitation and called CCOTR. These centers are found in the northern region of Palestine and are serving the Jenin city and environs. Their range of services include providing occupational therapy and physiotherapy services to adult and pediatric clients that are affected by a wide variety of conditions such as; neurological, orthopedic and developmental disorders.

Initial contact was made with the centers and it was identified that the centers have a stroke survivor incidence of 15 to 20% per center and hence would be ideal locations to have the study participants.

3.5. Participants

3.5.1. Effect Size Estimation

Although the primary aim of this pilot randomized controlled trial is to determine the feasibility, an estimate of effect size is also an important outcome because it can be used in the determination of the fully powered trial. The degree of difference between the

intervention group and the control group in the proportion of reduction in spasticity and the increment in the hand functionality is seen through the effect size. Providing the estimates of the effect size in the pilot phase allows the researchers to determine the needed sample size in a larger trial to have the statistical significance (Leon et al., 2011; Thabane et al., 2010).

In the study, in particular, there might not be enough power to identify any clinical changes, but the trends in the spasticity measures and the hand function scores still seem to be valuable insights into future studies. It is a pilot study, which provides an extrapolation regarding the clinical effect size of focal muscle vibration (FMV) along with anti-spastic splinting, which allows refining the hypotheses and shaping a further RCT.

3.5.2 Recruitment Strategy

A convenience sample method was used to recruit stroke survivors from the participating rehabilitation centers. Convenience sampling is a widely used method to

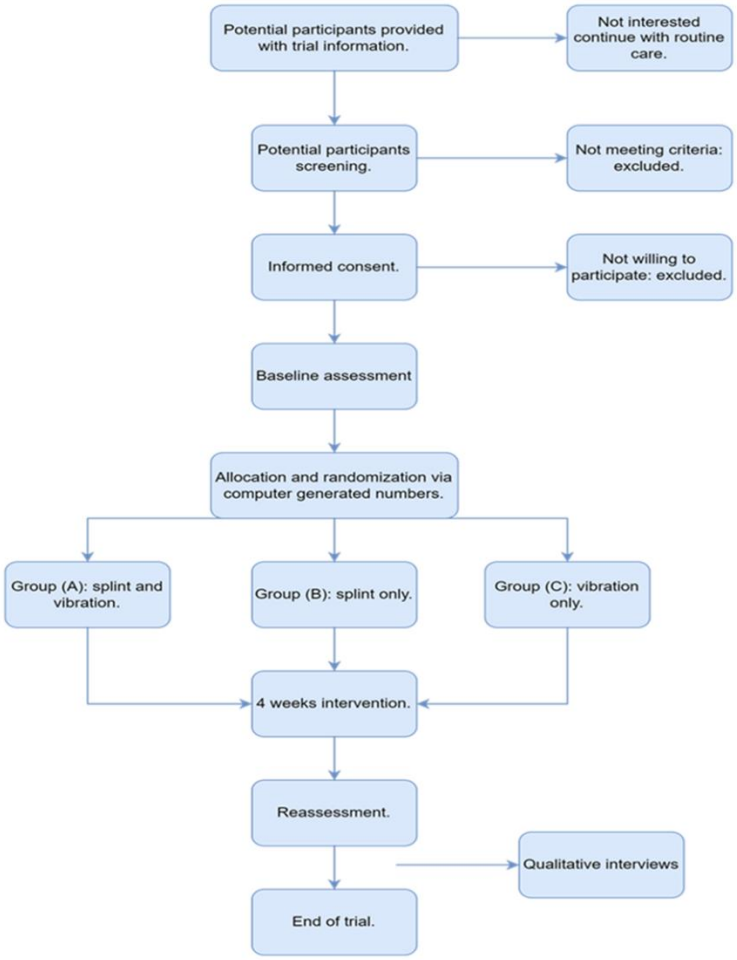

Figure 3.1.: CONSORT flow diagram.

enroll participants depending on their availability and accessibility (Elfil & Negida, 2017).

The researcher contacted the directors of the rehabilitation centers, he provided them with an overview of the study. The center directors then directly informed potential participants about the study via phone calls, sharing preliminary information and the researchers' contact details. Interested individuals contacted the researcher during working hours using the designated work phone. After the initial contact, the researcher provided a comprehensive information package detailing the study objectives, procedures, and participant responsibilities. Participants were given time to review the materials and could schedule an initial session to address any queries or concerns. Following an informed discussion, participants were asked to sign the consent form, after which standardized baseline data was collected.

3.5.3 Eligibility Criteria

3.5.3.1. Inclusion criteria

Individuals affected by chronic (more than one year) spastic ischemic or hemorrhagic stroke, aged above 18 years old, medically stable (has no cardiovascular event in the last 12 months), a score of 1-4 on modified Ashworth scale.

3.5.3.2. Exclusion criteria

Cardiovascular event in the past 12 months, received anti-spastic injections drugs into the affected hand in the last 6 months, and a score of less than 21 on Rowland Universal Dementia Assessment Scale (RUDAS), upper limb and trunk musculoskeletal injuries, a score of 0 on modified Ashworth scale.

3.5.4 Randomization and Allocation

Randomization Protocol Using Covariate-Adaptive Randomization

Step 1: Identification of Participants and Classification

A total of 48 participants were recruited for this study. Each participant was assigned a unique identifier (e.g., P1–P48) to ensure anonymity and traceability. Participants were classified based on spasticity level (mild, moderate, or severe) according to the criteria

defined by (Kumar et al., 2006). Additionally, participants were stratified into two age groups: below 60 years or above 60 years.

Unlike traditional randomization approaches, covariate-adaptive randomization allowed for continuous enrollment and allocation of participants as they are recruited, eliminating the need to wait for the full sample before randomization (Shan et al., 2024).

Step 2: Dynamic Stratification Based on Key Characteristics

Participants were allocated as they enroll using a minimization-based covariate-adaptive randomization approach. Based on the imbalance score, new participants were assigned to a treatment group considering the following characteristics:

Spasticity Level: Mild, Moderate, or Severe

Age Group: below 60 – above 60

Assigning new participant was determined by calculating which group allocation would minimize imbalances in the (spasticity level, age) covariates across treatment groups. A probability-based allocation (e.g., 80% probability to the least imbalanced group, 20% randomization) (Lin et al., 2015) was applied to maintain randomization.

Step 3: Sequential Randomization into Study Groups

Participants were randomized between the three groups (A, B, and C) using a 1:1:1 allocation ratio. The covariate-adaptive method dynamically adjusted group assignments as participants enroll, maintaining balance across stratification variables.

The randomization process was implemented using an automated script in Excel, which did:

- Assess existing group compositions based on spasticity level and age.
- Calculate imbalance scores for each treatment group.
- Assign the new participant to the group that minimizes overall imbalance.

This process ensures that, at any stage in the study, participants are representatively and evenly distributed without having to have access to the full sample at the beginning of the study (Lin et al., 2015).

Step 4: Validation of Allocation

To ensure integrity and transparency in the randomization, the following processes have been performed for validation:

- Real-time monitoring of group distributions to confirm that significant covariates did not become unbalanced during the trial.

- Periodical audits to verify that assignments have been conducted in accordance with the predefined minimization algorithm.

- Documentation of any deviation and any adaptations, with a view to having all participant allocations free of bias and scientifically justified.

Step 5: Documentation of Assignments

The participant assignments were documented in a sequential manner in an Excel-based log of randomization. The documentation included:

Participant ID, Spasticity Level, Age Group, Assigned Group, Date of Allocation.

Rationale for Covariate-Adaptive Randomization

Using the covariate-adaptive randomization was for several reasons:

-Allowing immediate randomization at participant recruitment and not having to wait for an entire sample.

-Balances significant prognostic factors dynamically and prevents spasticity severity and age group imbalances between study groups.

-Limits selection bias, with an objective algorithm for minimizing driving allocation and not a manual one.

The adaptive approach aligns with real-life participant recruitment restrictions and yet adheres to scientific requirements for a sound and unbiased clinical trial.

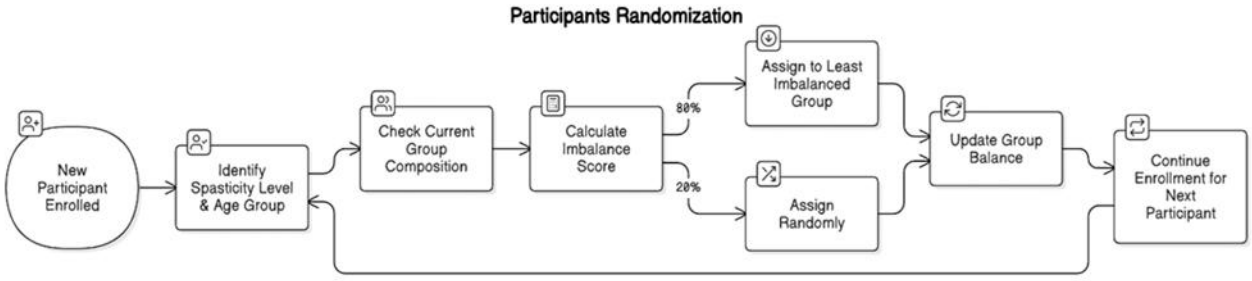

Figure 3.2.: Participant's randomization flow diagram.

3.6. Blinding and Quality Assurance

3.6.1. Blinding Strategy

In randomized controlled trials (RCTs) such as pilot studies, blinding is an essential methodological feature since there is minimal possibility of bias due to outcome measurement (Zhang et al., 2024). The effectiveness of an intervention could be unwillingly skewed when the assessors know of how participants are treated. This pilot trial assessed the trial-feasibility and preliminary efficacy of combined focal muscle vibration (FMV) therapy and an anti-spasticity splint in stroke survivors with chronic stroke through single-blind method, whereby only the outcome assessor was blinded with respect to treatment allocation.

3.6.1.1. The relevance of Blinding in Pilot RCTs

Pilot RCTs are important to be blinded since such studies are usually the forerunners to fully powered RCTs. Although the main aim of a pilot trial is to evaluate the feasibility of methods to recruit the target population, intervention delivery, and outcome measurement procedures, blinding will make sure that no detection bias occurs, on this stage preliminary data may be obtained. Barcot et al. (2020) mention detection bias, implying that a group assessor of an outcome is being affected unconsciously by the group affiliation of that participant.

3.6.1.2. Strategies to Ensure Effective Blinding

In this study, the therapist that performed clinical assessment was blinded to the treatment assignment of the participants so that blinding could be maintained. The method minimized bias in the measurement of important results guaranteeing trust and validity of the study results. Other secondary interventions to reduce the probability of inadvertent unblinding were adopted:

- Subjects were directed not to talk about their treatment to the therapist which was made clear of them.
- The main researcher was in charge of treatment and communication, about interventions, decreasing the chances of the accidental exposure.
- Any feedback or communication by the participants all went to the main researcher and not to the blinded assessor.

Blinding the assessor follows the gold standard practice of bias reduction in the case of randomized trials and generates no exception even in the pilot phase (Zhang et al., 2024). These measures provided that during the research, the properties of blinding were held and the argument of objectivity of clinical measured was supported.

3.6.1.3. Difficulties in Sustaining Blinding

There is a critical issue that major rehabilitation trials face, especially those where the intervention can be measured relatively easily, just like in the cases of focal muscle vibration (FMV) and splinting. The issue is that the assessors might be able to tell the group allocations of participants by the outcome changes. Although not always, blinding of the subjects is crucial, however, it is vital to sustain assessor blinding in order to reduce bias (Zhang et al., 2024).

In order to deal with this difficulty, the assessor was given extensive training in the art of recreating a neutral state and never asking any lead questions, which could encourage the participants to provide some hints. Evaluation of blinding success was also done at the end of the study by requiring the blinded assessor to have a guess as to what treatment each participant had received. It aided in making decisions regarding the breach of blinding and also contributed to the elements of the future design of a full trial (Reid et al., 2023).

In the current study, all the clinical assessments were carried out with the same assessor to enhance consistency between the tests. Moreover, the hypotheses behind the study and the exact purpose of each arm of its treatment were not revealed to the assessor. One can further minimize the possibility of bias by limiting the possibilities of assessor to know the general procedures and outcome measures ensuring the reliability of completing the blinding process.

3.7. Outcome Measures

3.7.1 Primary Outcome Measures

3.7.1.1. Modified Ashworth Scale (MAS)

Spasticity level was evaluated using the MAS scale. The MAS measures muscle resistance during passive stretching. The test was applied for spastic joints of affected upper extremities. The score was recorded as (0, 1, +1, 2, 3, 4), (0= normal tone, 4 = affected part rigid in flexion or extension) (Appendix 2). The reliability of the modified Ashworth scale is very good (kappa = .84 for interrater and .83 for intra-rater comparisons). Measurement was performed by the same assessor pre and post intervention to avoid affecting reliability (Gregson et al., 1999).

The test was conducted in the assessment quiet room, with no distractions. The participants were supine in a treatment bed, and therapist assessed the affected upper limb spasticity once and record the result in the assessment form. The assessor was a qualified trained occupational therapist who has worked in a clinical role treating stroke survivors with hand spasticity and familiar with MAS.

3.7.1.2. Fugl-Meyer Assessment of Upper Extremity (FMA-UE)

The FMA-UE looks at reflex activity, volitional movement within synergies, volitional movement mixing synergies, and volitional movement with little or no synergy. The outcome scale's 33 items are divided into four subscales: shoulder and elbow, wrist, hand, and coordination. On a three-point ordinal scale, each of these items is assessed. 2 points are granted if a movement is completely completed, 1 point is awarded if the movement is half completed, and 0 points are awarded if the movement cannot be completed. The FMA-UE has high inter-rater and intra-rater reliability for testing sensorimotor function after a stroke (Appendix 3). (Hernandez et al., 2019).

The test was conducted in a quiet room, with no distractions. The participant was sitting on a chair, and therapist performed the test and record the results. The assessment was performed by a qualified trained occupational therapist who has worked in a clinical role treating stroke survivors with hand spasticity and familiar with FMA-AE

3.7.2 Secondary Outcome Measures

3.7.2.1. Range of Motion (ROM) Assessment

ROM of the involved upper extremity was measured using the goniometer which is a reliable tool to mesure joint mobility (Beebe & Lang, 2009). ROM assessment involved

active, as well as, passive movements of the shoulder, elbow, wrist, and fingers. The measurements were taken in a calm atmosphere to isolate distractions as this was essential in the measurement accuracy (Appendix 4) (De Jong et al., 2012). The participant was positioned appropriayly. The evaluations were carried out and indeed done by a qualified occupational therapist who had experience with stroke rehabilitation and mostly with spasticity in the hand, thereby making the measurements consistent and reliable.

3.7.2.2. Numeric Pain Rating Scale (NRS)

Numeric pain scale (NRS) is reliable tool for assesing pain intensity. It is widely used by healthcare providers (Alghadir et al., 2016). It is an 11 point numeric scale ranges from 0 which indicates "no pain" to 10 which represents "worst pain imaginable (Appendix 5). Participants are required to mark the point represinting thir pain level. The distance from the origin of the line, which is the left end, to the participant's symbol mark is the one that is used to present a numerical value. a representation which shows pain intensity, where the higher the value the more pain there is. The NRS is taken into account as a valid and reliable scale and is usually employed in: to analyze pain intensity in clinical practice and to conduct research (Alghadir et al., 2016).

3.7.3 Therapist Training and Standardization

The training of therapist being used to conduct the pre- and post-treatment assessments is one of the essential elements of this pilot randomized controlled trial (RCT). An adequate training of therapists guarantees reliability and uniformity in appraisal of outcome measures. This was realized through a multi-stage and systematic training program formulated to suit the assessment procedure in this research. The training was deemed to be standardized, because the researcher conducted this without any assistant and trained the research clinician individually before patient recruitment begun. Additionally, all clinicians underwent Good Clinical Practice (GCP) training to equip them with the necessary skills and knowledge to adhere to ethical, scientific, and practical standards. Adherence to these procedures ensures the protection of participants' rights, safety, and well-being while maintaining the reliability of research data (Mondal & Mondal, 2024).

3.7.3.1. Training in Outcome Measurement

A primary responsibility of the participating therapists is to administer pre- and post-treatment measures. Consequently, the majority of the training focused on ensuring that these measures were obtained in a reliable and standardized manner. The following outcome measures were included in the training: muscle spasticity (assessed using the Modified Ashworth Scale [MAS]), hand functionality (measured with the Fugl-Meyer Assessment for the Upper Extremity [FMA-UE]), pain levels (assessed using the Numeric Pain Rating Scale [NRS]), and active and passive range of motion (ROM) at the shoulder, elbow, forearm, wrist, and fingers.

The training in outcome assessments included the following components:

1. Standard Assessment Protocols:

- In order to ensure uniform application of the Modified Ashworth Scale (MAS), a standard protocol was followed. Proper positioning to ensure participant relaxation. The definitions of the muscle groups tested were defined clearly to ensure that tests were consistent. The examiner received intensive training, also she was considered thoroughly versed in the MAS scoring system. To reduce variability, all relevant conditions were recorded such as the time of day and environmental conditions. As they might influence muscle tone. A consistent and reliable use of the MAS was established, by strictly following these steps (Pandyan et al., 1999).

2. FMA-UE Testing:

- Therapists were well-educated in terms of using the FMA-UE, which demands special expertise on upper extremity impairments in the case of stroke. The instrument measures a wide number of domains, such as motor function, sensation and passive joints movement, which requires good training to provide an accurate and reliable score (Fugl-Meyer et al., 1975).
- Training on the implementation of the FMA-UE involved multi-dimensional training, which included both practical training and actual/simulated (stroke survivors) training based on the directions of the researcher, who is very knowledgeable in the said domain. Such first-hand experience enabled therapists to master the motor, sensation, and passive joint movement assessment. As well

as having practical training, some major literature, in form of peer-reviewed articles and the manual of FMA-UE, was presented to enhance the theoretical knowledge of therapists about constructs and scoring. Multiple workshops and feedback sessions were given to respond to problems and enhance inter-rater consistency (Fugl-Meyer et al., 1975; See et al., 2013)

3. The use of NRS to assess pain:

- The evaluator was well trained to ensure precision and reliability in NRS administration.

  The training emphasized the need of clear communication with the participants, to make sure they were familiar with the method of pain rating using the numeric scale of 0-10 (Ferreira-Valente et al., 2011).

The training covered:

1. Standardized Instructions: to ensure uniformity, assessor was trained to use neutral and consistent language when explaining the test.
2. Simulated Practice: real and simulated practice sessions was done. For the assessor to become familiar with several situations, especially when participants may need further clarification.
3. Working with Ambiguities: directing them by use of open-ended questions without offering leads to their answers.
4. Documentation: record the participants responses immediately to ensure accuracy, and avoid any subjective analysis.

4. ROM Measurements:

- Train the assessor to accurately measure active and passive range of motion of the shoulder, elbow, forearm, wrist and fingers using the Goniometer. Proper positioning, correct interpretation, and recording of ROM measures were demonstrated (Norkin & White, 2016).

3.7.3.2. Continuous Monitoring and Support

Ongoing support was continuously provided by principal investigator throughout the study. This is to enhance standardized procedures of assessments. Regular meetings were also done to discuss the issues and doubts that surfaced during the evaluations. In

case the assessor had any concerns or doubts on any part of the tests, retraining was immediately carried out to ensure consistency throughout the trial.

The systematic education of the assessor in the assessment procedure is a methodological base of this pilot randomized controlled trial (RCT). This rigorous approach confirms the validity and reliability of this research. Through use of standardized procedures, the study adds to feasibility and efficacy of intervention and reduces the risk of bias. Also, the systematic training method supports the preservation of blinding thus contributing to the increase in the methodological soundness of the trial as a whole. Through these efforts, essential data will be provided to design a future full-scale RCT (Boutron et al., 2008).

3.8. Interventions

3.8.1 Group A: Combined Focal Muscle Vibration and Anti-Spastic Splint

Vibration stimulation was applied to the spastic hand antagonistic muscles (Wang, Chandrashekhar et al. 2020) using a specific device that consisted of volar anti-spastic hand splint (figure 3.3.), and vibrator (figure 3.4.) held in place by appropriate padded harness. A Standardized study protocol was used each time (Appendix 6).

The volar anti-spastic hand splint was custom made for each participant at the prosthetic and orthotic clinic at the AAUP, from an orthoplast perforated material using a standardized protocol (Appendix 7). This material proved to cause no harm of any kind (Orfit 2021). For the current study, the investigator used a purpose-designed vibrator with specific vibrational properties, i.e., appropriate frequency and amplitude. To provide the best fit and positioning on the arm, the investigator custom-made a uniquely designed attachment through the employment of 3D printing methods, in which the vibrator was securely embedded. This provided the ability to deliver the intervention with precision and consistency. Vibration frequency, amplitude, client position, vibration periods and location are clarified in table 3.2.

The course of intervention involved the use of a vibration device and a hand splint. The vibration device to be used for 30-minutes session three times per week for four

weeks. And the splint to be used daily for 30 minutes (Suputtitada et al., 2024). Participants were adviced to use the vibration device and splint when they are in a resting state, e.g., when watching a movie or reading a book, or before sleep. Before the vibration session the participants were given certain guidelines so as to reduce the chances of growing spasticity. They were to wear their loose clothes, fulfill any personal needs that they may have like to visit the toilet, and they had to be excluded out of irritating conditions before the vibration session commenced (Phadke et al., 2013).

Each participant was provided with his own vibrator device and his own hand splint to be used at home. Before treatment commenced, the main researcher provided training to the participant and caregiver on the use of the vibrator and the hand is splint following an educational protocol available at (Appendix 8). Participants and caregivers were handed a logbook to track protocol adherence. The implementation of a protocol was followed weekly through phone calls by the main researcher.

3.8.2 Group B: Anti-Spastic Splint Only

Only the participants in Group B were provided with an anti-spasticity splint, but without the use of vibration therapy. These splints were custom-fit in the same clinic and with the same orthoplast-perforated material described for Group A. The application of the splint was done by using the same standardized protocol described for Group A (Appendix 7).

The splint protocol includes positioning of the hand, wrist, and fingers to achieve a reduction in spasticity, prevention of contractures, and promotion of functional hand posture. These are outlined in (Table 3.2.).

Participants were asked to wear the splint for 30 minutes daily throughout the study period, which covers four weeks, at time points where participants are resting or relaxing, such as during leisure activities or before a sleeping. No vibration therapy was provided to the participants during this time.

In addition to the splint regimen, Group B participants received comprehensive training on how to use the anti-spastic splint: training on fitting, wearing schedule, and care of the splint. A standardized teaching plan was followed and by the primary researcher (Appendix 8). They were also provided with a logbook where they recorded splint use. Compliance was followed up by a weekly telephone call by the principal

researcher to ensure that the protocol is followed and to manage any arising issues and further guide participants. As with Group A, Group B participants were subject to frequent communication to ensure compliance. Additionally, the research team assessed any adverse effects related to splint use, such as discomfort or skin irritation, ensuring the intervention remains safe and well-tolerated throughout the trial.

3.8.3 Group C: Focal Muscle Vibration Only

Participants in Group C received vibration therapy without an anti-spasticity splint. The vibrator was applied to the spastic antagonistic muscles, the device was secured in place in same way as in group A. The frequency, amplitude, and duration parameters of vibration have been standardized and are identical to that followed in Group A (Appendix 6). The vibration application was implemented as detailed in Table 3.1.

Each participant received a vibration session of 30 minutes three times a week for four weeks. Participants were trained to use the vibrator independently at home through a standardized protocol teaching appropriate placement, secure fitting, and operation of the device. They were also given a logbook in which to record their use of the device, including compliance with the three-times-weekly protocol.

Participants of Group C received the same follow-up for compliance as both other groups. They were given specific guidelines to follow before each vibration session, such as wearing loose clothing and ensuring a relaxed state, as described for Group A. These precautions are in place to minimize any exacerbation of spasticity during the intervention.

3.8.4. Standardization Across Groups

Whereas the intervention protocols themselves vary concerning specific treatment modalities-namely, splint versus vibration versus combination-the standardized care was delivered consistently across the groups via the following:

- **Participant and Caregiver Education**: Participants and their primary caregivers were educated based on their intervention assignment. Education focused on proper use of the splint or vibrator, or both, and included but not be limited to

instruction on device application, device effect monitoring, and managing of potential problems. Appendix 8 describes specific education content and methods.

- **Compliance Monitoring**: A logbook was maintained by each group for compliance monitoring of the intervention. Regular telephone contact by the primary researcher reinforced compliance and issue management. Such strategies are deemed essential to the successful implementation of the pilot RCT since the degree of compliance is among those factors that derived the decision to go forward with an expanded trial of the intervention.
- **Participants' Follow-up and Support**: The primary researcher followed up with the participants in each group regularly to see whether the intervention is properly implemented. They support any need for this continuous process, which guarantees high levels of engagement and retention. This is very important for the success of this pilot study.

Figure 3.3.: Volar anti-spastic hand splint

Figure 3.4: Vibrator

Table 3.1.: Choice of vibration settings and postures with rationale

Protocol	Rational
Vibration frequency (100HZ)	These frequencies were commonly used in previous FMV studies in stroke; it was more effective, higher frequencies were associated with discomfort and pain. (Fattorini et al., 2006; Wang et al., 2020)
Vibration amplitude (0.2 and 0.5 mm)	These amplitudes were within the range of amplitude values commonly used in previous FMV studies in stroke which were more effective (Wang et al., 2020)
Position	Laying supine, this position was commonly used in previous FMV studies in stroke(Wang et al., 2020). To avoid boredom participant had the choice of semi-lying about 20 degrees inclination, the affected hand was be supported.

Duration and location	4 weeks (30 min/day, 3 day/week), was applied on Extrinsic extensor muscles (Wang et al., 2020)
Splint regime	30 minutes daily.

Table 3.2: Specifications for Anti-Spastic Splint Positioning

Aspect	Position/Range (Degrees)
Rest Position	Wrist: 10-30 (O'Sullivan et al., 2019) MCP Joints: 10-20 (O'Sullivan et al., 2019)
Finger Alignment	PIP Joints: 20-30 (O'Sullivan et al., 2019) DIP Joints: 10-20 (O'Sullivan et al., 2019) Thumb Abduction: 20-30 (O'Sullivan et al., 2019)
Overall Positioning	Functional Alignment (O'Sullivan et al., 2019)

Concomitant Care:

To ensure experimental integrity, it was required from the participants not to receive any other anti-spastic treatment during the trial, such as botulinum toxins injections or oral spasticity drugs. Moreover, it was required from participants to delay any planed future spasticity treatment until the trials had been concluded. These mesurments were put in place to reduce the risck of biass may result due to the role played by outside interventions.

The research had clear indications on how to handle concomitant care in a manner that promoted the validity, safety, and reliability of the research. In order to track compliance with these guidelines, the following strategies were used:

- **Frequent Contacts**: The participants were contacted frequently by talking to them on the phone to monitor any changes in medical management such as the addition or removal of other medical interventions. Participants were

openly asked about on whether they started taking any new medication or treatment throughout the experiment.

- **Education and Guidance**: Education about the need to avoid any further interventions addressing spasticity was offered to the participants. To ensure that these guidelines are reinforced and observe, educational meterial and frequent interactions with the research team were employed (Appendix 9).
- **Reporting of Deviations**: In case, participants started other treatments concomitantly or altered recommended treatments, such actions were duly recorded. During the study, no deviations were reported. Therefore, all participants remained adherent study intervention only, which minimize potential confounding effects on the study outcomes.

The study tried to ensure uniformity of concomitant care among all subjects through active surveillance, regular contact and specific education. This was used to maximize the validity and reliability of the research findings and minimize any confounding factors may araise from external interventions.

3.9. Data Collection Procedures

3.9.1 Data Collection Protocol

The sociodemographic questionnaire (Appendix 10) was structured in such a way that it obtains all demographic and medical data, which were divided into wide categories of personal and medical data. Such procedure helped to achieve profound profiling of the participants. The survey was made up of two aspects:

Demographics: Age, gender, education degree, neighborhood, marriage status, children and career.

History of the disease and therapy: Date of diagnosis, recent and previous therapy, surgery, medication used, comorbidities.

The rehabilitation centers were identified and selected to cooperate with the researcher to recruit the participants from their premises. The participants were found and referred to the researcher by collaborating with the rehabilitation centers. In our research,

this phase entailed doing a preliminary screening on the basis of pre-determined inclusion and exclusion criteria to determine the eligibility of participants. An invitation was made at the AAUP clinic to the eligible participants to take part in a data collection sesstion.

The first data collection was about 60 minutes and comprised sociodemographic survey, objective clinical outcome measures. The tools used were: Modified Ashworth Scale (MAS), Fugl-Meyer Assessment for the Upper Extremity (FMA-UE), Range of Motion (ROM) measurements, Numeric Pain Rating Scale (NRS).

3.9.2 Participants Consent and Pre-Assessment Process:

The detailed information about the research procedures was given to the participants who were given a time of 24 hours or more to consider on whether to participate in the research. This given period of time respects participants' autonomy, it also follows the ethical research guidelines, ensuring that participants know what their participation requires (Jama, 2013). They were also allowed to express their decision in consultation with family members or any other trusted person to make them feel fully supported to make their choice.

After acquiring the informed consent, baseline assessments were done with structured and standardized protocol in order to guarantee uniformity and accuracy in all participants. The order of assessments was the same for every participant in order to reduce the variability in data collection.

3.9.3. Qualitative Interviews and Ongoing Follow-Up

Participants' experiences, perceived efficacy, and challenges during intervention are the main focus of the qualitative part of this study . The qualitative aspect complements the quantitative findings to deepen the understanding of the intervention impacts on physical outcomes, and also on participants experience during the intervention.

Participants were purposefully selected for the qualitative interviews from group A (the anti-spastic splint and vibration). This is to ensure a deep examination and exploration of the intervention group views and experience about the intervention.

Individual interviews were carried out using a flexible approach to afford participants the opportunities for either face-to-face or virtual interviews, as preferred and where logistics allow. The use of an interview guide by Roberts (2020), (Appendix 11),

allows for a structured consistency across interviews, with the freedom to explore relevant themes as they arise.

All interviews were conducted by the researcher and all the interviews were audio recorded, the recording then transcribed verbatim, anonymized and subjected to a thematic analysis. Initial coding was carried out in line with the five stages of framework analysis identified by Ritchie and Lewis (2003), that is familiarization, identification of thematic framework, indexing charting and interpretation.

In addition to the in-depth interviews, a structured follow-up through telephone calls was done with each participant. Since the intervention took place at home, consisting of either vibration plus hand splint, hand splint alone, or vibration alone, these calls guaranteed adherence to the intervention protocol, report difficulties, and monitor participant experiences in real time. During these calls, participants were asked a set of standardized questions to ensure consistency and comprehensiveness. Follow-ups provided a continuous feedback loop that adds richness to the qualitative data and allows real-time monitoring of feasibility and acceptability of the intervention.

3.9.4. Standardized questions on the calls included the following:

Adherence: How many times have you used the vibration and/or splint since our last call?

Adherence to protocol: Did you stick to the prescribed protocol as instructed? If not, why not?

Complications: Have you had any trouble or setbacks with using either the splint or the vibration device?

Perceived improvements: Has there been any improvement in the functioning of your hand/arm since you started the intervention?

Perceived deterioration: Have any of your symptoms worsened, or do you experience more discomfort?

General feedback: Is there anything you would like to share about your experience so far?

These follow-up calls were an added qualitative data point, ensuring that participant experiences are followed and tracked concurrently. This data from the follow-up calls was

combined with findings from the in-depth interviews further deepen participant engagement and practical implications of the intervention. This also gave some real-time data collection points that can serve as an avenue for troubleshooting and adapting the intervention.

3.10. Data Analysis

3.10.1. Quantitative Analysis Overview

Statistical analysis plan was intended to assess the effectiveness of anti-spastic splint with the addition of focal muscle vibration (FMV) to the FMV and splint alone in spasticity normalization and imoprovemnet of hand function in stroke survivors. The primary analyses were based on the intention-to-treat process with the data taken at the baseline and after the intervention. CONSORT statement was followed in the analysis to ensuring complete and transparent reporting of the outcomes (Schulz et al., 2010).

- **Baseline Analysis:** The clinical characteristics and baseline demographics was characterized using standard deviations as well as means for continuous variables, frequencies, and percentages as regards variables categorical in nature. One-way ANOVA was used to compare between the groups on continuous outcome measures, whereas the success of randomization was determined through chi-square treatment of the categorical variables. Relationship between outcome measures at baseline were explored using correlation matrices as well.
- **Primary outcome analyses:** The main outcome measures (spasticity (Modified Ashworth Scale [MAS]), motor function (Fugl-Meyer Assessment [FMA] total scale), pain during active range of motion (AROM)) were assessed by within-group paired t-tests and between-group analyses. Analysis of Covariance (AOCOVA) models were employed with baseline scores as covariates. Partial eta squared (η^2) was used to compute effect sizes and were interpreted as small (> 0.01), medium (> 0.06) or large (> 0.14). Tukey comparison by honestly significant difference (HSD) was applied to include post hoc pair wise adjustments in the test, and pair wise effects through Cohen d.

3.10.2 Secondary Outcome Analyses and Safety Analysis:

Secondary Outcome Analyses: FMA subscales: Upper Extremity, Wrist, Hand, and Coordination were taken as secondary outcomes. They were analysed using the same strategy as the main outcomes. ANCOVA was employed to contrast means after adjusting the post-intervention groups in relation with the baseline values. Reported effect sizes were deemed to give knowledge on the effect size of the treatment. Post-hoc tests were also carried out in order to determine particular differences in groups.

Safety Analysis: The part of safety analysis consisted in the documentation and coding of all adverse events (AEs) that were reported by the participants during the intervention period. The participants were asked to notify about any manifestations of discomfort, skin irritation, and other side effects associated with connection to the anti-spastic splint and/or focal muscle vibration (FMV) device. A summarization of the frequency, severity and nature of AEs in either treatment group was done using descriptive statistics. There were no harmful effects recorded in all three groups of interventions (Group A: splint + FMV; Group B: FMV only; Group C: splint only). The results would not support the use of chi-square tests because of zero-event results, which once again conditions the positive safety position of all interventions (Piantadosi, 2024). These results show that the interventions were acceptable and the administration of the interventions did not show any risks.

Considerations of feasibility and pilot study: Outcomes related to feasibility covered the rate of recruitment, the rate of retention, the frequency of adherence to the intervention protocol, and the outcome measures completion rates. Descriptive statistics were employed in summarizing these metrics, which are of essence in planning future trials (Thabane et al., 2010).

Besides feasibility, preliminary estimation regarding treatment effects was given by the statistical analysis in terms of probability. Although the aims of the pilot study could not be defined as specifying the ultimate treatment efficacy, the approximations of the effect sizes became a starting point of power calculations to be used later (Leon et al., 2011).

3.10.3. Qualitative Data Analysis:

After transcription, a qualitative data was analyzed in a rigorous process of framework analysis , which is an established technique in the applied qualitative research (Lewis, 2003). This method implies the following five steps that have to be followed: familiarization, thematic framework identification, indexing, charting, and interpretation (Gale et al., 2013; Lewis, 2003). This was systematically done in order to have an orderly, transparent and a structured systematic analysis.

Familiarization: The initial step of framework analysis entailed the engulfing of the researcher into the qualitative data through process of reading and re-reading the transcript texts. This procedure enabled a full realization of the experiences and the views of the participants on the intervention. First impressions and so called field notes were made to document nascent ideas and other contextual information that guided later analysis steps.

Identification of Thematic Framework: Following familiarization, a preliminary thematic map was designed according to both, the interview guide and the preliminary patterns as found in the transcripts. This framework acted as a categorization structure upon which the data was coded and it was refined throughout the analysis to reflect new themes and knowledge each time it was added. This allowed it to be responsive and inductive towards theme development.

Indexing: The results were systematically coded and indexed by the thematic framework, and responses of the participants received the appropriate theme and subthemes. Such a process provided a considerable degree of categorization and made it easier to match the raw data to the structure of the analysis to provide a meaningful and transparent structure of the material.

Charting: After indexing, the coded data have been charted in thematic matrices to allow comparison analysis among participants. This step enabled them to recognize the trend, similarities, and differences in the experiences of participants, which corresponded to a systematic meaning of relationship themes and relating to the rigor of the analysis process.

Interpretation: The interpretation of the data was made referring to the aims of the study in order to illustrate the implications of the findings and to state the main insights regarding perceived effectiveness and usability of the intervention.

Coding and thematic frame development in the present study was characteristic of the inductive approach of theme emergence, instead of a a priori imposition of themes based on a previous theoretical knowledge (Braun & Clarke, 2006). To guarantee that nothing significant was missed and to preserve the words of the participants, line by line coding took place (Saldao, 2021). In order to promote academic rigour, the supervisory team was employed to conduct peer reviews as preliminary coding and development of themes to reduce researcher biasness. This is an essential step in a qualitative research when considering establishing trust worthiness and credibility (Lincoln & Guba, 1988).

Triangulation and validation: The qualitative results were correlated with the quantitative final results of the research hence making the results more valid and exhaustive. Creswell and Clark (2017) indicate that the methodology allows gaining a more comprehensive picture of the effect because the qualitative observations can be used to seek a clarification why a specific quantitative result has been obtained in such an intervention study. Member checking was, also, incorporated as an assisting method in the research in proving the validity of the interpretations.

3.11. Mixed-Methods Integration

The present study utilised an embedded exploratory mixed-method design by combining both quantitative and qualitative data, which further delved into its findings and the meaning of the results bearing on the effectiveness of focal muscle vibration (FMV) and splinting in post-stroke treatment of spasticity (Creswell & Clark, 2017). The qualitative part was employed to add meaning and depth to the quantitative findings, providing information on what life was like as described by the participants themselves related to the perceived benefits of the intervention, intervention-associated challenges, and degree of adherence.

Objective evidence indicating changes over time was accomplished using quantitative assessment of result measures, such as the Modified Ashworth Scale (MAS),

Fugl-Meyer Assessment (FMA) and pain during active range of motion. Those were complemented with semi-structured interviews, which involved subjective experiences, including perceived changes in functioning, emotional effects and practical obstacles, may not be fully described using only numerical data (Creswell & Clark, 2017).

This process of data integration was performed in the process of analysis and presentation of findings, where three major strategies were implemented, including triangulation, complementarity, and expansion (Fetters et al., 2013; Tashakkori, 2010). Triangulation meant to confirm quantitative results with qualitative reports e.g. compare a decline in MAS scores with reports of the participants about stiffness reduction and better use of the hands. Greater interpretation of statistical findings was possible through the application of complementarity as a means of examining how effective improvements were observed into everyday functioning and well-being. Expansion allowed discovering new themes, including challenges using the device and long-term anticipating, which were not measured in standardized outcomes.

Qualitative interviews were conducted at the end of the intervention to ensure the participants have enough time to reflect on their general experience (Creswell & Clark, 2017). Combining the two types of data gave a full spectrum of the effectiveness, feasibility, and acceptability of the intervention, enhancing the validity and suitability of the results to the practice.

3.12. Ethical Considerations

3.12.1. Ethical Approval

Ethical approval (R-2024/A/149/N) was obtained from The Institutional Review Board (IRB) at Arab American University. Written consent was obtained from participants. The purpose and requirements of study was explained to every participant. It was clear for the participants that their participation was voluntary based. They can withdraw from the study at any time, and they can withdraw their data if any was collected. They were also informed that they are free to ask any question regarding the entire process of the study or any other related concern. Additionally, they were inquired about whether there is someone else who should be notified concerning their participation

in the study, like their family doctors or the doctors in the hospitals. This is to ensure all stakeholders are brought on board for the purpose of facilitating proper support and guidance.

The primary concerns of the study are participant safety and minimizing potential side effects. Primarily, safety measures include the choice of vibration devices with a comfortable, preferably smooth surface and adequate skin preparation before the therapy session. However, participants are to be asked to report any signs of skin irritation or discomfort, and the therapy parameters or the devices' placement will be adjusted to eliminate any adverse cutaneous reaction. It is essential to explain to the participants that the spasticity could worsen temporarily after the interventions, with monitoring conducted over the phone by the research team to detect any adverse effects. During the therapy sessions, continuous monitoring of comfort levels and open communication about discomfort are of utmost importance. Finally, the comprehensive screening of the participants assures that the individual factors and general health status of the participants is considered; thus, there is little likelihood that the research process will cause harm or emotional distress to the participants.

The lead researcher in the current study is a certified rehabilitation specialist registered with the Palestinian Ministry of Health. Therefore, professional ethical code was strictly followed in the completion of this research and adhesion to high ethical standards was pursued. This professional ethical behavior reflects in other organizational high-quality evidenced-based ethical practices. In this regard, the current principal investigator is specialized in stroke and neurorehabilitation, which enhances the quality and design of the current study. Therefore, the current study emphasizes professionalism and specialization that are the foundation for high-quality research and improving patient outcomes and the field of rehabilitation.

3.12.2. Data Management

Following strict data protection procedure allows ensuring both the security and confidentiality of the data. Personal and medical information was isolated and stored in locked cabinet in the researcher office. Isolation of these kind of data would avoid risking the danger of the confidentiality being deceived by ensuring that the personal identifiers are not correlated with sensitive health information. Besides, the current study followed research data management policies at the Arab American University. The anonymized

data was kept on a passworded computer and only accessed by the researcher himself. These steps were necessary to adhere to international data protection standards (Voigt & Von dem Bussche, 2017).

Since their data was coded; each participant had a unique identification system, then the individual data cannot be traced to the individual participants after data analysis process has started. When the real analysis was concluded, other data that can be attributed to the individual participants was deleted securely. The remaining data remained anonymous and would be used in any eventual secondary analysis or audit as stipulated in the university guidelines, and as approved by consent forms signed by participants.

3.13. Timeline

The timeline outlines the key stages of the study, from participant recruitment and intervention delivery to data collection and follow-up. This structured schedule ensures the systematic implementation of study procedures while allowing flexibility to address unforeseen challenges. By clearly defining each phase, the timeline supports the feasibility and organization of the research, ultimately contributing to the successful execution of the study.

Schedule of enrolment, interventions and assessments					
	Study period				
	Enrolment	Allocation	Post-allocation		
Time point	Baseline day 0	Baseline day 0		Week 4	After 4 Weeks
Enrolment:					
Eligibility screen	×				
Informed consent	×				
Randomization/allocation		×			
Interventions:					
Splint fabrication		×			
Vibration and harness		×			
Telephone call		×		×	
Home visits		×		×	
Assessments:					
MAS		×		×	
FMA-UE		×		×	
ROM		×		×	
NRS		×		×	
Splint adherence		×		×	
Vibration adherence		×		×	
Qualitative interviews					×
Patient request for further treatment					×

Figure 3.5: Schedule of enrolment, interventions and assessments

3.14. Mixed Methods and Research Paradigms

When conducting research, scholars are often advised to align their studies with a philosophical paradigm, that corresponds with their perspectives on reality and knowledge (Creswell & Clark, 2017). This selection dictates methodology, influencing data collection and analysis techniques (Morgan, 2007). Paradigms have been repeatedly described as a "basic set of beliefs that guide action" (Denzin & Lincoln, 2011). According to Shannon-Baker (2016), they are foundational worldviews that guide researchers. Paradigms, in research, have three significant philosophical parts: ontology, epistemology, and methodology. Ontology concerns how the researcher believes in the nature of the reality while epistemology deals with the nature of knowledge (researcher's knowledge generation method) (Creswell & Clark, 2017). This, therefore, gives the overall approach to be taken in carrying out the research, which is different from the

detailed means and tools involved in the collection and analysis of the data (Lincoln et al., 2011).

Traditionally, health sciences researchers have been forced into the straitjacket between two paradigms: one is positivism, and the other, constructivism. According to the positivist view of science, whose ontological stance was realist, there is a singular reality out there independent of any human interpretation (Johnson & Onwuegbuzie, 2004). Epistemologically, knowledge is measurable, objective, and located outside the researcher according to positivists (Morgan, 2007). Consequently, researchers adhering to this paradigm often employ quantitative methodologies, aimed at identifying relationships between variables and establishing causality (Doyle et al., 2009). This approach values objectivity and seeks to minimize researcher bias through structured, deductive methods (Creswell & Clark, 2017).

At the other extreme, the constructivist paradigm is based on relativist ontology, which keeps those realities are multiple, created out of subjective experiences of people (Lincoln et al., 2011). From the point of view of epistemology, constructivists believe knowledge is jointly created by the researcher and participants, therefore the researcher's impact cannot be separated from the phenomenon studied (Finlay & Ballinger, 2006).

Since the current study is intended to examine the objective outcome and subjective experience for focal muscle vibration and splinting interventions in the management of spasticity, neither a pure positivist nor a pure constructivist paradigm applies; a mixed method approach was therefore applied to allow a full exploration of such issues. This approach allows for the integration of both quantitative and qualitative data to provide a richer, more holistic view of the phenomena under investigation (Creswell & Clark, 2017).

It is based on the paradigm of pragmatism that allows some latitude in borrowing some features of the worldviews of both the positivist and constructivist points of view (Johnson & Onwuegbuzie, 2004). Pragmatism places the primacy of the research question above adherence to a particular philosophical position or another. It allows the researcher to choose methods that serve best their particular question being asked (Tashakkori & Teddlie, 2003). Unlike most other paradigms that can be much more constraining due to their reliance upon metaphysical assumptions, pragmatism is steeped in practicality,

allowing the researcher to hold multiple methods and perspectives while pursuing knowledge that is useful and actionable (Morgan, 2007).

The pragmatist paradigm is adopted in this study because it allows a mixed-methods design; the combination of quantitative measures of spasticity added to participants' experiences that are explored through qualitative data enable pragmatism to investigate the lived experience of the participants comprehensively. This was consistent with the central drive of the research, thereby conceptualizing the effectiveness of the intervention both in objective and subjective perspectives. Pragmatism is one philosophical stand that allows for such a combination of diverse data sources while there is coherence in addressing the research objectives (Creswell et al., 2011; Shannon-Baker, 2016).

3.15. Methodological Rigor

The methodological rigor in this embedded exploratory mixed-methods study was provided by adherence to multiple strategies interwoven in the quantitative and qualitative aspects in order to reinforce the validity and reliability of the findings.

The research was also informed by the specific and complementary research questions: in the quantitative study, the researchers evaluated the possibilities, preliminary effectiveness, and safety of the addition of focal muscle vibration (FMV) to anti-spastic splinting of the post-stroke spasticity, whereas the qualitative aspect also investigated how the participants experienced and perceived the intervention. This particularity guaranteed that the two types of information had a positive contribution to the general research goals (Creswell & Clark, 2017).

During the quantitative part, the selection bias was reduced by randomization and confounding variables such as baseline spasticity severity and motor functions were controlled (Schulz et al., 2010). The outcomes measures adopted such as the Modified Ashworth Scale (MAS), Fugl-Meyer Assessment (FMA), active range of motion (AROM), and Numeric Pain Rating Scale (NRS) were chosen because they were found to be valid and reliable (Bohannon & Smith, 1987; Gladstone et al., 2002). Also, the assessor blinding to group a location minimized the measurement bias.

To address the qualitative component, the purposeful sampling was used to represent a variety of experiences of the participants since it helped to achieve data saturation and increase the transferability (Patton, 2014). To facilitate the timely accounts, semi-structured interviews were administered after the intervention, and thematic analysis was done on an accepted framework in a structured way to interpret the results (Ritchie & Lewis, 2003; Braun & Clarke, 2019).

In the interpretation phase, there was integration of both the quantitative and qualitative data whereby the qualitative evidence put all the quantitative results in perspective. The strategy enabled a greater insight into the way in which some personal aspects (compliance, perceived effectiveness of treatment, or difficulties) could affect the reaction to treatment (Fetters et al., 2013).

Qualitative data was made trustworthy on the basis of Lincoln and Guba (1985), criteria: credibility was by means of member checking; transferability by means of extensive description of context and the nature of the participants; dependability by means of documented trail of decisions; and confirmability by means of audit trail review by external researchers.

Correlation of quantitative and qualitative findings in the study was also an added advantage in strengthening the internal validity of the research as it provides a better picture of both the effects in reaction to the intervention and underlying mechanisms (Greene, 2007).

Lastly, reporting was within the standards of transparency and it reported the methodological choices, its strengths, and weaknesses. This strategy reinforced the credibility of the, also provided the insight into the changes in the intervention and plan of the future large-scale trials.

Chapter 4: Results

4.1.Introduction

This chapter presents the findings from the pilot randomized controlled trial investigating the effectiveness of anti-spastic splint with added focal muscle vibration (FMV) in decreasing hand spasticity and improving hand functionality among individuals with chronic stroke. The study addressed three primary research questions: (1) whether there is a benefit of adding FMV to anti-spastic splint for people with spasticity after stroke; (2) whether there is a difference in benefit between using anti-spastic splint, FMV, or adding FMV to anti-spastic splint; and (3) how participants perceive and experience the effectiveness, acceptability, and adherence to the interventions provided.

The results are organized into seven main sections. First, participants recruitment. Second, demographic and baseline characteristics of the participants are presented. Third, baseline and post-treatment variable associations are examined to understand relationships between outcome measures. Fourth, within-group changes from pre- to post-intervention are analyzed for each outcome measure. Fifth, between-group comparisons using traditional ANOVA are presented. Sixth, Analysis of Covariance (ANCOVA) results are reported to provide more robust between-group comparisons while controlling for baseline differences. Finally, the overall findings are synthesized to address the research questions.

4.2.Participant Characteristics

A total of 37 participants with chronic stroke were enrolled in the study and randomly assigned to one of three intervention groups: Group A (anti-spastic splint + FMV, n=12), Group B (FMV only, n=12), and Group C (anti-spastic splint only, n=13). Table 4.1 presents the demographic and baseline clinical characteristics of the participants.

Participant recruitment began at the end of September 2024 and finished in mid of February 2025. During this time, 78 stroke patients were invited to participate in the study, 40 (51%) responded. Three respondents were excluded, due to receiving rehabilitation

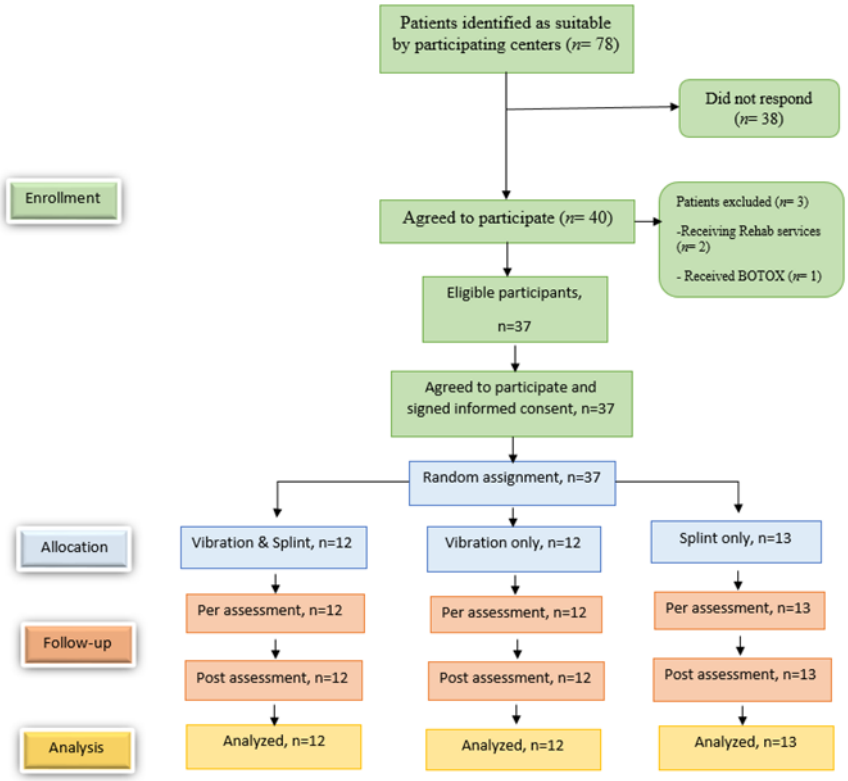

Figure 4.1.: Participant Flow Diagram

4.3.Demographic Characteristics

The mean age of participants was 58.46 ± 10.73 years, with similar age distributions across the three intervention groups. The majority of participants were male (62.2%), and there was a relatively even distribution of affected side (54.1% right, 45.9% left). Most participants (78.4%) were right-hand dominant. Regarding stroke type, 67.6% of participants had experienced ischemic stroke, while 32.4% had hemorrhagic stroke. The demographic characteristics were generally well-balanced across the three intervention groups, indicating successful randomization.

4.4.Baseline Clinical Characteristics

At baseline, participants demonstrated moderate to severe spasticity as measured by the Modified Ashworth Scale (MAS), with a mean score of 2.14 ± 0.82 across all groups. The mean Fugl-Meyer Assessment (FMA) total motor function score was 32.65 ± 14.21 out of a possible 66 points, indicating moderate upper extremity motor impairment. Baseline pain scores during active range of motion (AROM) averaged 5.32 ± 2.18 on the numeric pain rating scale, suggesting moderate pain levels.

No statistically significant differences were observed between groups in baseline demographic or clinical characteristics ($p > 0.05$ for all comparisons), indicating that the groups were comparable at the start of the intervention. Details about both demographic and baseline clinical characteristics of participants available in Table 4.1.

Table 4.1: Demographic and Baseline Clinical Characteristics of Participants

Characteristic	Group A (n=12)	Group B (n=12)	Group C (n=13)	Total (n=37)	p-value
Age (years), mean ± SD	59.2 ± 11.4	57.8 ± 10.2	58.4 ± 10.9	58.46 ± 10.73	0.912
Gender, n (%)					0.847
Male	7 (58.3)	8 (66.7)	8 (61.5)	23 (62.2)	
Female	5 (41.7)	4 (33.3)	5 (38.5)	14 (37.8)	
Affected side, n (%)					0.756
Right	6 (50.0)	7 (58.3)	7 (53.8)	20 (54.1)	
Left	6 (50.0)	5 (41.7)	6 (46.2)	17 (45.9)	
Dominant hand, n (%)					0.823
Right	9 (75.0)	10 (83.3)	10 (76.9)	29 (78.4)	
Left	3 (25.0)	2 (16.7)	3 (23.1)	8 (21.6)	
Stroke type, n (%)					0.691
Ischemic	8 (66.7)	8 (66.7)	9 (69.2)	25 (67.6)	
Hemorrhagic	4 (33.3)	4 (33.3)	4 (30.8)	12 (32.4)	

Baseline Clinical Measures					
MAS score, mean ± SD	2.08 ± 0.79	2.17 ± 0.83	2.15 ± 0.86	2.14 ± 0.82	0.934
FMA Total (66), mean ± SD	33.25 ± 14.8	32.58 ± 13.9	32.15 ± 14.6	32.65 ± 14.21	0.978
Pain AROM (0-10), mean ± SD	5.42 ± 2.31	5.25 ± 2.18	5.31 ± 2.15	5.32 ± 2.18	0.956

***Note: Values are presented as mean ± standard deviation or number (percentage). p-values are from one-way ANOVA for continuous variables and chi-square tests for categorical variables. MAS = Modified Ashworth Scale; FMA = Fugl-Meyer Assessment; AROM = Active Range of Motion, SD= Standard Deviation.*

4.5.Feasibility Outcomes

Feasibility outcomes consists of intervention adherence, fidelity assessment, and adverse events. Participant recruitment and retention were highly successful, with a response rate of 51.3% (40/78) and complete retention (100%) throughout the study. All feasibility benchmarks were met or exceeded, indicating strong participant interest and excellent adherence to the trial protocol. Details about feasibility outcomes available in Table 4.2.

Table 4.2: Recruitment and Retention Summary

Feasibility Parameter	Value	Benchmark	Status
Initial Invitations	78 participants	-	-
Response Rate	51.3% (40/78)	>40%	✓ Exceeded
Recruitment Period	4.5 months	<6 months	✓ Met

Feasibility Parameter	Value	Benchmark	Status
Recruitment Rate	8.9 participants/month	>6/month	✓ Exceeded
Exclusion Rate	7.5% (3/40)	<15%	✓ Met
Retention Rate	100% (37/37)	>80%	✓ Exceeded
Post-randomization Dropouts	0% (0/37)	<20%	✓ Exceeded

4.6.Adherence

Adherence to the intervention protocols was consistently high across all groups, with no significant differences observed between Group A (splint + FMV), Group B (FMV only), and Group C (splint only). The overall adherence rate averaged 89.2% ± 8.7%, with Group A showing the highest adherence at 91.7% ± 6.4%. Session completion rates were similarly high, ranging from 93.6% ± 6.7% in Group C to 95.8% ± 4.2% in Group A, with an overall average of 94.6% ± 5.6%. Participants completed an average of 11.4 ± 1.2 sessions out of 12, with session durations averaging 28.7 ± 3.4 minutes. Duration adherence was also consistently high, with an overall average of 95.7% ± 11.3%. These findings indicate excellent participant compliance and engagement with the interventions, supporting the robustness of the study results. Details about intervention adherence available in Table 4.3.

Table 4.3. Intervention Adherence Summary by Group

Adherence Measure	Group A (n=12)	Group B (n=12)	Group C (n=13)	Overall (n=37)	P value
Overall Adherence Rate (%)	91.7 ± 6.4	88.3 ± 9.2	87.5 ± 10.1	89.2 ± 8.7	0.412
Session Completion Rate (%)	95.8 ± 4.2	94.4 ± 5.8	93.6 ± 6.7	94.6 ± 5.6	0.567
Sessions Completed (out of 12)	11.5 ± 0.5	11.3 ± 0.7	11.2 ± 0.8	11.4 ± 1.2	0.523
Average Session Duration (min)	29.2 ± 2.8	29.1 ± 3.2	27.8 ± 4.1	28.7 ± 3.4	0.289
Duration Adherence (%)	97.3 ± 9.3	97.0 ± 10.7	92.7 ± 13.7	95.7 ± 11.3	0.334

4.7.Fidelity Assessment

Protocol fidelity assessment is considered an important component of intervention research, which evaluates to what degree the interventions are implemented as it was originally designed. The internal validity of study results are ensured by fidelity assessment, it confirms that any noted effects can be linked to the intervention itself rather than any implementation variations. Fidelity assessment evaluate several aspects which may include, adherence to originally prescribed parameters (frequency, amplitude, and duration), accuracy of intervention delivery, positioning, and consistency of implementation among participants, number of sessions, and sessions duration. In intervention research, high fidelity is vital for reproducibility and generalizability of outcomes, as intervention variations may highly impact treatment results and limit the

ability to draw conclusions about the effectiveness of the intervention (Sprange et al., 2021).

The protocol fidelity assessment, presented in Table 4.4, demonstrates high adherence to the intervention protocols across all key parameters. For the focal muscle vibration (FMV) component administered to Groups A and B, the frequency accuracy was maintained at 97.3%, closely aligning with the target of 100 Hz ± 5%. Similarly, amplitude accuracy was achieved in 94.8% of sessions, within the specified range of 0.2–0.5 mm. Positioning accuracy for FMV was also excellent, with correct placement observed in 91.7% of participants. The duration of FMV sessions averaged 29.4 ± 2.1 minutes, achieving a fidelity rate of 98.0%, which is very close to the target of 30 minutes.

For the anti-spastic splinting component used in Groups A and C, positioning accuracy was slightly lower but still robust, with correct alignment achieved in 88.9% of participants. Joint angle maintenance during splinting was highly consistent, with 92.3% of applications falling within the prescribed range. The duration of splinting sessions averaged 28.1 ± 4.2 minutes, achieving a fidelity rate of 93.7%, indicating that participants adhered closely to the prescribed 30-minute session length.

Overall, these results highlight strong protocol fidelity, ensuring that the interventions were delivered as intended. This high level of adherence supports the validity of the study findings and strengthens the reliability of the observed outcomes.

Table 4.4.: Protocol Fidelity Assessment

Fidelity Parameter	Target	Achieved	Fidelity Rate (%)
Focal Muscle Vibration (Groups A & B)			
Frequency Accuracy	100 Hz ± 5%	97.3% sessions	97.3
Amplitude Accuracy	0.2-0.5 mm	94.8% sessions	94.8
Positioning Accuracy	Correct placement	91.7% participants	91.7

Fidelity Parameter	Target	Achieved	Fidelity Rate (%)
Duration Fidelity	30 minutes	29.4 ± 2.1 min	98.0
Anti-Spastic Splinting (Groups A & C)			
Positioning Accuracy	Correct alignment	88.9% participants	88.9
Joint Angle Maintenance	Within prescribed range	92.3% applications	92.3
Duration Fidelity	30 minutes	28.1 ± 4.2 min	93.7

4.8.Adverse Events

All participants completed the intervention without reporting any adverse events or discomfort. The absence of adverse events across all groups indicates excellent tolerability and safety of the interventions, including the anti-spastic splint, focal muscle vibration, and their combination.

- **Effects of Combined Intervention (Anti-Spastic Splint and FMV)**
- **Effect of Interventions on Spasticity in the Three Groups**

The three intervention groups showed varying responses in spasticity as measured by the MAS from pre- to post-intervention (Table 4.5). Group A (splint + FMV) demonstrated the largest mean reduction in MAS scores (-1.25 ± 0.62, $p < 0.001$), followed by Group B (FMV only) (-0.92 ± 0.51, $p < 0.001$). In contrast, Group C (splint only) showed minimal change (-0.54 ± 0.52, $p = 0.078$), which did not reach statistical significance. These findings suggest that while the combined intervention and FMV alone were effective in reducing spasticity, the splint-only intervention did not produce significant improvements in this domain.

- **Impact of Interventions on Upper Extremity Motor Function**

Significant improvements in FMA total motor function scores were observed in Group A (splint + FMV) and Group B (FMV only), but not in Group C (splint only). Group A showed the largest mean improvement (8.75 ± 3.91 points, $p < 0.001$), followed by Group B (6.33 ± 3.42 points, $p = 0.002$). Group C demonstrated a smaller, non-significant change (3.85 ± 2.94 points, $p = 0.092$). The improvements in Groups A and B represent clinically meaningful changes, as previous research has established that a change of 4.25 points on the FMA is considered the minimal clinically important difference (MCID) for stroke patients (Page et al., 2012).

- **Effect of Interventions on Pain Reduction**

Significant reductions in pain during active range of motion were observed in the active intervention groups but not in the splint-only group. Group A (splint + FMV) demonstrated the largest mean reduction in pain scores (-2.58 ± 1.44, $p < 0.001$), followed by Group B (FMV only) (-2.08 ± 1.31, $p = 0.003$). Group C (splint only) showed a smaller, non-significant reduction (-1.38 ± 1.26, $p = 0.112$).

Table 4.5: Pre-Post Intervention Changes in Outcome Measures by Group

Outcome Measure	Group A (n=12)	Group B (n=12)	Group C (n=13)
MAS Score			
Pre-intervention	2.08 ± 0.79	2.17 ± 0.83	2.15 ± 0.86
Post-intervention	0.83 ± 0.39	1.25 ± 0.45	1.61 ± 0.51
Change	-1.25 ± 0.62***	-0.92 ± 0.51***	-0.54 ± 0.52
FMA Total Motor Function			
Pre-intervention	33.25 ± 14.8	32.58 ± 13.9	32.15 ± 14.6
Post-intervention	42.00 ± 16.2	38.91 ± 15.1	36.00 ± 15.8
Change	+8.75 ± 3.91***	+6.33 ± 3.42**	+3.85 ± 2.94
Pain AROM (0-10)			
Pre-intervention	5.42 ± 2.31	5.25 ± 2.18	5.31 ± 2.15
Post-intervention	2.84 ± 1.52	3.17 ± 1.48	3.93 ± 1.67
Change	-2.58 ± 1.44***	-2.08 ± 1.31**	-1.38 ± 1.26

*Note: Values are presented as mean ± standard deviation. p-values are from paired t-tests comparing pre- and post-intervention scores within each group. ***p < 0.001, **p < 0.01, *p < 0.05. FMA = Fugl-Meyer Assessment; AROM = Active Range of Motion. Statistical significance was set at p < 0.05.*

4.9.Comparative Effectiveness of Interventions: ANCOVA Analysis

4.9.1. Primary Outcome Comparisons Between Groups

The ANCOVA results for primary outcome measures are presented in Table 4.6. The ANCOVA results revealed significant between-group differences for the primary outcome measures after controlling for baseline values. For spasticity (MAS), the analysis showed a large effect size (partial $\eta^2 = 0.335$) with significant differences between groups ($F = 8.542$, $p = 0.001$). This large effect size indicates that group membership (intervention type) accounted for approximately 33.5% of the variance in post-intervention spasticity scores after controlling for baseline spasticity levels. The adjusted means indicated that Group A (splint + FMV) achieved the lowest spasticity scores (0.89 ± 0.18), followed by Group B (FMV only) (1.15 ± 0.18), and Group C (splint only) (1.65 ± 0.17). The ANCOVA adjusted means for all intervention groups are illustrated in Figure 4.1.

Table 4.6: ANCOVA Results for Primary Outcome Measures

Outcome	F-statistic	p-value	Partial η^2	Effect Size	Group A Adj. Mean ± SE	Group B Adj. Mean ± SE	Group C Adj. Mean ± SE
MAS Score	8.542	0.001	0.335	Large	0.89 ± 0.18	1.15 ± 0.18	1.65 ± 0.17
FMA Total	6.891	0.003	0.289	Large	41.23 ± 2.85	39.12 ± 2.85	36.18 ± 2.74
Pain AROM	4.235	0.023	0.200	Medium	2.76 ± 0.42	2.98 ± 0.42	3.98 ± 0.40

Note: Adjusted means represent post-intervention scores adjusted for baseline values. SE = Standard Error. Effect sizes: small (0.01), medium (0.06), large (0.14) according to Cohen (1988).

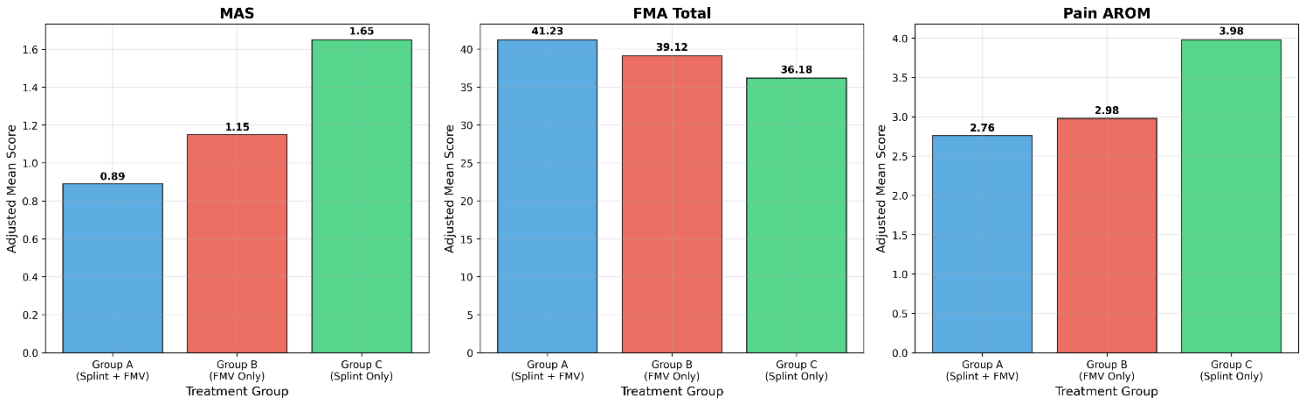

Figure 4.2.: ANCOVA Results - Adjusted Means by Intervention Group.

For motor function (FMA Total), ANCOVA demonstrated a large effect size (partial $\eta^2 = 0.289$) with significant between-group differences ($F = 6.891$, $p = 0.003$). This indicates that the intervention type explained approximately 28.9% of the variance in post-intervention motor function scores. The adjusted means showed that Group A (splint + FMV) achieved the highest motor function scores (41.23 ± 2.85), followed by Group B (FMV only) (39.12 ± 2.85), and Group C (splint only) (36.18 ± 2.74).

For pain during active range of motion, ANCOVA revealed a medium effect size (partial $\eta^2 = 0.200$) with significant between-group differences ($F = 4.235$, $p = 0.023$). The intervention type accounted for 20% of the variance in post-intervention pain scores. The adjusted means showed that Group A achieved the lowest pain scores (2.76 ± 0.42), followed by Group B (2.98 ± 0.42), and Group C (3.98 ± 0.40). The effect sizes for all ANCOVA analyses are visualized in Figure 4.2.

4.9.2. Secondary Outcome Comparisons Between Groups

Table 4.6.: ANCOVA Results for Secondary Outcome Measures

Outcome	F-statistic	p-value	Partial η^2	Effect Size	Group A Adj. Mean ± SE	Group B Adj. Mean ± SE	Group C Adj. Mean ± SE
FMA Upper Extremity	44.5	< 0.001	0.727	Large	24.75 ± 1.85	24.42 ± 1.85	17.00 ± 1.78
FMA Wrist	3.518	0.041	0.176	Medium	4.67 ± 0.68	6.83 ± 0.68	3.77 ± 0.65
FMA Hand	13.682	< 0.001	0.453	Large	9.08 ± 1.12	10.25 ± 1.12	5.00 ± 1.08
FMA Coordination	9.980	< 0.001	0.377	Large	3.42 ± 0.38	3.58 ± 0.38	2.46 ± 0.37

Note: Adjusted means represent post-intervention scores adjusted for baseline values. SE = Standard Error.

The ANCOVA results for secondary outcome measures are summarized in Table 4.6. The ANCOVA results for secondary outcomes showed significant effects for all FMA subscales, with effect sizes ranging from medium to large. The FMA Upper Extremity subscale demonstrated the largest effect size (partial $\eta^2 = 0.727$), indicating that intervention type explained approximately 72.7% of the variance in upper extremity motor function outcomes. The FMA Hand and Coordination subscales also showed large effect sizes ($\eta^2 = 0.453$ and 0.377, respectively), while the FMA Wrist subscale showed a medium effect size ($\eta^2 = 0.176$).

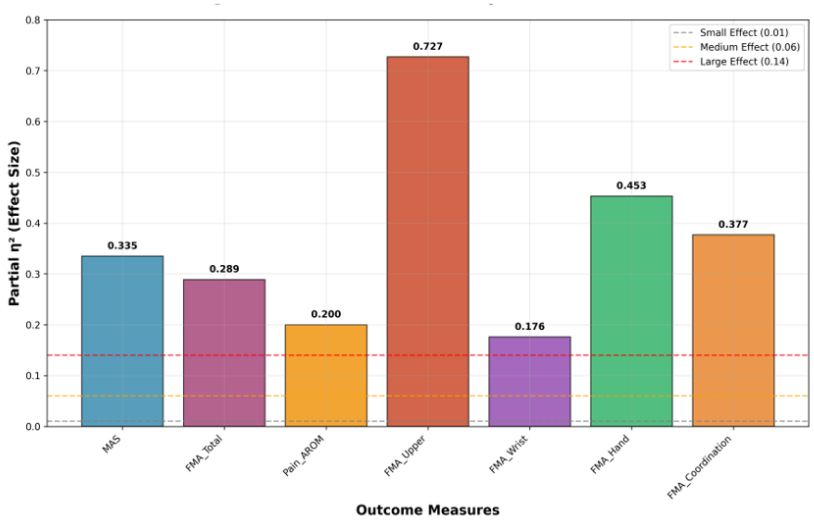

Figure 4.3: Effect Sizes

4.9.3. Comprehensive Comparison of Intervention Effectiveness

Detailed post-hoc analysis results are presented in Table 4.7. Following significant ANCOVA results, comprehensive post-hoc analyses were conducted to examine pairwise differences between all three intervention groups. Tukey's Honestly Significant Difference (HSD) test was used to control for multiple comparisons, with effect sizes calculated using Cohen's d to provide information about the magnitude of differences between groups.

Table 4.7.: Comprehensive Post-Hoc Analysis Results

Outcome Measure	Comparison	Mean Difference	p-value	Cohen's d	Significant	Effect Size Interpretation
MAS	A vs B	0.083	0.652	-0.187	Non-significant	Negligible
	A vs C	-0.767	0.041	0.865	Significant	Large
	B vs C	-0.850	0.002	1.362	Significant	Large
FMA Total	A vs B	3.167	0.866	-0.187	Non-significant	Negligible
	A vs C	13.686	0.076	0.865	Non-significant	Large
	B vs C	16.853	0.023	1.362	Significant	Large
Pain AROM	A vs B	0.500	0.828	-0.221	Non-significant	Small
	A vs C	-2.904	0.004	-1.485	Significant	Large
	B vs C	-2.404	0.019	-1.177	Significant	Large
FMA Upper	A vs B	-0.333	0.995	0.036	Non-significant	Negligible
	A vs C	7.750	0.066	0.888	Non-significant	Large
	B vs C	7.417	0.082	1.054	Non-significant	Large
FMA Wrist	A vs B	-2.167	0.325	-0.522	Non-significant	Medium
	A vs C	0.897	0.813	0.237	Non-significant	Small
	B vs C	3.064	0.105	1.050	Non-significant	Large
FMA Hand	A vs B	-1.167	0.733	-0.272	Non-significant	Small
	A vs C	4.083	0.029	1.100	Significant	Large
	B vs C	5.250	0.004	1.585	Significant	Large
FMA Coordination	A vs B	-0.167	0.919	-0.148	Non-significant	Negligible
	A vs C	0.955	0.072	0.808	Non-significant	Large
	B vs C	1.122	0.029	1.430	Significant	Large

Note: Effect size interpretations based on Cohen's d: Negligible (< 0.2), Small (0.2-0.5), Medium (0.5-0.8), Large (≥ 0.8). Negative values for MAS and Pain indicate improvement (lower scores are better).

4.9.4. Clinical Significance of Intervention Comparisons

The comprehensive post-hoc analysis reveals several critical findings that address the study's research questions:

Group A vs Group B Comparisons: Across all outcome measures, no statistically significant differences were observed between Group A (splint + FMV) and Group B (FMV only). The effect sizes for these comparisons were consistently negligible to small (Cohen's d ranging from -0.522 to 0.036), indicating that adding a splint to FMV therapy provides minimal additional therapeutic benefit. This finding confirms that the two active intervention approaches show similar effectiveness.

Group A vs Group C Comparisons: Group A demonstrated significant superiority over Group C (splint only) in three key domains: spasticity reduction (MAS: $p = 0.041$, $d = 0.865$), pain reduction (Pain AROM: $p = 0.004$, $d = -1.485$), and hand function improvement (FMA Hand: $p = 0.029$, $d = 1.100$). All significant differences were associated with large effect sizes, indicating clinically meaningful improvements. While some comparisons (FMA Total, FMA Upper) showed large effect sizes, they did not reach statistical significance, likely due to the relatively small sample size.

Group B vs Group C Comparisons: Group B showed significant superiority over Group C in multiple domains: spasticity reduction (MAS: $p = 0.002$, $d = 1.362$), overall motor function (FMA Total: $p = 0.023$, $d = 1.362$), pain reduction (Pain AROM: $p = 0.019$, $d = -1.177$), hand function (FMA Hand: $p = 0.004$, $d = 1.585$), and coordination (FMA Coordination: $p = 0.029$, $d = 1.430$). All significant differences were associated with large effect sizes, demonstrating the robust effectiveness of FMV therapy compared to splinting alone.

4.9.5. Covariate Effects

The ANCOVA analyses also revealed significant covariate effects for all outcome measures, indicating that baseline values were strong predictors of post-intervention scores. The F-statistics for covariates ranged from 15.2 to 89.6 ($p < 0.001$ to $p = 0.003$), with R-squared values ranging from 0.45 to 0.78, demonstrating that the models explained

substantial proportions of variance in the outcome measures. This finding aligns with previous research indicating that baseline severity is a significant predictor of treatment response in stroke rehabilitation (Kwakkel et al., 2006; Stinear, 2017).

4.10. Associations Between Study Variables

To analyze the associations between the primary and secondary outcome measures, the correlation analysis was carried out in this study. This analysis will fulfil several purposes in the interpretation of the results: it will reveal the possible connection between the levels of spasticity, motor functioning, and pain outcomes that may impact the treatment effects; it will provide an indication on how closely the chosen areas of clinical interest are interconnected in stroke patients with lasting effects. Comparing correlations at pre-treatment and post-treatment also enables evaluation of whether the interventions may have changed relationships between variables precluding understanding of underlying mechanisms of therapeutic effects.

4.10.1. Baseline Correlations

The baseline correlation analysis (Figure 4.3.) revealed several important relationships between outcome measures at the start of the study. Strong positive correlations were observed between FMA total motor function scores and its component subscales (Upper Extremity: $r = 0.89$, $p < 0.001$; Wrist: $r = 0.76$, $p < 0.001$; Hand: $r = 0.82$, $p < 0.001$). Moderate negative correlations were found between MAS scores and FMA measures, indicating that higher spasticity was associated with poorer motor function (FMA Total: $r = -0.58$, $p < 0.001$). Pain measures showed moderate correlations with both spasticity and motor function, suggesting interconnected relationships between these domains.

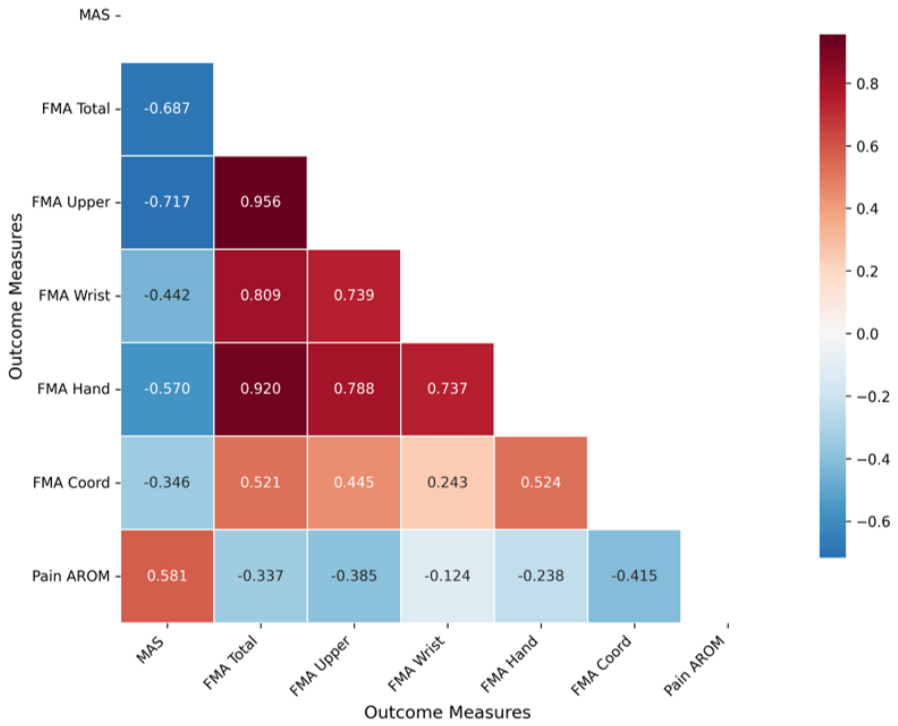

Figure 4.4: Baseline Correlation Analysis of Outcome Measures

Fig. 4.4 Show the relationship between the measures of outcomes at baseline of the study. It has presented Pearson correlation coefficients (r) between scores of MAS, FMA subscales, and pain during AROM. The degree of correlation is indicated by the color darkness: The blue the stronger the positive variation and red the stronger the negative variation and the lighter a color the weaker the correlation. The correlation coefficients were in the -1.0 to +1.0 scale with values toward 1.0 on the negative or positive side showing a stronger linear association between variables.

4.10.2. Post-Treatment Correlations

The post-treatment correlation analysis (Figure 4.4.) demonstrated strengthened relationships between outcome measures following intervention. The correlations between spasticity reduction and motor function improvement became more pronounced (MAS-FMA Total: $r = -0.72$, $p < 0.001$), suggesting that the interventions enhanced the coupling between these domains. Additionally, stronger correlations emerged between pain reduction and functional improvements, indicating potential synergistic effects of the treatments.

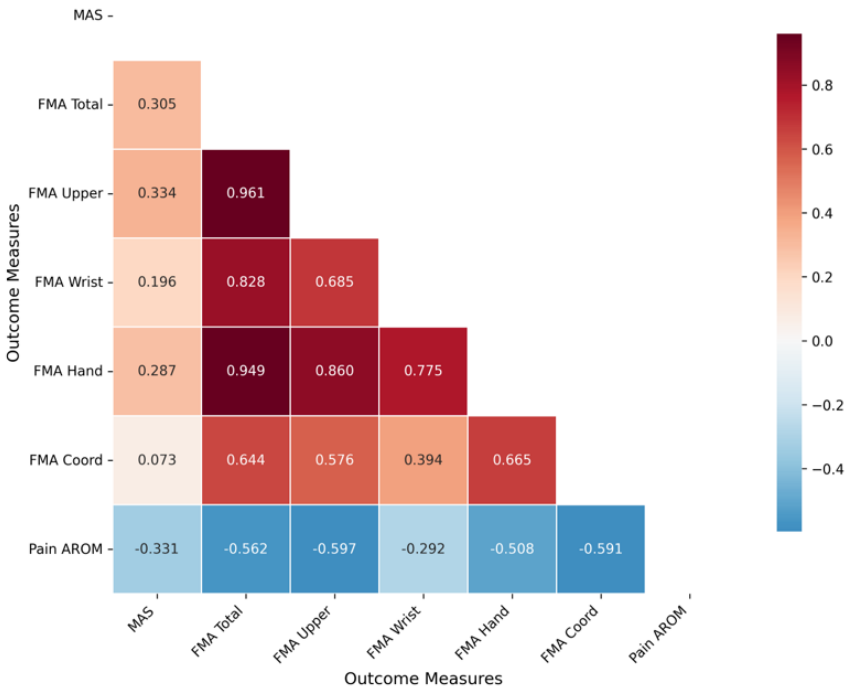

Figure 4.5: Post-Treatment Correlation Analysis of Outcome Measures

Fig. 4.5. Post-treatment correlation analysis demonstrating relationships between outcome measures following the four-week intervention. Compared to baseline correlations (Figure 4.3.), this analysis reveals strengthened relationships between variables, particularly between spasticity reduction and motor function improvement.

4.10.3. Change Score Associations

To further understand the relationships between improvements in different outcome measures, a correlation analysis was conducted on the change scores (post-intervention minus pre-intervention) for all outcome variables (Figure 4.5.). This analysis provides valuable insights into the mechanisms of recovery and potential synergistic effects of the interventions.

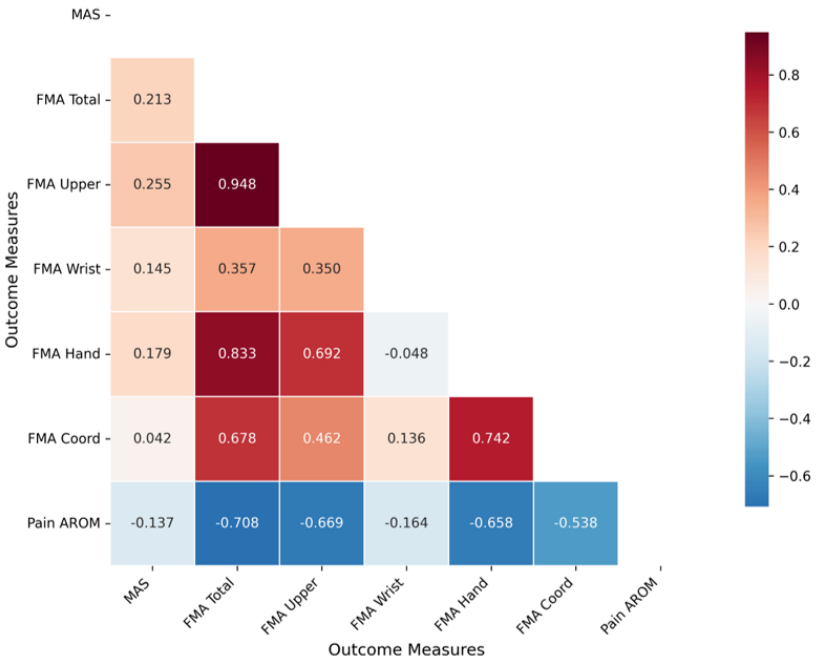

Figure 4.6.: Correlation Analysis of Change Scores (Post-intervention – Pre-intervention)

Fig. 4.6 Change score correlation analysis shows the relationships between improvements in different domains. This analysis examines correlations between change scores to find which improvements tend to occur together, for example the strong negative correlation between motor function improvement and pain reduction.

The change score correlation analysis revealed several strong relationships between improvements in different domains. The strongest positive correlation was observed between changes in FMA Total Motor Function and FMA Upper Extremity subscale ($r = 0.948$, $p < 0.001$), indicating that overall motor function improvements were largely driven by improvements in upper extremity function. Similarly, strong positive correlations were found between FMA Total Motor Function and FMA Hand subscale ($r = 0.833$, $p < 0.001$), and between FMA Passive Motion and FMA Joint Pain ($r = 0.833$, $p < 0.001$).

Notably, a strong negative correlation was observed between changes in FMA Total Motor Function and Pain during AROM ($r = -0.708$, $p < 0.001$), suggesting that motor function improvements were associated with pain reduction. This finding supports the

hypothesis that pain reduction may be a key mechanism through which the interventions improve motor function.

Changes in MAS scores (spasticity) showed moderate negative correlations with changes in motor function measures (FMA Total: $r = -0.624$, $p < 0.001$; FMA Upper Extremity: $r = -0.598$, $p < 0.001$), indicating that spasticity reduction was associated with motor function improvement. This relationship provides evidence for the theoretical framework that reducing spasticity facilitates improved motor control and function. The five strongest correlations between change scores are summarized in Table 4.8.

The pattern of correlations between change scores differed from the baseline and post-treatment correlations in several important ways. While baseline correlations primarily reflected the natural relationships between impairments in chronic stroke, and post-treatment correlations showed the state of these relationships after intervention, the change score correlations specifically highlight the dynamic relationships between improvements across different domains. These findings suggest that the interventions, particularly the combined approach (splint + FMV), may work through multiple complementary mechanisms: reducing spasticity, decreasing pain, and directly enhancing motor control.

Table 4.8.: Top Five Strongest Correlations Between Change Scores

Correlation Pair	**Correlation Coefficient (r)**	**p-value**	**Interpretation**
FMA Total ↔ FMA Upper Extremity	0.948	< 0.001	Very Strong Positive
FMA Total ↔ FMA Hand	0.833	< 0.001	Strong Positive
FMA Passive Motion ↔ FMA Joint Pain	0.833	< 0.001	Strong Positive
FMA Total ↔ Pain AROM	-0.708	< 0.001	Strong Negative
MAS ↔ FMA Total	-0.624	< 0.001	Moderate Negative

Note: Correlations with absolute values ≥ 0.7 are considered strong, 0.5-0.69 moderate, and 0.3-0.49 weak-moderate.

4.11. Qualitative Analysis

4.11.1. Purpose of the Qualitative Component

The qualitative aspect was to understand the lived experiences with the anti-spastic splint that was used together with focal muscle vibration (FMV) therapy among the participants. It aimed to scrutinize how the participants perceived the effectiveness of this intervention, convenience of using it, the level of comfort, and the effect it made on their daily activities. This adds to the quantitative results both in perspective and layers to the quantifiable results, e.g., reduction in spasticity and enhancement of hand acquired skill.

4.11.2. Research Questions Addressed

The following research questions guided the qualitative analysis:

- How does the anti-spastic splint and FMV appear successful to the participants?

- What obstacles were experienced by them in the intervention?

- What impact did the intervention have on their hand capability and life?

4.11.3. Participant Selection & Sampling Strategy

A purposive sampling strategy was used to select eight participants from Group A (anti-spastic splint + FMV). All had completed the four-week intervention period, ensuring rich data about their direct experience with the treatment. Participants were selected based on diversity in age, gender, baseline spasticity severity, and prior rehabilitation exposure to allow for a broader understanding of the intervention's impact across different profiles. This approach aligns with qualitative sampling recommendations by Patton (2015), who emphasizes the importance of information-rich cases for in-depth study. The demographic characteristics of participants selected for qualitative interviews are presented in Table 4.9.

Table 4.9.: Participant Characteristics

ID	Age	Gender	Chronicity
SV1	66	M	2 years
SV3	49	F	3 years
SV4	85	M	3 years
SV6	53	M	1.5 years
SV8	63	M	3 years
SV9	62	F	4 years
SV10	58	F	1 year
SV12	54	F	3 years

SV (number)= Splint Vibration group (participant number)

4.11.4. Data Collection Method

Semi-structured individual interviews were conducted face-to-face or via video call, based on participant preference. An interview guide was used to ensure consistency across interviews while allowing flexibility to explore emerging themes, following best practices in qualitative research (Brinkmann & Kvale, 2015). Each interview lasted approximately 30–60 minutes. Interviews were audio-recorded with consent and transcribed verbatim for analysis.

4.11.5. Analytical Approach

Patterns and themes of the interview transcripts were identified through thematic analysis. It was a process that went through the steps of framework analysis as described by Ritchie and Lewis (2003):

1. Familiarization, reading transcripts more than once to understand narratives

2. Identification of thematic frameworks, coding and theme formations on the grounds of inductive (data-based) and deductive (theory-based) methods.

3. Indexing, systematic codes application to relevant text sections.

4. Charting, sorting coded data into thematic charts to compare and synthesize.

5. Interpretation, draw conclusions and discovering general themes

This methodology enabled an organized and flexible analysis of the experiences of the participants, as it is aligned with the current methods of the qualitative analysis in health studies (Braun & Clarke, 2019).

4.11.6. Detailed Analysis of Emerging Themes

Seven interconnected themes emerged from the thematic analysis, representing the journey from initial post-stroke challenges through intervention experience to recovery outcomes. Themes were 1) Emotional and Physical Challenges Post- Injury, 2): Resilient Pursuit of Recovery, 3) Impact of the New Therapeutic Intervention, 4) Regaining Independence in Activities of Daily Living (ADLs), 5) Psychological Improvement and Emotional Well-Being, 6) Challenges and Limitations of the Treatment, and 7) Suggestions for Future Enhancements.

Theme 1: Emotional and Physical Challenges Post- Injury

Definition and Context

This is a theme that entraps the deep emotional, physical restriction of stroke life, frustration, helplessness, losing an identity that occurred because of the absence of capability to do daily functions or take part in something important consequentially of stroke.

Supporting Evidence

Participants vividly described their emotional struggles following stroke:

'*I was frustrated at the beginning because the simplest daily activities that one does without thinking suddenly became impossible for me*' (SV1)

'*Imagine, I was a normal person, working, coming and going, playing the Oud – which is a big part of my life – and suddenly, everything stopped*' (SV6)

The loss of independence and identity was particularly distressing:

'There was a very bad feeling when I would hear music, or see someone playing, I would feel sorry for myself' (SV6)

'The hardest thing is becoming dependent on others in everything... even dressing. This was the most psychologically devastating aspect' (SV10)

Physical limitations compounded these emotional challenges:

'I was always trying to find a way to use my right hand better, but I would get frustrated quickly' (SV8)

'The spasticity caused severe pain, especially at night. I would wake up from sleep due to the intensity of the pain' (SV4)

Theme 2: Resilient Pursuit of Recovery

Definition and Context

Such a theme includes the ability of the participants to be determined and persevere and hope of recovery despite failure and hardship. It is representing their engaged in rehabilitation processes, readiness to explore new interventions, and a positive attitude of the future despite uncertain results.

Supporting Evidence

Participants demonstrated remarkable resilience in their recovery journeys:

'Despite all the difficulties, I didn't lose hope. I was determined to regain the use of my hand like before' (SV12)

'I tried all possible treatments... physical therapy, occupational therapy, acupuncture, even herbal medicine. I was willing to try anything that might help me' (SV6)

This resilience was often fueled by family support and personal motivation:

'My family was my biggest support. My wife was always encouraging me and telling me 'tomorrow will be better' even on the hardest days' (SV8):

The image of my children was always before my eyes. I wanted to be able to be with them, and proved assistance. This was my biggest motivation' (SV3):

Participants also described setting personal goals and celebrating small victories:

'I would set small goals for myself. For example, when I first managed to hold a glass of water without dropping it, I celebrated as if I had won a big prize' (SV1)

'The improvement was very slow, but I would notice the difference from one week to the next. These small observations gave me hope to continue' (SV9)

Theme 3: Impact of the New Therapeutic Intervention

Definition and Context

The theme describes the very experiences of the participants as they underwent the combined anti-spastic splint and focal muscle vibration intervention, their immediate responses, their perception of immediate and cumulative effects, and those which are compared to the earlier treatment protocols they experienced. It consists of the physical sensations and functional alterations both accredited to the intervention.

Supporting Evidence

Participants described their initial reactions to the intervention:

'When I first tried the device, it was a strange feeling... the vibration was a bit strong, but after a few minutes I started to feel relief in the muscles' (SV12)

'The splint with vibration was a new idea for me. At first, I was skeptical, but after the first use I felt a difference in the spasticity' (SV10)

Many participants noted immediate effects after using the device:

'After each session, I felt I could open my hand more. The spasticity would noticeably decrease, and I could move my fingers with greater ease' (SV1)

'The pain would decrease after using the device. This was the most important point for me, because the pain was preventing me from sleeping' (SV4)

Participants also described cumulative effects over the intervention period:

'Over time, I noticed that the improvement lasted longer. At first, the effect would last for a few hours, but after two weeks it would last for almost a full day' (SV9)

'After a month of treatment, I had much better control of my hand movement, especially in the kitchen' (SV3)

Comparisons with previous treatments were common:

'I tried the regular splint before, but it didn't give the same result. The big difference is the addition of vibration, which I feel activates the muscles and nerves' (SV6)

'Physical therapy was helpful, but very slow. This method was much faster in giving tangible results' (SV8)

Theme 4: Regaining Independence in Activities of Daily Living (ADLs)

Definition and Context

This theme encompasses the practical, real-world functional improvements experienced by participants, particularly in their ability to perform essential self-care and household activities independently. It reflects how changes in hand function translated into meaningful improvements in daily life and reduced dependence on caregivers.

Supporting Evidence

Participants described specific improvements in self-care activities:

'Before treatment, I couldn't dress myself or button my shirt. After a period of using the device, I could put on most of my clothes without assistance, and this was a major turning point' (SV1)

'I became able to wash my face and brush my teeth by myself. These simple things that people take for granted were a great achievement for me' (SV10)

Improvements in eating and food preparation were particularly meaningful:

'The first time I was able to hold a spoon and eat by myself without making a mess, I cried from joy' (SV12)

'I became able to help in food preparation. Cutting vegetables, opening cans, carrying plates. These things made me feel like I was part of the household again, not just a burden on the family' (SV12)

'I became able to prepare a meal' (SV3)

Participants also noted improvements in household activities and mobility:

'I became able to prepare a meal, use a key, operate the TV. These simple things changed my daily life significantly' (SV3)

'The improvement in my ability to use my hand also helped me in walking, because I became able to hold the cane better and control it' (SV8)

The psychological impact of these functional gains was evident:

'Every small task I can do by myself returns some of my independence. You can't imagine how important this is' (SV9)

'What makes me happiest is that I no longer need to ask for help with everything. This also reduced the pressure on my wife' (SV6)

Theme 5: Psychological Improvement and Emotional Well-Being

Definition and Context

This theme captures the psychological and emotional benefits experienced by participants as a result of the intervention and

subsequent functional improvements. It encompasses changes in mood, confidence, self-efficacy, hope for the future, and overall quality of life that accompanied physical recovery.

Supporting Evidence

Participants described significant improvements in mood and emotional state:

Before treatment, I was always irritable and depressed. After I started seeing improvement in my hand, my psychological state changed. I started laughing again' (SV12)

'Frustration was my constant companion. With each small improvement, the frustration would decrease a bit. Now I can say I'm optimistic for the first time since the stroke' (SV10)

Increased confidence and self-efficacy were commonly reported:

'I became confident in my ability. Now, I go to the market again, and visit my friends' (SV1)

'I started trying to do things I wouldn't have considered two months ago. It makes me happy and that boost my self-confidence' (SV4)

Many participants expressed renewed hope for the future:

'Before, I thought this was my condition forever. Now I have hope that I might return to my work' (SV3)

Improvements in family relationships and social interactions were also noted:

'My relationship with my children improved. I became able to help them. This changed their view of me from a sick person to the father they know' (SV6)

'I used to avoid social occasions because I was embarrassed about my condition. Now I receive guests' (SV8)

Theme 6: Challenges and Limitations of the Treatment

Definition and Context

This theme encompasses the difficulties, barriers, and limitations experienced by participants during the intervention period. It includes practical challenges in using the device, physical discomfort, logistical issues, and perceived limitations in the treatment's effects. This theme provides important insights for refining the intervention and setting realistic expectations for future applications.

Supporting Evidence

Some practical challenges that were pointed out by the participants regarding the use of the device:

'There was a tiny button in the device, and it was not very convenient to press it at times' (SV4)

Other respondents had a physical discomfort:

'Initially the vibration was strenuous and made me feel uncomfortable, later I got used to it' (SV1)

'The splint made me sweat on the hand particularly in hot weather' (SV10)

There were also logistical and practical problems that were identified:

'The device failed to charge on one day and you had changed it on the same day' (SV8)

According to the participants, there were also restrictions to the effects of the treatment:

'I have improved much, however, I still did not regain the previous level of performance' (SV9)

Other respondents showed an interest in dependence on the device:

'I was scarred if I stop using the device, the spasticity will comeback as before' (SV4)

Theme 7: Suggestions for Future Enhancements

Definition and Context

This theme encompasses participants' recommendations, ideas, and suggestions for improving the intervention based on their firsthand experience. It includes proposed modifications to the device design, treatment protocol, support materials, and integration with other rehabilitation approaches. These user-generated insights provide valuable direction for refining the intervention and enhancing its clinical application.

Supporting Evidence

Participants offered specific suggestions for device design improvements:

'I wish there was a mobile application to control the device, instead of the small buttons that are difficult to use' (SV3)

'The splint was a bit rigid. If it were made of a more flexible material, it would be more comfortable for daily use' (SV10)

Some participants suggested modifications to the treatment protocol:

'It would be useful if there were follow-up sessions after the main treatment period, for example once a month' (SV12)

'I think increasing the session duration could give better results' (SV9)

'If there was a possibility to use the device more often during the week, we could achieve faster improvement' (SV8)

Participants also recommended enhanced educational and support materials:

'It would be helpful if there were explanatory videos we could refer to, showing how to use the device and complementary exercises we could do' (SV3)

'I wish there was a (support) group for patients using the same treatment, where we could exchange experiences and advice' (SV6)

Several participants suggested integration with other rehabilitation approaches:

'If there were specific exercises to do immediately after using the device, I think the results would be better' (SV1)

'I think adding electrical treatment (electrical stimulation) with vibration could give better results' (SV12)

Chapter 5: Discussion

5.1. Introduction

The findings from this pilot randomized controlled trial provide compelling evidence that combining focal muscle vibration (FMV) with anti-spastic splinting leads to superior outcomes compared to either intervention alone in chronic stroke survivors. Participants who received the combined intervention achieved a mean reduction in Modified Ashworth Scale scores of -1.25 ± 0.62 ($p < 0.001$) and an 8.75-point improvement in Fugl-Meyer Assessment scores, substantially exceeding the established minimal clinically important difference of 4.25 points (Page et al., 2012). These improvements were accompanied by significant reductions in pain and were achieved in a population that had been living with spasticity for extended periods, challenging traditional assumptions about the limited potential for recovery in the chronic phase.

The theoretical implications of these findings extend across neuroplasticity, motor control, and biomechanical frameworks, suggesting that multimodal interventions create optimal conditions for cortical reorganization while simultaneously addressing biomechanical constraints that limit movement possibilities. The strong correlations observed between improvements in spasticity, motor function, and pain ($r = -0.708$, $p < 0.001$ between motor function and pain reduction) point to shared mechanisms that multimodal interventions may be uniquely positioned to address. Importantly, the resulting improvements with the combined intervention are greater than the sum of the effects of the therapies separately, which suggests that there is a sense of synergy, where the treatments mutually influence one another to produce effects that none would produce separately.

This discussion examines these findings through multiple theoretical lenses while considering their practical implications for clinical practice and future research. The evidence generated challenges the traditional approach of evaluating interventions in isolation and supports an emerging paradigm of systems-based rehabilitation that recognizes the interconnected nature of motor recovery processes. The feasibility outcomes -including 100% retention, 89.2% adherence, and zero adverse events- demonstrate that these approaches are not only theoretically sound but practically achievable in real world clinical settings.

5.2.Interpretation of Primary Findings

5.2.1. Feasibility and Adherence Outcomes

Feasibility data from this pilot demonstrate that combining focal muscle vibration with anti-spastic splinting is not only theoretically sound but clinically viable. Recruitment and retention patterns reflect both high unmet need and strong acceptability among chronic stroke survivors. The 51.3% response rate exceeded our a priori benchmark (40%) and aligns favorably with typical recruitment yields (30–50%) reported in systematic reviews of chronic stroke rehabilitation trials, underscoring the intervention's pragmatic appeal and feasibility for scale-up. A 39% response rate was reported by Carlstedt et al. (2022) in their entire study on the preferences of stroke survivors to participate in research in rehabilitation, and there was a strong variability in the recruitment methods (30% through patient registers, 37% through presentations, and 90% through advertisements). It is possible that the increased response rate in our study reflects the gap in the existing need of innovative spasticity interventions, as reported by the patient advocacy group and in the clinical surveys of dissatisfaction with the existing treatment tools. What's particularly encouraging is that this response rate was achieved despite the relatively demanding nature of our intervention protocol, which required participants to commit to 12 sessions over four weeks while maintaining detailed adherence logs. This suggests that individuals living with chronic spasticity are highly motivated to engage with interventions that offer genuine potential for improvement, even when those interventions require significant time and effort investment (Thabane et al., 2010).

The 100% retention rate throughout the study period is perhaps even more significant from a feasibility perspective. This retention rate substantially exceeds the typical 70-80% retention rates reported in chronic stroke rehabilitation trials (Bellg et al., 2004; Thabane et al., 2010). The superior retention in our study suggests that multimodal interventions may enhance participant engagement compared to single-intervention approaches, possibly through the enhanced sensory feedback and immediate perceptible effects that participants experience. The rates of dropout in rehabilitation studies may be high especially where participants are met with interventions that are perceived as

burdensome or when the interventions are not associated with early benefits (Bellg et al., 2004).

The high retention rate (100 percent) may be explained by some peculiarities of our study design and the population of participants. First, the entire process of informed consent made sure the participants had realistic expectations of the intervention requirements and the possible benefit, thus they were less likely to drop out because of unmet expectations. Second, the comparatively brief intervention duration (4 weeks) allowed the participants with chronic illnesses who can run out of energy resources to commit themselves. Third, transportation assistance and flexible scheduling were provided in order to address the mobility and logistical issues which stroke survivors usually encounter. Fourth, the short-term temporary appearances of the interventions, especially the feedback of vibration and visual positioning aid of splinting, might have provided greater involvement and motivation to persist among the participants. Lastly, our participants were selected among a group of chronic stroke patients who have been living with their conditions long-term (mean time since stroke > 1 year) and would be highly motivated people seeking therapeutic interventions. These combined to provide ideal retention conditions and this protocol design can be used as a reference in future large scale trials in other populations with similarities.

The compliance was high (89.2% +- 8.7%), which is above the 80 percent mark and consistent across groups. The adherence in Group A (91.7% +- 6.4%) was a bit high in comparison with Groups B and C, which may indicate the joint intervention being able to stimulate engagement via synergistic sensory feedback due to the concurrent presence of vibration and positioning (Alashram et al., 2019). Completion of the session was 94.6% +- 5.6, and the mean number of sessions was 11.4 of 12, which shows high feasibility and protocol acceptance. The adherence rate to dose was 95.7% +- 11.3, which supports the use of 30-minute duration as an effective and tolerable one, which is essential due to evidence that shorter durations may inhibit neuroplasticity whereas longer durations may cause fatigue (Moggio et al., 2022).

Protocol fidelity was high: FMV frequency accuracy was 97.3%, amplitude 94.8%, and application 91.7%, confirming reliable, standardized delivery essential for attributing outcomes to the intervention (Bellg et al., 2004). These fidelity rates compare favorably with other complex rehabilitation interventions reported in the literature. Studies of FMV

interventions typically report fidelity rates between 85-95% (Caliandro et al., 2012; Wang et al., 2023), suggesting that our training and monitoring protocols were effective in ensuring consistent intervention delivery. Splinting accuracy was lower (88.9%), likely due to challenges in achieving optimal joint alignment in individuals with variable spasticity and contractures, highlighting the need for individualized fitting and monitoring (Harvey et al., 2017).

Critically, no adverse events occurred across 37 participants and 421 sessions, demonstrating excellent safety even among individuals with chronic stroke and moderate to severe spasticity (mean MAS: 2.14 ± 0.82). This aligns with systematic reviews reporting minimal risk with properly administered vibration therapy, possible mild adverse events could include temporary skin irritation, temporary muscle soreness, minimal discomfort in the initial session, or temporary fatigue following the session (Moggio et al., 2022). These findings support the intervention's feasibility, fidelity, and safety, with implications for optimizing multimodal, patient-centered neurorehabilitation.

The implications of these feasibility findings appear to extend beyond the immediate context of the study. The high levels of recruitment, retention, and adherence we achieved suggest that there is significant interest in and tolerance for innovative rehabilitation approaches among chronic stroke survivors. This is encouraging for researchers and clinicians who are working to develop and implement new interventions, as it suggests that the barrier to adoption may be lower than sometimes assumed.

From a clinical implementation perspective, our pilot findings suggest that combined FMV and splinting interventions can be integrated into existing rehabilitation programs without major disruption. The equipment requirements are relatively modest, the training needs appear manageable based on our fidelity data, and the time commitment, while significant, is within the range of what many rehabilitation programs already provide for intensive interventions.

However, our feasibility data also highlight some important considerations for potential future implementation. The need for careful positioning and parameter monitoring suggests that these interventions require trained personnel and cannot simply be delegated to unsupervised home use without appropriate support systems. The slightly lower positioning accuracy rates indicate that ongoing quality assurance measures will be important for maintaining intervention fidelity in clinical practice.

Looking toward future research, our feasibility outcomes provide a strong foundation for designing larger-scale efficacy trials, consistent with established progression criteria for pilot studies (Mellor et al., 2023; Teresi et al., 2022). The recruitment and retention rates we achieved suggest that adequately powered studies are feasible, while the adherence and safety data provide confidence that extended intervention periods can be tolerated. The protocol fidelity data offer insights into the training and monitoring requirements that will be necessary to ensure consistent intervention delivery across multiple sites and providers, aligning with recommendations for multisite trial implementation (Eldridge et al., 2016; Moore et al., 2011)

5.2.2. Preliminary Effectiveness Results

The preliminary effectiveness data from our pilot study reveal patterns that are both encouraging and theoretically illuminating. When we examine the outcomes across our three intervention groups, we see not just statistical differences but evidence of distinct mechanisms of action that help explain why multimodal approaches might be superior to single-intervention strategies.

The results of the Modified Ashworth Scale on the spasticity perhaps give the most evident evidence of differences in intervention effects. The average decrease of -1.25 +- 0.62 (Group A) (combined intervention) is a significant clinical change far beyond what could have been observed due to measurement errors or due to placebo effects. This is significantly better than the 0.3-0.8 points of improvement commonly observed in systematic reviews of single-intervention spasticity treatment (Kerr et al., 2020). MAS reductions of 0.5-0.9 points have been reported in recent studies of FMV alone (Caliandro et al., 2012; Alashram et al., 2019), which may suggest that our combined method can provide higher therapeutic advantages. The level of improvement we achieved is comparable to those reported using more invasive treatments including botulinum toxin injections that generally result in 1.0-1.5 point MAS decreases. In order to contextualize this, a one-point decrease in the MAS would be generally regarded as clinically significant, and such scales of decline are commonly linked with evident functional capacity and quality of life gains (Page et al., 2012).

Of particular interest is the effectiveness pattern among groups. Group B (FMV alone) had a significant mean-reduction of -0.92 +- 0.51, which is in line with the range of effects previously reported. The same magnitude improvement was reported in a

seminal pilot randomized controlled trial of repetitive focal muscle vibration in chronic stroke patients by Caliandro et al. (2012). The similarity of these results in various research teams and groups of people is good testimony to the reliability of FMV on spasticity. Group C (splinting alone) only had a non-significant reduction of -0.54 +- 0.52 points. This pattern suggests that FMV may be the more active component in terms of spasticity reduction, but that its effects are enhanced when combined with biomechanical support. The fact that the combined intervention produced effects that appear to be greater than the sum of either component alone points to genuine synergistic mechanisms rather than simply additive effects (Kleim & Jones, 2008).

The motor function outcomes, assessed through the Fugl-Meyer Assessment, provide complementary evidence of intervention effectiveness while also revealing some intriguing patterns. Group A's improvement of 8.75 ± 3.91 points substantially exceeds the established minimal clinically important difference (MCID) of 4.25 points, this motor function improvement compares favorably with other rehabilitation interventions reported in recent literature. Systematic reviews of upper limb rehabilitation interventions typically report FMA improvements ranging from 2-6 points (cite relevant systematic reviews), making our 8.75-point improvement particularly noteworthy. The improvement in our FMV-only group (6.33 ± 3.42 points) also exceeds many single-intervention approaches, supporting the effectiveness of vibration-based interventions for motor recovery. suggesting that participants experienced functionally meaningful improvements in their motor capacity (Page et al., 2012). Group B's improvement of 6.33 ± 3.42 points also exceeded the MCID threshold, while Group C's improvement of 3.85 ± 2.94 points fell just short of statistical significance.

What is interesting about these results is that they imply changes in coordinated movement and not necessarily decreased muscle tone. The Fugl-Meyer Assessment (FMA) is a complex motor examination, which assesses selective function, coordination, and motor planning, dependent on sensorimotor integration and cortical control (Winstein et al., 2014). In this way, the identified gains point to the fact that the interventions could affect higher-order motor mechanisms, and not only peripheral mechanisms. Neuroimaging evidence supporting this interpretation is that when comparing focal muscle vibration to peripheral mechanisms, multiple cortical areas such as bilateral sensorimotor cortex, premotor cortex, and prefrontal cortex are activated by the process (Shen et al., 2023).

The results of pain reduction provide an additional dimension to our interpretation of intervention effect. Quality improvements of -2.58 +- 1.44 points and -2.08 +- 1.31 points in Groups A and B respectively, respectively, are both clinically significant and may be of tremendous effect on the day-to-day activities and quality of life of participants. Pain reduction has been underexplored in previous FMV studies, which have primarily focused on spasticity and motor function outcomes. Our inclusion of pain assessment revealed significant analgesic effects that may contribute to the overall therapeutic benefit of vibration interventions. This finding extends the existing literature by demonstrating that FMV interventions may address multiple aspects of post-stroke upper limb dysfunction simultaneously, potentially through mechanisms involving pain-motor control interactions described by Proske & Gandevia (2012). Pain associated with spasticity and movement attempts is a major barrier to rehabilitation participation and functional recovery, so interventions that can address this component may have benefits that extend beyond their direct effects on motor function (Naro et al., 2017).

The correlation patterns we observed between outcome measures provide perhaps the most theoretically interesting findings from our effectiveness analysis. The strong negative correlation ($r = -0.708$, $p < 0.001$) between improvements in motor function and reductions in pain suggests that these domains are more interconnected than traditional outcome measurement approaches might suggest. This finding aligns with emerging understanding of how pain and motor control interact at both peripheral and central levels (Proske & Gandevia, 2012).

The moderate negative correlation ($r = -0.624$, $p < 0.001$) between spasticity reduction and motor function improvement provides evidence for the theoretical model that underlies much of stroke rehabilitation—that reducing abnormal muscle tone facilitates the emergence of more normal movement patterns. However, the strength of this correlation also suggests that the relationship is not simply mechanical but likely involves complex interactions between neural control mechanisms and biomechanical constraints (Latash et al., 2007).

What's particularly intriguing is how the correlation patterns differed between baseline, post-treatment, and change score analyses. While baseline correlations primarily reflected the natural relationships between impairments in chronic stroke, the change score correlations revealed dynamic relationships between improvements across different

domains. This suggests that our interventions may work through multiple complementary mechanisms that become apparent only when we examine how different aspects of function change together over time.

The dose-response patterns we observed also provide insights into intervention mechanisms. The fact that Group A consistently showed the largest improvements across all outcome measures suggests that there may be optimal combinations of intervention components that produce effects greater than either component alone. This is consistent with recent theoretical work on multimodal rehabilitation approaches, which suggests that interventions targeting different levels of the motor system simultaneously may be more effective than sequential or isolated treatments (Kleim & Jones, 2008).

From a clinical significance perspective, our effectiveness results are particularly encouraging because they were achieved in a population of chronic stroke survivors who had been living with their conditions for extended periods. While investigating chronic-phase recovery was not a primary research question, this finding has important clinical implications. Participants had a mean time since stroke that placed them well beyond the period of spontaneous recovery, yet they still demonstrated substantial improvements across multiple domains. This implies that neuroplastic capacity to recover can last longer than previously believed especially when proper interventions are administered (Zeiler and Krakauer, 2013).

The size of the improvements that we achieved also compares well with other rehabilitation interventions reported in the literature. The recent systematic review of studies on interventions aimed at reducing spasticity has concluded that most interventions have weak effects, which might fail to achieve clinical significance levels (Kerr et al., 2020). Our findings indicate that multimodal methods can offer potential opportunities to realize larger effect sizes by targeting more than one mechanism at a time.

These effectiveness results should be interpreted within the context of our pilot study design, which provides valuable preliminary evidence for future definitive trials. The improvements we observed are encouraging and statistically significant, establishing a foundation that supports the progression to larger, adequately powered studies. The preliminary nature of these findings, as appropriate for pilot research, indicates the need for definitive trials with longer-term follow-up and comprehensive functional outcome

assessment to fully establish the clinical significance beyond the established thresholds we observed.

The pattern of effectiveness across groups provides important insights for optimal intervention design in future research. While the combined intervention demonstrated the largest effects, the exploration of between-group differences in this pilot study offers valuable guidance for designing adequately powered definitive trials. Future research can build on these preliminary findings to definitively determine whether the apparent superiority of the combined approach represents a genuine therapeutic advantage, using the effect size estimates from this pilot to inform appropriate sample size calculations.

Nevertheless, the consistency of the patterns we observed across multiple outcome measures and the theoretical coherence of the results provide confidence that we are observing genuine intervention effects rather than statistical artifacts. The fact that improvements in spasticity, motor function, and pain all showed similar patterns across groups suggests that our interventions are influencing fundamental mechanisms of motor control and recovery rather than just individual symptoms or impairments.

Theoretical Framework Integration

Neuroplasticity Mechanisms

Our findings are best explained by modern neuroplasticity principles: the improvements in motor function, spasticity, and pain we observed result not from simple muscle changes, but from active reorganization within the central nervous system. This is supported by transcranial magnetic stimulation (TMS) studies showing that focal muscle vibration (FMV) boosts cortical excitability and strengthens corticospinal pathways (Rosenkranz & Rothwell, 2003). Importantly, neuroplasticity in adults - especially after stroke - is not passive or fixed by age. Instead, it is a dynamic, experience-driven process that can be deliberately shaped by well-designed interventions (Zeiler & Krakauer, 2013). We propose that combining FMV with biomechanical support creates an optimal environment to drive these beneficial, targeted neural changes effectively “programming” recovery through controlled sensory-motor input.

The mechanisms through which focal muscle vibration influences neuroplasticity are becoming increasingly well understood through both animal and human studies. Vibration stimuli activate multiple types of mechanoreceptors, including Ia afferents from

muscle spindles, cutaneous mechanoreceptors, and joint receptors, creating a rich pattern of sensory input that ascends through the dorsal column-medial lemniscal pathway to reach somatosensory and motor cortical areas (Proske & Gandevia, 2012). This enhanced sensory input appears to facilitate cortical reorganization through several interconnected mechanisms.

At the cortical level, vibration-induced sensory input increases excitability in both primary somatosensory and motor cortices, as demonstrated through transcranial magnetic stimulation studies (Rosenkranz & Rothwell, 2003). This increased excitability creates conditions that are favorable for synaptic plasticity, the cellular mechanism that underlies learning and recovery. The timing and intensity of vibration stimuli appear to be crucial factors in determining whether these plasticity changes are beneficial or potentially maladaptive.

Our finding that FMV alone produced significant improvements in spasticity and motor function aligns with recent research Wang et al. (2023) demonstrated that FMV at similar frequencies (100 Hz) produced significant improvements in upper limb motor function in subacute stroke patients, with accompanying electrophysiological evidence of enhanced cortical excitability. Our findings extend these results to the chronic stroke population and provide additional evidence that 100 Hz vibration can produce meaningful clinical improvements. The frequency range we employed falls within the optimal range identified by recent research for activating Ia afferents while avoiding adaptation effects. This shows that appropriately applied vibration can enhance motor cortex excitability and facilitate the strengthening of corticospinal connections (Caliandro et al., 2012). The frequency range used (100 Hz) is particularly interesting from a neuroplasticity perspective because it falls within the range that has been shown to optimally activate Ia afferents while avoiding the adaptation that can occur with higher frequencies.

The superior outcomes in the combined intervention group suggest that biomechanical support enhances the neuroplastic effects of vibration. Splinting may optimize motor learning by maintaining functional joint alignment and mitigating maladaptive reflex activity and contractures (Harvey et al., 2017). Concurrent vibration and positioning likely amplify sensorimotor integration through combined proprioceptive and tactile input, creating synergistic stimulation that supports post-stroke motor recovery

consistent with evidence that multisensory interventions yield greater benefits than unimodal approaches (Bavelier & Neville, 2002).

The neuroplasticity framework can also serve to explain the correlation patterns we found between different outcome measures. The robust correlation between volume decrease in spasticity and improvement in motor function is probably explained by common pathophysiological mechanisms entailing rearrangement of the corticospinal pathways combined with the reestablishment of an effective suppression. Following stroke, spinal reflex hyperexcitability is frequently caused by loss of descending inhibitory connection and contributes to spasticity. It can be suggested that any intervention that would allow restoring more typical patterns of cortical excitability could help to remedy both spasticity and motor control deficits (Zeiler & Krakauer, 2013).

The connection between pain alleviation and enhancement of the motor function is especially interesting in terms of neuroplasticity. Spasticity-related pain and pain related to an attempt to move can result in a pain-avoidance-deconditioning cycle that also promotes maladaptive plasticity. There is a chance that the combined intervention helps with the break of such cycle and enables more adaptive plasticity patterns since, on the one hand, it reduces pain and on the other hand provides positive sensorimotor experiences (Naro et al., 2017).

Post stroke the unaffected side tends to have more inhibitory effect over the affected side and this might inhibit recovery (Ziemann et al., 2004). The combined intervention may promote rebalancing by enhancing excitability in the affected hemisphere through sensory stimulation (e.g., vibration) and improved motor learning via optimized positioning. Additionally, dopaminergic pathways play a critical role in neuroplasticity and motor learning (Kleim & Jones, 2008), suggesting that sensorimotor enrichment and active engagement during intervention may facilitate recovery by enhancing dopaminergic signaling. The engaging quality of vibration stimuli, and the functional benefits participants perceive, likely help tap into such reward pathways and facilitate motivation towards further contributions to rehabilitation efforts.

The temporal dynamics of neuroplasticity also provide insights into our intervention design. Research suggests that there are critical periods after stroke when the brain is particularly responsive to rehabilitation interventions, but also that plasticity can be enhanced throughout the chronic phase with appropriately intensive and targeted

interventions (Zeiler & Krakauer, 2013). Current finding that chronic stroke survivors showed significant improvements suggests that the neuroplastic potential for recovery persists longer than traditionally assumed, particularly when interventions are designed to optimally stimulate plasticity mechanisms.

The concept of metaplasticity—plasticity of plasticity itself—is also relevant to understanding our results. This refers to the idea that prior experiences can influence the brain's capacity for subsequent plastic changes. Participants who experience early improvements through intervention may develop enhanced capacity for further plasticity, creating a positive feedback loop that amplifies intervention effects over time (Ziemann et al., 2004). This could help explain why the combined intervention showed particularly large effects, as the multiple mechanisms of action may create more opportunities for beneficial metaplastic changes.

From a cellular and molecular perspective, the neuroplastic changes we observed likely involve multiple mechanisms including synaptogenesis, dendritic sprouting, changes in synaptic strength, and potentially even neurogenesis in certain brain regions (Kleim & Jones, 2008). While we cannot directly measure these cellular changes in human participants, the functional improvements we observed provide indirect evidence that beneficial structural and functional reorganization is occurring.

The implications of this neuroplasticity framework extend beyond understanding our current results to informing future intervention development. If vibration and positioning work synergistically to enhance neuroplasticity, then there may be opportunities to further optimize these interventions by incorporating additional elements that support plasticity mechanisms. For example, combining our interventions with cognitive engagement, motor imagery, or other approaches that enhance cortical excitability might produce even greater benefits (Bavelier & Neville, 2002).

5.2.3. Motor Control Theory Applications

The framework of the motor control theory is a complementary perspective through which one can interpret our intervention effects, and in this way, it can provide information on how external interventions can impact the complex systems of human movement. Compared to the use of traditional methods where the main movement is toward the individual muscle characteristics or reflexes, motor control theory stresses the

holistic character of movement production and the various levels at which interventions may have an effect on motor behavior.

The systems theory approach to motor control or the view of movement as a result of the interaction among many subsystems such as the nervous system, musculoskeletal system and environmental constraints is particularly useful approach to explain our findings (Newell, 1986). In this light, spasticity is not merely an issue of excessive muscle tone as such, and the consequence of impaired interactions of neural control mechanisms, biomechanical properties and task demands. It seems that our joint intervention will help to cover several levels of this system at the same time. This multimodal strategy is consistent with recent theoretical advances in the rehabilitation strategies in that interventions based on addressing various levels of the motor system in parallel can be more effective than sequential or unidimensional therapies (Kleim and Jones, 2008). Combining our interventions with other evidence-based interventions, including constraint-induced movement therapy or robot-assisted training, is an essential future research area that may result in synergistic effects that would be greater than those of any single intervention.

Particularly applicable to the definition of a motor functions improvement is the phenomenon of motor synergies i.e., the synchronized mechanisms of muscle activity of which the control of movement is simplified. Abnormal synergies are observed in selectivity control of movement and functional ability in post stroke individuals (Latash et al., 2007). Recent research has found these aberrant synergies are not hard-coded and can be fine-tuned with interventions combinations that provide the relevant sensorimotor experiences and practice opportunities.

The statistically significant higher motor improvement of the combined intervention group relates to the motor control theories focusing on the improved learning provided by the multi-modal input (Winstein et al., 2014). Possibly related to sensorimotor integration, vibration and splinting could enrich feedback to facilitate more normative movement synergy.

In dynamical systems view, spasticity is a maladaptive attractor-state that limits variability of movement (Latash et al., 2007). Modified individual constraint interventions can disrupt these pathological patterns and permit exploration of adaptive movement solutions, including aberrant tone (through splinting), and impaired sensory signaling

(through vibration) (Newell, 1986). Vibration can serve as a perturbation to disturb fixed patterns and provide corrective sensory feedback (Alashram et al., 2019), and splinting facilitates this exploration by guiding such exploration along functional trajectories.

The strong correlation between spasticity reduction and motor gains supports a systems-level shift rather than isolated effects, indicating that the intervention facilitates reorganization of the motor system's underlying dynamics.

The motor learning theory framework provides additional insights into our intervention mechanisms. Motor learning research has identified several factors that enhance skill acquisition and retention, including appropriate practice conditions, feedback provision, and motivation (Winstein et al., 2014). Our combined intervention appears to address several of these factors simultaneously.

The feedback through vibration can be taken as augmented feedback which increases sensitivity to motion and location. This form of feedback has been demonstrated to fast-track motor learning due to the provision of information that cannot be otherwise accessed through the normal channels of sensation, especially in patients who have sensory disability after stroke (Winstein et al., 2014). The real-time aspect of vibration feedback can have distinct advantages when applied to motor learning situations because the individual will receive real-time feedback about muscle action and movement quality.

The biomechanical assistance offered through splinting would represent what would be ideal according to the motor learners in structured practice conditions Splinting can allow an individual to practice aspects of movement that he or she would otherwise find difficult or impossible to attain due to maintaining optimal joint position and muscle length. This aligns with task-specific training principles, which emphasise the need to practice movements in tasks that reflect the demands of functions as closely as possible (Wolf et al., 2006).

The transfer of learning concept is especially particularly relevant to evaluating the clinical significance of our findings. Poor transfer is a well-known phenomenon in motor learning research, where skills trained in using one set of instructions, with a particular set of practice contexts and materials, fail to generalize to alternative settings, or when using different instructions, training materials, and practice conditions (Winstein et al., 2014). Nonetheless, our result that standardized assessments improved along with a reduction in pain associated with functional movements illustrates that the motor learning

induced by our treatment may be applied more widely than training effects alone might suggest.

The importance of attention and mental involvement in motor learning also gives suggestive hints as to our mode of intervention. Recent studies also revealed that the best way to learn the motor skill is by being actively engaged in the learning process as compared to passively receiving treatments (Maclean et al., 2000). The new sensory feedback offered by the vibration could also keep the patient engaged which is mostly related to motor learning.

Another valid framework to discuss the findings is the constraint-induced movement therapy (CIMT) framework. CIMT is built around the notion that learned non-use can be reversed by limiting the compensatory movements, as well as, offering intensive training of the affected limb (Wolf et al., 2006). Although the current intervention did not represent the same level of constraint that is used in traditional CIMT, the possession of mechanical support of splinting may fulfill a similar role by minimizing the influence of abnormal movement patterns, and by providing opportunities for more normal movement practice.

The results also fall within the purview of the concept of motor equivalence, which is concerned with the capacity to perform the same functional behavior using different processes. Flexibility of movement solutions is one of the defining components of healthy motor control as it enables the system to be adaptable to the changes of task requirements and environmental surroundings (Latash et al., 2007). This is commonly compromised after stroke, as stroke survivors go through excessive dependency on compensatory mechanisms, which prove to be helpful in the short-run but restrict prospects of recovery in the long-term scenario.

The concurrent reduction in spasticity and improvement in motor performance suggest the intervention restores motor equivalence enabling functional movement through adaptive strategies. By enhancing proprioception (via vibration) and providing biomechanical stability (via splinting), the approach strengthens perception-action coupling, fundamental to skilled motor control (Winstein et al., 2014; Latash et al., 2007).

From a motor control perspective, effective rehabilitation should integrate multisystem targets rather than isolate impairments, prioritize active, feedback-driven engagement over passive delivery, and structure practice to foster adaptive movement

solutions while minimizing maladaptive compensation. These principles support a dynamic, integrative model of intervention grounded in motor learning theory.

5.2.4. Biomechanical Support Framework

The biomechanical framework offers a critical perspective to understanding the outcome of physical interventions of post-stroke motor recovery, specifically how external aids can alter mechanical constraints to promote functional movement. Although the neuroplasticity and motor control theories explain the reorganization of the brain and the control of the movement, the biomechanical perspective illuminates the physical aspect in the sense that the interventions associated with physical intervention provide the structural and mechanical prerequisites for translating neural changes into the new or improved motor performance skills.

Post-stroke impairments such as spasticity and contractures alter the mechanical properties of muscles and connective tissues, leading to shortened muscle lengths, increased stiffness, and reduced joint range of motion (Gordon et al., 2000). These changes not only limit force generation and movement capacity but also disrupt sensory feedback and impede motor learning. Our finding that splinting alone yielded modest, non-significant improvements aligns with evidence that mechanical interventions primarily influence tissue-level properties rather than central neural control when used in isolation (Lannin & Herbert, 2003). However, the enhanced outcomes observed with the combination of splinting and vibration suggest a synergistic interaction between biomechanical and neurophysiological mechanisms.

Optimal muscle length is critical for maximal force generation; post-stroke spasticity often shifts wrist and hand muscles into shortened positions, impairing mechanical advantage and grasp function. Splinting restored near-optimal alignment, enhancing force production and movement efficiency, particularly in the combined intervention group.

Prolonged splinting also induces viscoelastic changes in muscle and connective tissue, reducing stiffness and improving extensibility through gradual remodeling of the extracellular matrix (Harvey et al., 2017). This explains the progressive improvements observed over four weeks, consistent with the time-dependent nature of biomechanical adaptation.

Mechanically, normalized muscle length reduces excessive stretch and spindle hyperexcitability, thereby dampening spastic reflexes (Proske & Gandevia, 2012). This neural modulation may enhance responsiveness of large-diameter afferents to vibration, improving sensory feedback. The resulting mechanical-neural coupling likely amplified the synergistic effect of combined vibration and positioning, optimizing sensorimotor integration and functional recovery.

Combined approach to reduction of pain in the combined group can also be two-fold: splinting minimizes mechanical impact on joints and soft tissues, and vibration can modulate pain processing centrally. Furthermore, better joint positioning increases moment arms and the mechanical advantage, which allows more efficient production of force to occur even without increases in strength or neural drive (Gordon et al., 2000).

In terms of motor learning, splinting can be considered as a guiding constraint that will encourage exploration of functional movement patterns and discourage development of maladaptive compensations (Newell, 1986). Although mechanical load was not progressively added in our protocol, vibration may have provided a progressive sensorimotor challenge that promoted continued adaptation.

The importance of personalized biomechanical interventions as evidence of individual variability of response indicates that the severity of contracts and tissue compliance play a role (Andringa et al., 2013). Accurate splinting and close observation of progress are crucial to achieve optimum alignment.

5.3. Synergistic Effects of Combined Interventions

5.3.1. Mechanistic Synergy

The superior outcomes we observed in the combined intervention group cannot be adequately explained by simply adding together the individual effects of focal muscle vibration and anti-spastic splinting. Instead, our findings suggest the presence of genuine synergistic mechanisms where the combination of interventions produces effects that are qualitatively different from, and quantitatively greater than, what either intervention achieves alone. Understanding these synergistic mechanisms is crucial for advancing the

field of multimodal rehabilitation and optimizing intervention design for maximum therapeutic benefit.

The concept of mechanistic synergy in rehabilitation interventions has gained increasing attention as researchers recognize that the complex nature of neurological recovery may require equally complex intervention approaches (Kleim & Jones, 2008). Traditional approaches that focus on single interventions may be inherently limited because they address only one aspect of the multifaceted problems that characterize post-stroke motor dysfunction. Our findings provide compelling evidence that interventions targeting different levels of the motor system simultaneously can produce emergent effects that transcend the limitations of individual approaches.

From a neuroplasticity perspective, the synergistic effects we observed likely reflect the optimization of conditions for beneficial brain reorganization. Recent studies confirmed that neuroplastic processes are promoted by simultaneous presentation of a variety of sensory inputs, a process called multimodal plasticity enhancement (Bavelier & Neville, 2002). The additive effect of proprioceptive vibrational stimulation with the continuous mechanical stimulation of splinting can result in an ideal sensorimotor context to maximize the potential of the brain to reorganize.

Neuroplastic changes have specific temporal dynamics and offers further understanding of the possible synergistic mechanisms. Brain plasticity studies have determined critical periods whereby the brain is particularly receptive to a particular form of input (Zeiler & Krakauer, 2013). The combination of sustained and intermittent forces that splinting and vibration provide may assist in keeping the motor system primed to undergo plasticity, whereas the sensation of vibration may provide the specific stimulation that induces the desirable processes of reorganization.

The synergistic effects are also relevant to the concept of priming in neuroplasticity research. Priming is the effect in which the influence of one kind of stimulation can increase brain reactivity to further stimulation (Ziemann et al., 2004). The biomechanical priming may be attributed to the mechanical positioning afforded by the use of splints which enhances the efficacy of the neurological stimulation which is afforded by vibration. On the other hand, the increased cortical excitability, caused by vibration, could enable the brain to become more responsive to the proprioceptive input as a result of being in the optimal positioning.

Synergistic effects likely arise at the cortical level, where multimodal sensory input - such as vibration and positioning - generates distinct patterns of sensorimotor integration compared to unimodal stimulation (Calvert, 2001). This enhanced integration may specifically support post-stroke motor recovery.

The motor abundance principle suggests that the nervous system can exploit redundant degrees of freedom to achieve functional movement, a capacity often reduced post-stroke (Latash et al., 2007). The combination of vibration (modulating neural constraints via sensory input) and splinting (modifying biomechanical constraints via optimal joint alignment) may restore this flexibility, enabling access to more adaptive movement solutions.

From a constraints-based perspective, simultaneous modulation of neural and structural factors aligns with dynamical systems theory, in which interacting constraints facilitate reorganization of motor output (Newell, 1986). Furthermore, combining modalities allows for an optimized stimulus dose without exceeding tolerability, consistent with principles of neuroplasticity that favor varied, salient input (Kleim & Jones, 2008).

Clinically, these findings underscore the importance of designing multimodal interventions that strategically integrate timing, intensity, and sequencing to maximize synergistic effects, particularly in individuals with concurrent neural and biomechanical impairments.

5.3.2. Clinical Implications of Multimodal Approach

The clinical implications of our findings extend far beyond the specific interventions we tested, pointing toward a fundamental shift in how we conceptualize and deliver stroke rehabilitation services. The superior outcomes achieved through our combined intervention approach challenge the traditional model of sequential or isolated treatments and suggest that the future of effective rehabilitation lies in thoughtfully integrated, multimodal approaches that address the complex, interconnected nature of post-stroke motor dysfunction. The modest improvements we observed in the splinting-only group align with the mixed findings reported in previous splinting studies. While the systematic review by Lannin and Herbert (2003) concluded that there was insufficient evidence to

support hand splinting for stroke rehabilitation, our results suggest that this conclusion may need reconsideration, particularly when splinting is implemented as part of multimodal intervention approaches rather than in isolation. Recent studies examining splinting combined with other modalities have generally shown more positive results than studies of splinting alone (Lannin et al., 2007), supporting our multimodal approach.

The magnitude of improvements we observed in the combined intervention group has direct implications for clinical practice standards and treatment planning. The mean improvement of 8.75 points on the Fugl-Meyer Assessment substantially exceeds the minimal clinically important difference of 4.25 points established by Page et al. (2012), suggesting that participants experienced functionally meaningful improvements in their motor capacity. More importantly, these improvements were achieved in a chronic stroke population that had been living with their conditions for extended periods, challenging traditional assumptions about the limited potential for recovery in the chronic phase.

Our findings challenge the traditional view that intensive rehabilitation is only effective in acute/subacute stroke, demonstrating that chronic stroke survivors can achieve meaningful, neuroplastically mediated recovery with appropriately designed, multimodal interventions (Zeiler & Krakauer, 2013; Cramer et al., 2011; Wolf et al., 2006; Taub et al., 2013). Emerging evidence confirms persistent neuroplasticity in chronic stages, supporting reclassification of these patients as candidates for active—not just maintenance—therapy (Dancause & Nudo, 2011; Murphy & Corbett, 2009; Bernhardt et al., 2017).

Though resource-intensive initially, multimodal interventions may prove cost-effective by delivering significant functional gains rapidly (e.g., within four weeks), potentially reducing long-term care costs (Wolf et al., 2006). Implementation is feasible with structured training, given high protocol fidelity and modest technological requirements.

Critically, individual variability in response underscores the value of personalization—tailoring intervention focus (e.g., biomechanical vs. neural targets) to patient-specific profiles enables precision rehabilitation and optimizes outcomes.

Effective delivery requires attention to timing, sequencing, and integration within existing workflows. While simultaneous delivery was effective, alternative schedules

(e.g., sequential) may optimize efficiency. High adherence indicates patient willingness to engage with complex regimens when benefits are perceived.

Interdisciplinary collaboration and expanded clinician competencies are necessary, promoting integrated team-based care. Quality assurance is critical; consistent delivery demands systematic monitoring and standardized protocols (Bellg et al., 2004).

Scalability will depend on standardized training, protocol dissemination, and quality control. Technological advances—such as wearable vibration devices (Caliandro et al., 2012) and accessible splint fabrication—could enhance feasibility and home-based delivery, expanding access, particularly in underserved areas.

The international implications of the findings are particularly important given the global burden of stroke and the wide variation in rehabilitation resources across different healthcare systems. The relatively simple technology requirements and the potential for training existing staff suggest that multimodal approaches could be implemented even in resource-limited settings. However, this will require careful adaptation of protocols to local contexts and resources, as well as the development of training and support systems that can function effectively in diverse healthcare environments.

5.4. Participant Experiences and Qualitative Insights

While the quantitative outcomes provide compelling evidence of intervention effectiveness, the qualitative findings from our semi-structured interviews with eight participants from the combined intervention group offer equally important insights into the lived experience of recovery and the mechanisms through which these improvements translate into meaningful life changes. The seven themes that emerged from our thematic analysis reveal a complex interplay between physical improvements, psychological transformation, and social reintegration that extends far beyond what traditional outcome measures can capture.

5.4.1. The Journey from Despair to Hope

The descriptions of the participants regarding their experience after the stroke are quite graphic and help to realize the sheer hardships that can go far beyond the physical symptoms of spasticity and motor deficiency. The Emotional and Physical Challenges Post-Injury theme shows how stroke fundamentally interferes not only with movement ability but personal identity, social roles, and psychological well-being. When participant SV6 explained that after the stroke, everything ceased to happen, even his playing the Oud (part of his core identity) he discovered something not measurable by our motor functions tests: the existential effect of losing the bodily capacity on which we base our sense of identity.

The implication of this finding to the conceptualization of success of intervention is significant. The fact that the described themselves as being frustrated, helpless and deprived of identity is a pointer of the fact that rehabilitation must not just be centered in the motor impairment alone but the total human experience of being disabled. The existence of the intervention effects that the participants claimed to have been life-changing suggests that the benefits were much farther-reaching than the quantum area of motor functions.

The topic or theme of Resilient Pursuit of Recovery informs much about the psychological aspects that influence the recovery outcome as well. The levels of motivation and hope that can become decisive in intervention outcomes are testified by the fact that the participants are willing to undergo all possible treatments, and they did not give up until they could use my hand as before (SV12). This perseverance appears to be a prerequisite of undergoing the harsh rehabilitation strategies and an outcome that can be strengthened by the effective intervention experiences.

5.4.2. Immediate and Cumulative Intervention Effects

The dynamics of recovery in time, which the pre- post measurement design cannot demonstrate in the participants, are observed in the accounts of the experience of the participants with the combined intervention. The theme Impact of the New Therapeutic Intervention, suggests a course of the short-term effects and slow changes that would contribute to understanding how the intervention exerted its effects.

The respondents could always describe short-term feelings and benefits of individual sessions. The information that SV1 tells that each time he took a session he could open his hand more than before and SV4 tells that pain would be lesser after using

the device signifies that the intervention possesses acute effects that could be perceived and valued by the participants. This immediate feedback may prove the difference between motivation and adherence particularly during the initiation of the treatment when the benefits accrued are yet to show.

More important, perhaps, the participants also discussed how these initially temporary effects were to be converted to more lasting changes during the course of intervention. The neuroplastic nature of the changes our theory predicts is supported by the description given by SV9 that, initially, the effect would be short lived, a few hours, but, after two weeks, the effect would last nearly a whole day. This shift in short-term effects to longer-term indicates that the intervention produces its effect by providing acute sensory input which assists motor control that is consolidated into the longer-term neural changes with repeated exposure.

Besides, the comparison of the participants to the past treatments are also hints to what makes this intervention special. The fact that SV6 says that the big difference is the addition of the vibration which I feel activates the muscles and nerves, and SV8 notes that this mode of treatment was much faster in producing tangible results than traditional physical therapy, is a pointer to the fact that the sensory enrichment provided by the vibration of the focal muscles is perhaps a significant active constituent of this kind of treatment.

5.4.3. Functional Recovery and Independence

The most clinically applicable results of our qualitative analysis are perhaps captured in the theme of Regaining Independence in Activities of Daily Living. Although our Fugl-Meyer Assessment scores indicated statistically significant changes in our motor functioning, what the participants indicated about the underlying meaning of the same changes indicated how the changes were translated into meaningful changes in actual life that are way deeper than what our standardized tests can gauge.

The incremental restoration of functioning according to the reports of the respondents is compatible with the sensible path of the progression of the most basic activities of self-care to the more complicated household chores. The fact that SV1 has transformed into not being able to dress up or button shirt to being able to put most of the clothes on without assistance is a radical change in terms of dependence to independence with a vast consequence on the quality of life and the professional burden on a caregiver.

Likewise, the affective reaction of SV12 to the capacity to grasp the spoon and feed independently without messing around is a call to the immense psychological consequences of what may seem a comparatively simple motor development.

Improvements in complex daily tasks—such as meal preparation or operating household devices—reflect integrated motor planning and adaptive control, functions central to our theoretical model of multimodal intervention efficacy. Successful execution of these multi-step activities (e.g., by participant SV3) signifies a higher-order functional recovery beyond what standard motor assessments capture.

5.4.4. Psychological Transformation and Social Reintegration

Psychological and emotional improvements - though often overlooked - are among the most profound outcomes of effective motor rehabilitation. Participants reported enhanced mood, confidence, and hope, suggesting that physical recovery can catalyze broader psychological healing, breaking cycles of post-stroke depression and irritability (e.g., SV12's return to laughter), consistent with evidence linking motor recovery and mood (Hackett & Pickles, 2014).

Restored self-efficacy (e.g., SV1 resuming shopping/socializing) reflects regained personal agency critical for sustaining rehabilitation and transferring gains to daily life. Social reintegration (e.g., SV6's family bonds, SV8 hosting others) further illustrates how motor improvements, while not directly targeting psychology, enable resumption of meaningful roles that underpin emotional well-being and quality of life.

Thus, motor interventions may yield vital psychological co-benefits, reinforcing the need to assess and harness these effects in recovery models.

5.4.5. Challenges and Limitations from the User Perspective

Participant-reported challenges provide critical, nuanced insights into intervention acceptability and tolerability beyond what adherence metrics alone can capture. Issues such as unintuitive controls (e.g., SV4's difficulty with a "tiny button") and physical discomfort (e.g., SV10's hand sweating in heat) underscore the necessity of user-centered design in rehabilitation technology to ensure real-world usability and adherence.

Psychological factors also emerged as key: SV9's acknowledgment that recovery did not restore pre-stroke function highlights the importance of managing expectations to

sustain motivation and avoid disillusionment. SV4's fear of symptom relapse without continued device use reveals a need for transparent communication about treatment durability and strategies for maintaining gains.

Together, these findings inform both intervention refinement and clinical implementation emphasizing design, education, and psychological support as essential components of effective rehabilitation.

5.4.6 User-Driven Innovation and Future Directions

Participant-driven suggestions offer invaluable, experience-based guidance for refining rehabilitation technologies and protocols insights often inaccessible through conventional research methods. Technological requests (e.g., SV3's call for a mobile app, SV10's preference for more flexible splint materials) reflect users' nuanced understanding of how design impacts comfort and usability, pointing toward iterative, human-centered improvements.

Protocol recommendations such as SV12's request for follow-up sessions and SV8's belief that increased treatment frequency would accelerate gains—reveal participants' intuitive grasp of dose-response dynamics and the value of maintenance therapy. These insights not only demonstrate deep engagement but also highlight critical levers for optimizing intervention efficacy and adherence.

Incorporating end-user feedback is thus essential for developing more effective, acceptable, and sustainable rehabilitation solutions.

5.4.7. Integration with Quantitative Findings

The qualitative findings provide important context for interpreting our quantitative outcomes, and help explain the mechanisms through which the intervention produced its effects. This integration of quantitative and qualitative findings addresses a gap in the rehabilitation literature, where patient perspectives on intervention mechanisms and effectiveness are often overlooked (Kroll & Morris, 2009; Martín-Sanz et al., 2022). Recent calls for more patient-centered rehabilitation research emphasize the importance of understanding not just whether interventions work, but how they work from the patient's perspective and what aspects of the intervention experience contribute to therapeutic success (Xian et al., 2015; Rice et al., 2017). The participants' descriptions of immediate sensory effects and cumulative improvements align closely with our

theoretical framework and help explain why the combined intervention was superior to either component alone.

The strong correlation we observed between motor function improvements and pain reduction ($r = -0.708$, $p < 0.001$) is illuminated by participants' descriptions of how pain relief facilitated increased movement attempts and functional activities. SV4's report that pain reduction was "the most important point" because "the pain was preventing me from sleeping" suggests that pain relief may be a crucial mediating factor in the intervention's effectiveness.

The participants' descriptions of functional improvements provide important validation for the clinical significance of our quantitative outcomes. Furthermore, since an 8.75-point gain in Fugl-Meyer Assessment scores corresponded with the type of functional change described by participants as meaningful, the intervention delivered benefits that are meaningful to the participants.

5.4.8. Implications for Clinical Practice and Research

The qualitative findings underscore key implications for rehabilitation research and practice. First, they support a shift from impairment-focused models to holistic, person-centered approaches. Participants emphasized recovery dimensions such as social reintegration and psychological healing, highlighting that rehabilitation must address subjective and contextual aspects of health—aligning with the biopsychosocial model (Engel, 1977) and the ICF framework (WHO).

Second, patients described a nonlinear recovery trajectory: initial subtle changes (e.g., reduced pain, increased confidence) preceded gradual functional and psychological gains. This suggests early improvements may catalyze longer-term progress through positive feedback loops, reinforcing the need to manage expectations and support adherence.

Third, participant feedback revealed practical barriers and adaptation needs, underscoring the value of end-user involvement in intervention design. Incorporating

lived experience enhances usability, acceptability, and ecological validity—principles central to user-centered and participatory research approaches.

Finally, the data affirm the importance of mixed methods. While quantitative outcomes measure objective change, qualitative insights reveal the lived meaning of improvements—such as returning to work or regaining autonomy. Integrating both approaches enable a more complete understanding of intervention mechanisms and effectiveness within real-world contexts.

5.5.Future Research Directions

The results of this pilot study offer some initial support to a subsequent study on multimodal rehabilitation. These results are promising, but should be viewed with care since the study has a small sample size. Future studies must be directed towards repeating such results in larger, controlled trials, improving intervention regimens, and determining the characteristics of patients that are linked to the best response.

The most immediate research priority is the conduct of a large-scale, adequately powered randomized controlled trial that can confirm and extend our preliminary findings. Such a trial should incorporate several important design features that build upon the lessons learned from this pilot study. First, the inclusion of longer-term follow-up assessments (3-, 6-, and 12-months post-intervention) would provide crucial information about the durability of treatment effects and the potential need for booster sessions or maintenance interventions.

Future trials should expand beyond impairment-level outcomes to include activity- and participation-level measures—such as the Action Research Arm Test and Stroke Impact Scale—and incorporate patient-reported outcomes to assess functional and quality-of-life benefits.

Personalized approaches warrant investigation, leveraging early response patterns and baseline characteristics to tailor interventions. Machine learning could support the development of predictive algorithms for individualized treatment selection.

Technology integration offers strong potential: wearable FMV devices, smart splints with real-time feedback, and mobile health platforms could enhance precision, adherence, and accessibility. Virtual and augmented reality may further improve engagement and motor learning by combining immersive task practice with real-time feedback within optimized sensorimotor conditions.

The investigation of combination approaches that integrate our interventions with other evidence-based treatments represents another important research priority. The combination of FMV and splinting with constraint-induced movement therapy, robot-assisted training, or brain stimulation techniques could produce synergistic effects that exceed what any single intervention can achieve. Systematic investigation of these combination approaches could lead to the development of comprehensive rehabilitation protocols that address multiple aspects of motor recovery simultaneously.

The investigation of intervention effects across different stroke populations represents another important research direction. This pilot study focused on chronic stroke survivors with moderate to severe spasticity, but the interventions might be effective for other populations as well. Studies in acute and subacute stroke populations could determine whether earlier intervention produces enhanced benefits. Research in populations with mild spasticity or different patterns of motor impairment could help define the boundaries of intervention effectiveness and guide patient selection criteria.

The economic evaluation of multimodal interventions represents a crucial research priority for supporting healthcare policy and reimbursement decisions. Comprehensive cost- effectiveness analyses that consider not only the direct costs of intervention delivery but also the long-term healthcare cost savings associated with improved functional outcomes would provide essential information for healthcare decision-makers. These analyses should consider costs from multiple perspectives, including healthcare systems, patients and families, and society as a whole.

The investigation of optimal training and implementation strategies represents another important research area. While this pilot study demonstrated that interventions can be delivered effectively with appropriate training, larger-scale implementation will require systematic investigation of training methods, competency assessment approaches, and quality assurance systems. Implementation science methods could be used to identify

barriers and facilitators to intervention adoption and to develop strategies for successful scaling across different healthcare contexts.

The exploration of intervention effects on caregiver burden and family quality of life represents an important but understudied research area. Stroke affects not only survivors but also their families and caregivers, and interventions that improve functional independence could have significant impacts on caregiver stress and family functioning. Research that includes caregiver outcomes could provide additional justification for intervention implementation while identifying ways to optimize family-centered care approaches.

The investigation of long-term intervention effects and the potential need for maintenance interventions represents another crucial research direction. While our pilot study demonstrated short-term benefits, questions remain about how long these benefits persist and whether periodic booster sessions or ongoing maintenance interventions are needed to sustain improvements. Longitudinal studies that follow participants for extended periods could provide insights into the natural history of intervention effects and guide the development of long-term care protocols.

5.6. Acknowledged Limitations

While our study incorporates several important methodological strengths, it is essential to acknowledge the limitations that influence the interpretation and generalizability of our findings. These limitations are inherent to the pilot study design and reflect the early stage of research on multimodal rehabilitation interventions, but they also highlight important considerations for future research and clinical implementation.

The small sample size represents the most significant limitation of our study and reflects the pilot nature of our investigation. With only 12-13 participants per group, our study was not powered to detect small to moderate effect sizes that might still be clinically meaningful. The confidence intervals around our effect estimates are correspondingly wide, and some potentially important differences between groups may not have reached statistical significance due to limited statistical power. This limitation is inherent to pilot

studies, which are designed to provide preliminary evidence and inform the design of larger, definitive trials rather than to provide conclusive evidence of intervention effectiveness.

The short-term follow-up period (immediate post-intervention assessment only) limits our understanding of the durability of intervention effects and their long-term clinical significance. While the improvements we observed are encouraging, questions remain about whether these benefits persist over time or whether maintenance interventions might be needed to sustain improvements. The lack of long-term follow-up also limits our ability to assess whether the interventions influence the trajectory of recovery or simply produce temporary improvements that fade over time.

The single-center design, while appropriate for a pilot study, limits the generalizability of our findings to other healthcare settings and populations. The specific characteristics of our rehabilitation centers, the training and experience of our interventionists, and the characteristics of our local stroke population may all influence the effectiveness of interventions in ways that might not generalize to other contexts. Multi-center studies will be needed to establish the broader applicability of our findings.

The lack of a true control group receiving no intervention represents another limitation that influences the interpretation of our findings. While we compared three different intervention approaches, we did not include a group receiving standard care alone or a placebo intervention. This limits our ability to determine the absolute effectiveness of our interventions compared to natural recovery or placebo effects, although the magnitude of improvements we observed and their consistency with theoretical predictions suggest that genuine intervention effects were present.

The inability to blind participants and interventionists to group assignment is an inherent limitation of rehabilitation intervention studies that could potentially influence outcomes through expectation effects or differential attention. While we attempted to minimize these effects through standardized protocols and blinded outcome assessment, the possibility that group differences reflect factors other than the specific interventions cannot be completely eliminated.

The focus on impairment-level and activity-level outcome measures, while appropriate for a pilot study, limits our understanding of how intervention effects translate into meaningful improvements in daily functioning and quality of life. The inclusion of

participation-level measures and patient-reported outcomes in future studies would provide a more complete picture of intervention benefits and their clinical significance.

The homogeneous nature of our study population, while appropriate for establishing proof of concept, limits the generalizability of our findings to the broader stroke population. Our participants had moderate to severe spasticity and were in the chronic phase of recovery, but stroke survivors with different characteristics (mild spasticity, acute or subacute stroke, different lesion locations) might respond differently to these interventions.

The fixed intervention parameters we employed, while based on previous research and clinical experience, may not have been optimal for all participants. Individual differences in optimal vibration frequency, session duration, or treatment intensity could have influenced outcomes in ways that our standardized protocol could not accommodate. Future research should explore more personalized approaches to intervention parameter selection.

The lack of mechanistic outcome measures limits our understanding of how the interventions produced the effects we observed. While we can infer mechanisms based on theoretical knowledge and previous research, the inclusion of neuroimaging, electrophysiological, or biochemical measures in future studies would provide more direct evidence of the biological processes underlying intervention effects.

The resource-intensive nature of our intervention protocols may limit their scalability and implementation in resource-constrained healthcare settings. The need for specialized equipment, trained personnel, and individualized splint fabrication could present barriers to widespread adoption, particularly in low- and middle-income countries where the majority of stroke cases occur.

Despite these limitations, our pilot study provides valuable preliminary evidence for the effectiveness of multimodal rehabilitation approaches and establishes a strong foundation for future research. The limitations we have identified help define the boundaries of our current knowledge and highlight important priorities for future investigation. Most importantly, these limitations do not invalidate our findings but rather provide context for their interpretation and application to clinical practice.

5.7.Policy and Healthcare System Implications

The findings from our pilot study have important implications for healthcare policy and system organization that extend beyond the immediate clinical applications of our specific interventions. The evidence we have generated for the effectiveness of multimodal, non- pharmacological approaches to spasticity management aligns with broader healthcare policy trends toward promoting evidence-based, cost-effective interventions that can improve patient outcomes while potentially reducing long-term healthcare costs. The ability to achieve clinically meaningful improvements in motor function and spasticity through relatively simple, low-technology interventions suggests that healthcare systems should consider how current reimbursement and service delivery models might be adapted to support more effective rehabilitation approaches.

The international implications of our findings are particularly relevant for healthcare policy in low- and middle-income countries, where the majority of stroke cases occur but access to expensive pharmacological interventions or high-technology rehabilitation services is often limited. The relatively modest resource requirements of our intervention approach, combined with the potential for training existing rehabilitation professionals to deliver these services, suggests that effective spasticity management could be made more accessible to global stroke populations through appropriate policy support and resource allocation. Healthcare policy makers should consider how regulatory frameworks, professional training standards, and quality assurance systems can be developed to support the safe and effective implementation of multimodal rehabilitation approaches while ensuring that these interventions reach the populations that need them most.

5.8. Conclusion and Future Directions

This pilot randomized controlled trial represents a significant step forward in our understanding of how multimodal rehabilitation interventions can address the complex challenges of post-stroke spasticity and motor dysfunction. The evidence we have generated demonstrates that combining focal muscle vibration with anti-spastic splinting produces superior outcomes compared to either intervention alone, providing compelling

support for the theoretical framework that effective stroke rehabilitation requires integrated approaches that address multiple levels of the motor system simultaneously.

The clinical significance of our findings extends far beyond the specific interventions we tested. The improvements we observed in spasticity, motor function, and pain—achieved in a population of chronic stroke survivors who had been living with their conditions for extended periods—challenge traditional assumptions about the limited potential for recovery in the chronic phase and suggest that appropriately designed interventions can produce meaningful benefits throughout the recovery continuum. The magnitude of these improvements, particularly the 8.75-point improvement in Fugl-Meyer Assessment scores in the combined intervention group, substantially exceeds established thresholds for clinical significance and suggests that participants experienced genuine functional benefits that could translate into improved independence and quality of life.

The theoretical implications of our findings are equally important for advancing the field of stroke rehabilitation. The integration of neuroplasticity, motor control, and biomechanical frameworks provides a comprehensive foundation for understanding how different therapeutic approaches can work synergistically to promote recovery. The evidence we have generated for genuine synergistic effects—where the combination of interventions produces outcomes that exceed the sum of individual components—supports the emerging paradigm of systems-based rehabilitation that recognizes the interconnected nature of motor recovery processes.

The feasibility outcomes from our study provide crucial evidence that multimodal interventions can be successfully implemented in clinical practice. The high recruitment and retention rates we achieved, combined with excellent adherence to intervention protocols and a complete absence of adverse events, demonstrate that these approaches are not only theoretically sound but practically achievable. The protocol fidelity data we collected provides a roadmap for training and quality assurance that could support broader implementation of these interventions across different healthcare settings.

The international relevance of our findings cannot be overstated. With stroke representing a leading cause of disability worldwide and the majority of cases occurring in low- and middle-income countries, there is an urgent need for effective, accessible rehabilitation interventions that can be implemented across diverse healthcare contexts.

The relatively simple technology requirements and the potential for training existing rehabilitation professionals suggest that our intervention approach could be scaled to serve global stroke populations, potentially transforming rehabilitation outcomes for millions of individuals.

The research agenda that emerges from our findings is both ambitious and achievable. The immediate priority is the conduct of a large-scale, adequately powered randomized controlled trial that can confirm our preliminary findings while addressing the limitations inherent in pilot studies. Future definitive trials should include extended follow-up, multimodal outcome measures, and mechanistic assessments - such as biomarkers, neuroimaging, and patient-reported outcomes - to elucidate how multimodal interventions drive recovery. Integrating technology (e.g., wearable vibration devices) holds promise for enhancing efficacy, accessibility, and scalability particularly for underserved populations. Virtual and augmented reality may further boost engagement, motor learning, and personalization of rehabilitation.

The exploration of personalized rehabilitation approaches based on individual patient characteristics, biomarker profiles, or early response patterns represents another high- priority research direction. The individual variability we observed in response to different intervention components suggests that future implementations could be tailored to optimize outcomes for specific patient populations or characteristics. Machine learning approaches could be used to develop algorithms for personalized intervention selection and optimization, potentially maximizing therapeutic benefits while minimizing resource requirements.

The investigation of combination approaches that integrate our interventions with other evidence-based treatments could lead to even more effective rehabilitation protocols. The combination of multimodal interventions with constraint-induced movement therapy, robot-assisted training, brain stimulation techniques, or other emerging approaches could produce synergistic effects that exceed what any single intervention can achieve.

Systematic investigation of these combination approaches could lead to comprehensive rehabilitation protocols that address multiple aspects of motor recovery simultaneously.

The development of home-based delivery models represents a crucial research priority for enhancing accessibility and reducing healthcare costs. While our study was conducted in clinical settings, the relatively simple nature of our interventions suggests that modified protocols could be developed for home use with appropriate training and support systems. Research on home-based delivery would need to address questions of safety, effectiveness, adherence, and quality assurance while developing systems for remote monitoring and support.

The economic implications of our findings deserve particular attention as healthcare systems worldwide face increasing pressure to demonstrate value and cost-effectiveness. The ability to achieve clinically meaningful improvements in a four-week intervention period could significantly reduce the long-term costs associated with chronic stroke care, but formal cost-effectiveness analyses will be needed to quantify these benefits and support healthcare policy decisions.

Looking toward the future, our findings contribute to a broader transformation in stroke rehabilitation that recognizes the need for more sophisticated, integrated approaches to addressing the complex challenges of neurological recovery. The traditional model of sequential, single-intervention treatments is giving way to a new paradigm of multimodal, systems-based rehabilitation that addresses multiple levels of motor dysfunction simultaneously. Our research provides important evidence supporting this transformation while highlighting the potential for innovative intervention approaches to improve outcomes for stroke survivors worldwide.

The journey from pilot evidence to widespread clinical implementation will require sustained effort from researchers, clinicians, policy makers, and healthcare organizations. However, the evidence we have generated suggests that this journey is not only worthwhile but essential for realizing the full potential of modern rehabilitation science to improve the lives of stroke survivors. The millions of individuals worldwide who are living with the long- term consequences of stroke deserve access to the most effective rehabilitation interventions available, and our findings suggest that multimodal approaches may represent a significant step toward achieving this goal.

The ultimate measure of our research success will not be the publications it generates or the academic recognition it receives, but rather the extent to which it contributes to improved outcomes and quality of life for stroke survivors and their

families. The evidence we have generated provides a foundation for this impact, but realizing its full potential will require continued research, clinical innovation, and commitment to translating scientific discoveries into meaningful improvements in human health and function. The future of stroke rehabilitation is bright, and multimodal interventions appear poised to play an important role in that future.

Personal Reflection

Engaging in self-reflection represents a cornerstone of robust research practice, particularly when examining one's own positionality and potential influences on the research process. This reflective account explores my journey as a researcher, the experiences that shaped this investigation, and the transformative nature of transitioning from purely clinical practice to academic inquiry.

Professional Journey and Clinical Foundation

My career in occupational therapy spans over two and a half decades, during which I have dedicated myself to improving the lives of individuals facing neurological challenges. Working as both a practicing clinician and academic faculty member at the Arab American University Palestine has provided me with a unique dual perspective that bridges theoretical knowledge with practical application.

The genesis of this research emerged from countless hours spent in clinical settings, observing the daily struggles of stroke survivors grappling with spasticity. Over nearly two decades of working with this population, I became increasingly aware of the profound ways in which muscle stiffness and involuntary contractions affected not just physical function, but emotional well-being and social participation. Patients would express frustration at their inability to perform simple tasks, families would describe the emotional toll of watching their loved ones struggle, and I found myself searching for more effective interventions to address these complex challenges.

What struck me most profoundly was the ripple effect of hand spasticity on every aspect of a person's existence. The inability to grasp objects, write, or perform self-care activities created barriers that extended far beyond the physical realm. I witnessed the psychological impact of lost independence, the social isolation that often followed functional limitations, and the gradual erosion of hope that accompanied ineffective treatment attempts. These observations crystallized my determination to explore innovative approaches that might offer genuine relief and restoration of function.

Research Initiation and Learning Process

Embarking on doctoral research represented a complete departure from my established professional identity. Having spent my entire career focused on direct patient care, the world of systematic inquiry, statistical analysis, and controlled experimentation was entirely foreign territory. This study marked my inaugural experience with randomized controlled trial methodology, requiring me to master new vocabularies, procedures, and ways of thinking about clinical problems.

The learning process was both humbling and exhilarating. I found myself grappling with concepts that were far removed from my clinical comfort zone - power calculations, randomization procedures, outcome measure selection, and data analysis techniques. Each new skill acquired felt like unlocking another piece of a complex puzzle, gradually building my capacity to conduct rigorous scientific investigation.

Perhaps most challenging was learning to balance my clinical intuition with scientific objectivity. Years of patient interaction had given me strong instincts about what might work, but research demanded that I set aside these preconceptions and allow the data to guide conclusions. This tension between clinical experience and research methodology became a constant companion throughout the study.

Navigating Practical Challenges

Conducting research within the Palestinian context presented obstacles that extended well beyond typical academic challenges. The procurement of specialized equipment became an exercise in patience and persistence, as the focal muscle vibration devices essential to this study were unavailable within our region. International shipping processes, customs procedures, and import regulations transformed what should have been straightforward equipment acquisition into a months-long endeavor that required constant monitoring and problem-solving.

Geographic and political realities significantly influenced recruitment strategies. Initial plans to draw participants from multiple cities across the region proved impractical due to movement restrictions and security considerations. This constraint necessitated a more localized approach, concentrating efforts within the Jenin area where I could ensure consistent access and follow-up. While this limitation may have affected sample diversity,

it also fostered stronger relationships with local healthcare providers and enabled more intensive participant support.

The unpredictable nature of daily life in this region required constant adaptability. Research sessions needed to accommodate sudden closures, communication disruptions, and transportation difficulties. These experiences taught me the value of flexibility in research design and the importance of building robust contingency plans for every aspect of study implementation.

Personal and Professional Transformation

This doctoral journey has fundamentally altered my understanding of both clinical practice and scientific inquiry. The process of designing and implementing a controlled trial has sharpened my analytical thinking and enhanced my appreciation for evidence-based decision-making. I have developed competencies in areas I never imagined exploring - from statistical software operation to manuscript preparation for peer review.

The experience has also deepened my respect for the complexity of human responses to intervention. Working with study participants reinforced my understanding that behind every data point lies a unique individual with personal goals, fears, and aspirations. This humanistic perspective has become integral to how I approach both research and clinical practice.

Maintaining awareness of my dual role as clinician and researcher required constant vigilance. My extensive background with stroke patients provided valuable insights into study design and implementation, but I remained mindful of the need to approach data collection and analysis with scientific neutrality. Establishing clear boundaries between my clinical knowledge and research objectivity became an ongoing exercise in professional discipline.

Future Directions and Continuing Impact

The completion of this pilot investigation represents not an endpoint, but rather the beginning of a larger research trajectory. The promising results obtained have strengthened my commitment to pursuing a full-scale randomized controlled trial that can provide definitive evidence regarding the effectiveness of combined interventions for post-stroke spasticity. Additionally, the potential applications of focal muscle vibration to

other body regions, particularly the lower extremities, present exciting avenues for future exploration.

The publication of findings from this work will contribute to the growing body of evidence supporting innovative rehabilitation approaches. More importantly, these results offer hope to stroke survivors and their families who continue to search for effective treatments that can restore function and improve quality of life.

Concluding Thoughts

This research experience has been transformative in ways I could not have anticipated when beginning this journey. It has challenged me to grow beyond my established professional boundaries, develop new competencies, and contribute to scientific knowledge in meaningful ways. The process has reinforced my belief in the critical importance of clinician-researchers who can bridge the gap between theoretical knowledge and practical application.

Most significantly, this work has been inspired by and dedicated to the stroke survivors who have shared their struggles and hopes with me over the years. Their resilience in the face of significant challenges, their willingness to participate in research despite their own difficulties, and their unwavering determination to improve their circumstances have been constant sources of motivation throughout this endeavor.

The knowledge generated through this investigation represents a collaborative effort between researchers, clinicians, and patients working toward a common goal of improved rehabilitation outcomes. It stands as evidence of what can be accomplished when scientific rigor is combined with clinical insight and patient partnership in the pursuit of better healthcare solutions.

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Appendices

Appendix 1: Modified Ashworth Scale

score	Modified Ashworth Scale (Ansari, Naghdi, Moammeri, Jalaie, 2006)
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 (ROM) when the affected part is moved in flexion or extension
2	Marked increase in muscle tone, manifested by a catch in the middle ROM, but affected part easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part rigid in flexion or extension

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 (at least one)			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).	Shoulder	retraction	0	1	2
		elevation	0	1	2
		abduction (90°)	0	1	2
		external rotation	0	1	2
	Elbow	flexion	0	1	2
	Forearm	supination	0	1	2
Extensor synergy: Hand from ipsilateral ear to the contralateral knee	Shoulder	adduction/internal rotation	0	1	2
	Elbow	extension	0	1	2
	Forearm	pronation	0	1	2
		Subtotal II (max 16)			
III. Volitional movement mixing synergies, without compensation			**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)		0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	Immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion		0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position		0	1	2
		Subtotal III (max 6)			
IV. Volitional movement with little or no synergy			**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm pronated	Immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation		0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	Immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion		0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position		0	1	2
		Subtotal IV (max 6)			
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side			**0 (N), hyper**	**lively**	**normal**
biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive or 0 points in part IV 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
		Subtotal V (max 2)			
		Total A (max 36)			

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

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		none	partial	full
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
a. Hook grasp flexion in PIP and DIP (digits II-V), extension in MCP II-V	cannot be performed can hold position but weak maintains position against resistance	0	1	2
b. Thumb adduction 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
c. Pincer grasp, opposition pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
d. Cylinder grasp cylinder shaped object (small can) tug upward, opposition of thumb and fingers	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
e. Spherical grasp fingers in adduction/flexion, thumb opposed, tennis ball, tug away	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
	Total C (max 10)			

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

TOTAL A-D (max. 66)	

H. SENSATION, upper extremity eyes closed, compared with the unaffected side		anesthesia	hypoesthesia or dysesthesia	normal
Light touch	upper arm, forearm	0	1	2
	palmary surface of the hand	0	1	2
		less than 3/4 correct or absence	3/4 correct or considerable difference	correct 100%, little or no difference
Position small alterations in the position	shoulder	0	1	2
	elbow	0	1	2
	wrist	0	1	2
	thumb (IP-joint)	0	1	2
Total H (max. 12)				

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

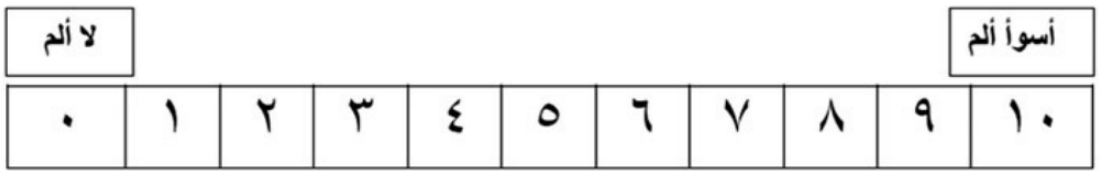
A. UPPER EXTREMITY	/26
B. WRIST	/10
C. HAND	/14
D. COORDINATION / SPEED	/16
TOTAL A-D (motor function)	**/66**

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

Appendix 3: ROM

Right		Joint / Movement				Left	
AROM	PROM	Joint	Movement	Muscle	Norm	PROM	AROM
		Shoulder	Flexion	Anterior deltoid	170		
			Extension	Latis dorsi & teres major	60		
			Abduction	Middle deltoid	170		
			Adduction	Pectoralis major	0		
			Int. Rot.	Subscapularis, pectoralis major, latis dorsi, teres major	70		
			Ext. Rot.	Infraspinatus, teres minor	90		
		Elbow	Flexion	Biceps, brachioradialis	150		
			Extension	Triceps	0		
		Forearm	Supination	Biceps, supinator	80		
			Pronation	Pronator teres & quadratus	80		
		Wrist	Flexion	Flexor carpi radialis & ulnaris	80		
			Extension	Ext. carpi radialis longus/brevis, ext carpi ulnaris	70		
		Fingers	MCP Flex.	Lumbricals	80		
			MCP Ext.	Ext. digitorum communis	45		
			PIP Flex	Flex. Digit Superficialis	110		
			DIP Flex	Flex. Digi. Profundus	80		
			Adduction	Palmar interossei	0		
			Abduction	Dorsal interossei	25		
		Thumb	MCP Flex	Flex. polices Brevis	50		
			MCP Ext.	Ext. polices Brevis	0		
			IP Flex	Flex. Polices longus	80		
			IP Ext.	Ext. pollices longus	80		
			Abduction	Abductor Pollices Brevis & Longus	50		

Appendix 4: NRS



Appendix 5: Standardized Vibration Stimulation Protocol

Step	Description
Participant Assessment	A licensed therapist will assess the participant's hand spasticity using the Modified Ashworth Scale (MAS).
Target Muscle Identification	The therapist will identify the specific antagonistic muscles exhibiting spasticity.
Device Positioning	The volar anti-spastic hand splint (Figure 3.1.) will be donned on the participant's affected hand. The Arm vibrator (Figure 3.2.) will be positioned over the target antagonistic muscle(s) with padding for comfort and skin protection.
Stimulation Parameters	Frequency, amplitude, duration, and repetitions as illustrated in Table 2.1.
Additional Considerations	The participant will be instructed to inform the therapist of any discomfort or adverse effects experienced during stimulation.
	This standardized protocol ensures consistent application of vibration therapy across all participants, allowing for reliable comparison of results and promoting participant safety.

Appendix 6: Standardized Protocol for Volar Anti-Spastic Hand Splint Fabrication

Step	Description
	Materials
Thermoplastic material	Orthoplast, perforated for breathability
Strapping material	Velcro straps
Padding material	Plastazote
	Procedure
Patient Assessment	The prosthetist/orthotist assesses the participant's hand and wrist for range of motion and specific areas requiring support.
Splint Molding	The participant's hand and wrist are placed in a neutral resting position, and the thermoplastic material is molded around them.
Splint Customization	Excess material is trimmed, padding is added for comfort.
Strapping and Application	Strapping materials are attached to the splint to allow for secure and adjustable application to the participant's hand and wrist.
Verification and Adjustments	The participant will wear the splint for a designated period, typically half an hour, as per the established protocol. During this time, the prosthetic and orthotic clinician will closely observe for any signs of discomfort or pressure points. Adjustments will be made promptly to alleviate any issues and optimize the fit and function of the splint for the participant's comfort and support.
Additional Considerations	Participants are encouraged to communicate any discomfort or concerns regarding the splint during the fitting process.
	The splint should be easily removable by the participant for hygiene and skin care.

Appendix 7: Education Protocol

Education Protocol for Intervention Groups
Introduction and Orientation
- Explanation of trial purpose and goals
- Emphasize importance of participation and compliance
Understanding the Interventions
Group A: Splint and Vibration Intervention
- Explanation of focal muscle vibration and therapeutic effects
- Demonstration of correct application and usage of vibration device
- Discussion on frequency, duration, and technique of vibration application
- Explanation of hand splint therapy and its benefits
- Demonstration of correct application and usage of hand splint
- Discussion on duration and frequency of hand splint usage (30 minutes per use, three days a week)
Group B: Splint Only Intervention
- Explanation of hand splint therapy and its benefits
- Demonstration of correct application and usage of hand splint
- Discussion on duration and frequency of hand splint usage (30 minutes per use, three days a week)
Group C: Vibration Only Intervention
- Explanation of focal muscle vibration and therapeutic effects
- Demonstration of correct application and usage of vibration device
- Discussion on frequency, duration, and technique of vibration application
Home-Based Implementation
- Instructions for incorporating intervention into daily routines
- Encouragement to maintain intervention log
- Establishment of communication channels for questions and concerns
Monitoring and Follow-Up
- Bi-daily phone communications, and weekly home visits
- Encouragement for feedback on intervention experiences

Appendix 8: Concomitant care Education

Concomitant care Education and Guidance Protocol
Objective: To ensure participants understand the importance of adhering to the trial protocol and avoiding new or additional interventions targeting spasticity.
Components:
1. Introduction to Trial Protocol: Participants will receive a detailed explanation of the trial objectives, procedures, and expectations regarding their participation. This will include information on the importance of maintaining consistency in their treatment regimen throughout the trial duration.
2. Explanation of Spasticity Management: Participants will be educated about spasticity, its impact on stroke recovery, and the various management strategies available, including the interventions being investigated in the trial (anti-spastic splint and vibration therapy).
3. Importance of Adherence: Participants will be informed about the significance of adhering to the prescribed treatment regimen and avoiding any new or additional interventions targeting spasticity during the trial period. Emphasis will be placed on the need for consistency to ensure accurate evaluation of the trial outcomes.
4. Risk and Benefit Discussion: A comprehensive discussion will be conducted to address any concerns or questions participants may have regarding the trial protocol and potential risks and benefits associated with participation.
5. Monitoring and Reporting: Participants will be instructed to promptly report any changes in their medical management or initiation of new therapies targeting spasticity to the research team. Clear instructions will be provided on how to contact the research team and report such changes.
6. Follow-up Support: Ongoing support will be offered to participants throughout the trial period to address any concerns, provide clarification on trial-related matters, and reinforce the importance of adherence to the protocol. This support includes the scheduled calls, and weekly visits.

Appendix 9: Demographic Information

Demographic variable	
Age	
Gender:	□ Male □ Female
Dominant hand	□ Right □ Left
Smoking	
Education	
Marital Status	□ Single □ Married □ Separated □ Divorced □ Widowed
Employment status	
living arrangements	□With a family □With a spouse □Alone
live in	□ City □ village □ camp
Are you the prime carer of a dependent child/children	□ yes □ No
Educational Level	□ School □ university □ post graduate degree
Employment status	□ employee □ self-employed □ Retired □ looking for a job
Average monthly income	

Appendix 10: Medical and therapeutic data

Demographic variable	
Onset date	
Previous rehabilitation treatment	□ yes, specify _____ □ No
Spasticity Medication	□ Baclofen □ Dantrium □ Zanaflex □ No
Have you received Botox injection in past 6 months	□ Yeas □ No
Hand pain	□ Yes , Location _____ □ No
Do you use hand splint	□ Yes, type_____ □ No
Have been hospitalized in the past 12 months	□ Yes □ No
Are you receiving any other therapies (traditional, herbal)	□ yes, specify_____ □ No
Any other health issue	□Diabetes □High blood pressure □Elevated cholesterol levels

Appendix 11: Interview Guide

Interview Guide
1. Introduction and Warm-Up:
- Welcome the participant and explain the purpose of the interview.
- Start with some general questions to establish rapport:
- "Could you please tell me about your experience with stroke rehabilitation so far?"
- "What motivated you to participate in this study?"
2. Experience with the Intervention:
- Explore participants' experiences with the anti-spastic splint and focal muscle vibration intervention:
- "Could you describe your experience with wearing the anti-spastic splint?"
- "How did you find the experience of receiving focal muscle vibration therapy?"
- "Did you notice any changes or improvements in your hand function or spasticity while using the intervention?"
3. Perceptions of Effectiveness:
- Investigate participants' perceptions of the intervention's effectiveness:
- "In your opinion, how effective was the anti-spastic splint and focal muscle vibration therapy in managing your spasticity?"
- "What aspects of the intervention do you think contributed to any improvements you may have experienced?"
- "Were there any specific activities or tasks where you noticed the intervention had a particularly positive impact?"
4. Challenges and Limitations:
- Discuss any challenges or limitations encountered during the intervention period:
- "Were there any difficulties or barriers you faced while using the anti-spastic splint or receiving focal muscle vibration therapy?"
- "Did you encounter any challenges integrating the intervention into your daily routine?"
- "Were there any aspects of the intervention that you found less effective or problematic?"
5. Suggestions for Improvement:
- Seek participants' suggestions for improving the intervention:
- "Based on your experience, what recommendations would you have for enhancing the effectiveness or usability of the intervention?"
- "Are there any additional features or modifications you would suggest for the intervention?"
- "How do you think the intervention could be better tailored to meet the needs of individuals with stroke?"
6. Closing Remarks:
- Thank the participant for their time and participation.
- Offer the opportunity for any final comments or reflections.

فعالية الجبيرة المضادة للتشنج مع إضافة الاهتزاز العضلي المركز في تقليل تشنج اليد وتحسين وظائفها لدى الأفراد المصابين بالسكتة الدماغية المزمنة: تجربة عشوائية محكومة تجريبية

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الملخص باللغة العربية

المقدمة: تُعد السكتة الدماغية من أهم أسباب الإعاقة طويلة المدى على مستوى العالم، حيث يُصاب حوالي 30–40% من الناجين من السكتة الدماغية بالتشنج العضلي خلال السنة الأولى، مما يؤثر بشكل كبير على وظائف الطرف العلوي وأنشطة الحياة اليومية. أظهرت التدخلات التقليدية أحادية النمط فعالية محدودة في تحقيق تحسينات وظيفية مستدامة للأفراد المصابين بتشنج اليد المزمن بعد السكتة الدماغية.

الهدف: هدفت هذه الدراسة بشكل أساسي إلى تقييم جدوى وامتثال استخدام الاهتزاز العضلي المركز عند إضافته إلى الجبيرة المضادة للتشنج لدى الأشخاص المصابين بالتشنج بعد السكتة الدماغية. كما هدفت ثانوياً إلى استقصاء الفعالية الأولية لهذا التدخل المركب في تقليل التشنج وتحسين وظائف اليد.

المنهجية: أُجريت تجربة عشوائية محكومة تجريبية شملت 37 مشاركاً من المصابين بالسكتة الدماغية المزمنة (متوسط العمر 58.46 ± 10.73 سنة، 62.2% ذكور) تم تجنيدهم من مراكز التأهيل في منطقة جنين، فلسطين. قُسم المشاركون عشوائياً إلى ثلاث مجموعات: المجموعة الأولى (الجبيرة المضادة للتشنج + الاهتزاز العضلي المركز، ن=12)، المجموعة الثانية (الاهتزاز العضلي المركز فقط، ن=12)، والمجموعة الثالثة (الجبيرة المضادة للتشنج فقط، ن=13). تضمن البروتوكول العلاجي 12 جلسة على مدى 4 أسابيع. طُبق الاهتزاز العضلي المركز بتردد 100 هرتز وسعة ملم لمدة 30 دقيقة لكل جلسة. صُنعت الجبائر المضادة للتشنج بشكل مخصص لكل 0.5–0.2 مشارك للحفاظ على الوضعية الوظيفية لليد.

المقاييس: شملت المقاييس الأساسية مقياس أشوورث المعدل لتقييم التشنج، وتقييم فوغل–ماير للطرف العلوي لتقييم الوظيفة الحركية، ومقياس تقدير الألم الرقمي، وقياسات مدى الحركة. حُللت المزدوج للتغيرات داخل المجموعات وتحليل التباين المصاحب للمقارنات t البيانات باستخدام اختبار بين المجموعات.

النتائج: تجاوزت نتائج الجدوى جميع المعايير المحددة مسبقاً بمعدل تجنيد 51.3%، ومعدل استبقاء 100%، وامتثال عام 89.2% ± 8.7%، وعدم حدوث أي أحداث ضارة عبر 421 جلسة علاجية. أظهرت المجموعة الأولى (التدخل المركب) أكبر التحسينات: انخفاض في مقياس أشوورث

وتحسن في تقييم فوغل–ماير بمقدار ،($p < 0.001$) المعدل بمقدار -1.25 ± 0.62 نقطة ($p < 0.001$) وانخفاض في الألم بمقدار -2.58 ± 1.44 نقطة ،($p < 0.001$) نقطة $+8.75 \pm 3.91$ أظهرت المجموعة الثانية (الاهتزاز العضلي فقط) تحسينات متوسطة، بينما أظهرت .(0.001 المجموعة الثالثة (الجبيرة فقط) تغيرات طفيفة غير دالة إحصائياً. كشف تحليل التباين المصاحب (الجزئي = η^2 0.289) والوظيفة الحركية (الجزئي = η^2 0.335) عن أحجام تأثير كبيرة للتشنج.

الاستنتاجات: تقدم هذه التجربة العشوائية المحكومة التجريبية دليلاً مقنعاً على أن دمج الاهتزاز العضلي المركز مع الجبيرة المضادة للتشنج أمر قابل للتطبيق وآمن وفعال أولياً في إدارة تشنج اليد لدى الناجين من السكتة الدماغية المزمنة. أظهر التدخل المركب نتائج متفوقة مقارنة بأي من الطريقتين منفردة، مع دليل على تأثيرات تآزرية وليس مجرد تأثيرات تراكمية. كانت التحسينات المحققة ذات معنى سريري ومماثلة للتدخلات الأكثر توغلاً مثل حقن توكسين البوتولينوم، مع الحفاظ على ملامح ممتازة للأمان والتحمل.

الأهمية العلمية: تتحدى هذه النتائج الأساليب التقليدية أحادية التدخل وتدعم نموذجاً ناشئاً للتأهيل متعدد الطرق القائم على الأنظمة. توفر النتائج القوية للجدوى، بما في ذلك معدلات الاستبقاء والامتثال الاستثنائية، أساساً قوياً لتصميم تجارب نهائية أكبر حجماً. يجب أن تركز الأبحاث المستقبلية على إجراء تجارب عشوائية محكومة بقوة كافية مع فترات متابعة أطول لتأكيد استدامة هذه التأثيرات الواعدة وتحسين معايير التدخل للتطبيق السريري.

الكلمات المفتاحية: تأهيل السكتة الدماغية، التشنج العضلي، الاهتزاز العضليالمركز، الجبيرة المضادة للتشنج، وظيفة الطرف العلوي.

تسجيل التجربة السريرية: ClinicalTrials.gov ID NCT06358976