Majalah Ilmiah Fisioterapi Indonesia
Indonesian Scientific Journal of Physiotherapy

Original Research Articles
ISSN (Print): 2303-1921
ISSN (Online): 2722-0443
Volume 14, Number 2, Pages 667-671 (2026)
DOI: https://doi.org/10.24843/mifi.000000760

Development and Content Validation of START: A Modified CIMT-Based Upper Limb Rehabilitation Tool

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Received 25 September 2025; Revised 9 October 2025; Accepted 11 October 2025; Published 31 May 2026

Abstract

Background: Stroke frequently causes upper limb dysfunction, resulting in reduced independence and limitations in activities of daily living. Accessible rehabilitation devices integrating motor and sensory training remain limited, particularly for home-based use.

Objective: To develop and evaluate the content validity of the Stroke Therapy Assistance and Recovery Tools (START), a modified Constraint-Induced Movement Therapy (m-CIMT)-based rehabilitation device for post-stroke upper limb recovery.

Methods: This Research and Development study followed the Sugiyono framework up to the design validation stage (Technology Readiness Level 5). The START device integrated strength, coordination, and sensory training components. Content validity was assessed independently by two physiotherapy experts using the Content Validity Index (CVI). Outcomes included Item-Level CVI (I-CVI), Scale-Level CVI Average (S-CVI/Ave), and Scale-Level CVI Universal Agreement (S-CVI/UA). Descriptive analysis was performed.

Results: The START device demonstrated high content validity, with an S-CVI/Ave of 0.90 and an S-CVI/UA of 0.80. Most assessment items achieved perfect agreement (I-CVI = 1.00), while two items showed partial agreement (I-CVI = 0.50). Experts recommended reducing device weight, improving ergonomic features, enhancing material durability, and incorporating automatic random light activation.

Conclusion: START demonstrated excellent content validity and feasibility as a low-cost upper limb rehabilitation tool for post-stroke individuals. The integration of strength, coordination, and sensory training supports its potential application in home-based rehabilitation. Further prototype refinement and clinical effectiveness testing are recommended.

Keywords

Stroke; Rehabilitation; Upper Extremity; Physical Therapy Modalities; Activities of Daily Living; Equipment Design.

Introduction

As individuals age, a gradual decline in bodily function occurs, and one of the most prevalent conditions associated with this decline is stroke. The World Health Organization (WHO) defines stroke as a neurological disorder that occurs suddenly due to the rupture or blockage of cerebral blood vessels, resulting in brain tissue damage that persists for at least 24 hours.[1] Individuals with low physical activity levels and poor dietary habits, particularly those high in fat and cholesterol, have an increased risk of developing stroke.[2] According to the Global Burden of Disease (GBD) 2021 report, stroke ranks among the top three causes of death and disability worldwide.[3] In Indonesia, data from the 2023 Indonesian Health Survey (SKI) reported 638,178 stroke cases among individuals aged over 15 years, with 501,037 experiencing disability.[4]

The most significant post-stroke disability commonly affects the upper extremities (50–70%) compared to the lower extremities.[5,6] Impairments in the upper limbs, such as reduced hand coordination and motor function, may lead to soft tissue shortening and spasticity.[7] Upper extremity spasticity tends to be more severe than that of the lower extremities, resulting in a slower recovery process.[8] In general, stroke survivors experience weakness in the facial, upper, or lower muscles due to hemiplegia or hemiparesis, leading to difficulties in walking, eating, toileting, and dressing independently.[9,10] The 2023 Indonesian Health Survey further revealed that among stroke survivors aged over 60 years, 3,102 individuals remained dependent on others for daily needs.[4] Additionally, many post-stroke individuals experience a loss of self-confidence as a result of decreased functional capacity, negatively impacting their overall independence and quality of life.[11]

Mlinac and Feng described Activities of Daily Living (ADL) as essential functional abilities required for basic physical needs, including self-care and mobility.[12] Therefore, rehabilitation programs should focus on promoting functional recovery to accelerate restoration. However, many stroke survivors neglect rehabilitation due to financial, time, or logistical constraints. Data from the 2023 Indonesian Health Survey showed that only 25,865 individuals utilized healthcare facilities for disability-related rehabilitation.[4] Therapeutic interventions, however, have been shown to enhance quality of life and reduce disability among post-stroke individuals.[13]

To address this, appropriate rehabilitation interventions are required, one of which is Constraint-Induced Movement Therapy (CIMT) or its modified version (mCIMT). Both methods have demonstrated effectiveness in improving upper extremity function and can be adapted for home-based rehabilitation.[14] CIMT encourages the affected limb to perform active movements, thereby restoring its function.[15] A previous study titled *"Modification of Constraint-Induced Movement Therapy Compared to Mirror Therapy on Improving Upper Extremity Function in Subacute Stroke Patients"* reported that CIMT-based training significantly improved upper extremity function, influenced by enhanced coordination and muscle strength.[16] Target participants for such training typically possess good cognitive function, intact comprehension, adequate vision, and a minimum Manual Muscle Testing (MMT) score of 3, allowing movement against gravity.[17] However, conventional CIMT approaches often rely on multiple separate tools, limiting accessibility and training efficiency.

Although several robotic-based rehabilitation devices have been developed for upper extremity recovery, most primarily focus on improving joint range of motion and motor function.[7,18] Furthermore, these devices are often expensive and not feasible for community or home-based use. Currently, there is a lack of low-cost, multifunctional rehabilitation tools that integrate strength, coordination, and sensory components within a single system.

To address this gap, the present study developed the Stroke Therapy Assistance and Recovery Tools (START) device, designed as a modification of the CIMT concept to enhance usability, affordability, and functionality. The study aimed to design and validate the START device for upper extremity rehabilitation in post-stroke individuals. By establishing its content validity, this research contributes to the advancement of accessible, locally developed rehabilitation technologies that support community-based rehabilitation and serve as innovative tools for physiotherapy education and future clinical research.

Results

The development of the Stroke Therapy Assistance and Recovery Tools (START) followed a Research and Development (R&D) framework consisting of four main stages: (1) problem and potential analysis, (2) prototype design, (3) expert validation, and (4) product revision. Each stage contributed to the creation of START as a modified Constraint-Induced Movement Therapy (m-CIMT)–based rehabilitation device designed to improve upper extremity functional ability in post-stroke individuals.

Stage 1: Problem and Potential Analysis

Post-stroke individuals commonly experience significant impairment in upper extremity function; however, affordable, multifunctional, and user-friendly rehabilitation devices remain limited. This lack of accessible tools often results in stroke survivors neglecting rehabilitation due to the time, effort, and financial burden associated with therapy. Therefore, the development of a low-cost, multifunctional device suitable for home-based rehabilitation was deemed essential. The START device was designed to address this need by integrating three functional training zones—strength, coordination, and sensory—into a single tool.

Stage 2: Prototype Design

The prototype design phase produced the first functional model of the START device, which incorporated three distinct training zones.

- The strength training zone utilized resistive media, including elastic rubber bands of varying intensities and a tennis (grip) ball.
- The coordination training zone employed visual stimuli through indicator lights that illuminated randomly, enabling users to practice movement precision, motor coordination, and upper limb control while also indirectly engaging upper limb muscle strength during repetitive reaching activities.
- The sensory training zone provided tactile stimulation using textured surfaces—rough (synthetic grass) and smooth (wallpaper)—to promote sensory re-education.

Each training zone was designed based on the task-oriented principle, targeting both motor and sensory recovery in post-stroke rehabilitation. The visual representation of the START prototype is shown in Figure 2.

Stage 3: Expert Validation

Expert validation was conducted by two qualified assessors using the Content Validity Index (CVI). The CVI is widely used to evaluate the clarity, relevance, and appropriateness of an instrument or device in relation to its intended purpose.[22] The results of the CVI are summarized in Table 1. Both experts' assessments yielded an S-CVI/Ave of 0.9, indicating an overall very high level of content validity, and an S-CVI/UA of 0.8, demonstrating 80% complete agreement between experts. According to the established criteria, an I-CVI ≥ 0.80 is considered acceptable for two validators, confirming that the START device achieved satisfactory validity.[21]

These findings suggest that the START rehabilitation device meets expert standards for relevance and feasibility, supporting its potential as an effective tool for upper extremity rehabilitation in post-stroke individuals. However, the use of only two experts represents a limitation, as a broader panel may enhance the robustness of the validation results. Items receiving an I-CVI score of 0.5 indicated partial agreement, where only one expert deemed the item appropriate. As shown in Table 1, items related to long-term safety and ergonomic suitability received lower agreement (UA = 0), suggesting that both aspects require improvement in future iterations.

Table 1. Content Validity Index Results

Item	Expert 1	Expert 2	Experts in Agreement	I-CVI	UA
P1	1	1	2	1	1
P2	1	1	2	1	1
P3	1	1	2	1	1
P4	1	1	2	1	1
P5	1	1	2	1	1
P6	1	0	1	0.5	0
P7	1	1	2	1	1
P8	1	1	2	1	1
P9	1	0	1	0.5	0
P10	1	1	2	1	1
S-CVI/Ave				0.9	
S-CVI/UA					0.8

Stage 4: Product Revision

During the revision phase, both experts provided constructive feedback for further refinement of the device:

1. Weight reduction – The device should be made lighter to enhance portability and ease of use.
2. Automatic lighting feature – The coordination zone (lights) should illuminate randomly and automatically to allow independent home training without external assistance.
3. Material safety and durability – Improvements in material selection are necessary to ensure the device remains safe and functional for long-term use.
4. Ergonomic adjustments – The handgrip dimensions and positioning need modification to accommodate varying hand sizes among post-stroke individuals. The current design posed a risk of discomfort and muscle fatigue during prolonged sessions.

These revisions aim to enhance the device's usability, comfort, and long-term functionality while maintaining its affordability and rehabilitative potential. The CVI results confirmed that the START device achieved high content validity, aligning with the study's objective to design and develop a feasible and appropriate tool for upper extremity rehabilitation in post-stroke individuals. Future development should proceed with product refinement and clinical testing to establish its functional effectiveness and therapeutic impact in real-world rehabilitation settings.

Discussion

Non-pharmacological management plays a crucial role in post-stroke rehabilitation to minimize secondary effects and prevent long-term disability in patients.[23] Common non-pharmacological interventions include joint range-of-motion exercises, coordination training, and repetitive strength training.[24] The START (Stroke Therapy Assistance and Recovery Tools) device was designed to incorporate three specific training zones—strength, coordination, and sensory stimulation—targeted at the upper extremities.

Neuroplasticity refers to the brain's ability to adapt by forming new neural pathways in response to learning, experience, or injury.[25] In post-stroke rehabilitation, neuroplasticity serves as a fundamental mechanism that allows undamaged regions of the brain to compensate for the functions of damaged areas.[26] Recent studies indicate that repetitive, structured, and functionally meaningful exercises can stimulate cortical reorganization, ultimately improving motor and sensory recovery in post-stroke individuals.[24,27] One of the rehabilitation approaches utilizing repetitive movement principles is Constraint-Induced Movement Therapy (CIMT).

The START device applies a modified CIMT (m-CIMT) principle in which the affected limb is compelled to move while the unaffected limb is functionally restricted.[15] This modification integrates task-oriented and function-based exercises that enhance the rehabilitation process by optimizing the traditional CIMT method. Within the START system, functional restriction is achieved through exercises that target strength, coordination, and sensory integration. By engaging these modalities simultaneously, START aims to facilitate sensorimotor integration and movement accuracy, both of which contribute to improved functional recovery.[24]

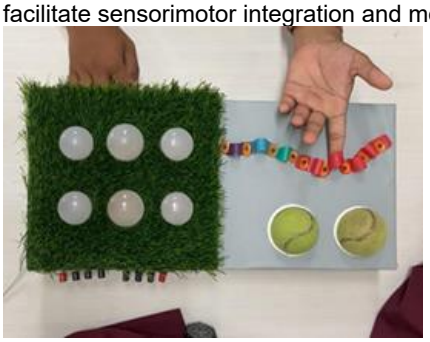

Figure 1. Exercise with rubber bands in the strength zone.

Figure 4 illustrates an example of strength training using rubber bands in the strength zone. The exercises incorporated in START are designed to stimulate the nervous system through three concurrent training zones—strength, coordination, and sensory stimulation—each supporting sensorimotor recovery in post-stroke individuals. The strength zone utilizes resistance media such as rubber bands and tennis balls to stimulate motor activation through repetitive muscle contractions, enhancing active range of motion (ROM). Resistance training has been shown to increase muscle tone, mass, and strength in weakened limbs.[28] Additionally, gripping exercises with tennis balls improve fine motor control and hand function essential for daily activities. This approach aligns with findings by Syamsuddin et al., who demonstrated that repetitive gripping exercises effectively enhance handgrip strength while being cost-efficient and feasible for home-based use.[17]

The coordination zone, involving visual stimuli from randomly illuminated lights operated by a therapist or caregiver, trains visuomotor integration, reaction time, and movement precision. Visual stimulation has been proven effective in improving coordination and upper-limb strength in post-stroke patients.[29] Meanwhile, the sensory zone provides tactile stimulation by differentiating between rough and smooth surfaces, aiding the recovery of tactile perception and proprioception. Such sensory stimulation promotes reorganization within the somatosensory cortex and enhances sensorimotor integration, thereby improving motor control in post-stroke individuals [30] Collectively, these exercises are expected to facilitate neuroplasticity—the formation of new neural connections—leading to functional recovery of motor, coordination, and sensory abilities.

In practical application, patient readiness must be carefully considered. Post-stroke individuals often experience decreased self-efficacy and lack of confidence, which may hinder participation in therapy.[11] Feelings of uncertainty or fear of failure can lead to premature cessation of exercises. Therefore, therapists and caregivers play an essential role in providing motivation and reassurance to strengthen patient confidence. When patients exhibit anxiety or hesitation during START therapy, it is advisable to first restore their emotional readiness before resuming training sessions.

Based on the Content Validity Index (CVI) analysis, the START device demonstrated high validity and feasibility for upper-limb rehabilitation to improve functional ability in post-stroke individuals. This finding is consistent with the work of Yusoff, who stated that a CVI value above 0.8 indicates an instrument's adequacy and scientific soundness for clinical application.[31] Accordingly, the high CVI values obtained in this study confirm that START's design aligns with neuroplasticity-based rehabilitation principles and holds strong potential for further development as a functional upper-limb rehabilitation tool. Theoretically, this reinforces the integrative approach to post-stroke rehabilitation, which combines motor, coordination, and sensory training as a unified intervention to stimulate brain plasticity simultaneously.

From a production standpoint, START was developed using readily available and low-cost materials to support scalability and affordability in future dissemination and commercialization. Consequently, START can be implemented by physiotherapists for mild to moderate stroke patients to train hand strength, coordination, and tactile sensation. Moreover, it supports home-based rehabilitation, which has been proven effective for upper-limb functional recovery in post-stroke patients [32] However, material durability and ergonomic refinement should be considered for future product development. The lower I-CVI value for ergonomic aspects suggests that, despite high overall content validity, further adaptation is needed to accommodate various hand sizes and ensure user comfort. Addressing these concerns may prevent muscle fatigue and improve exercise adherence.

In terms of accessibility and cost-effectiveness, START provides a more affordable alternative to robotic-based rehabilitation devices, which are typically expensive and require advanced facilities.[7] A literature review also highlighted that virtual reality (VR)-based exercises significantly improve upper-limb function and reduce fall risk in post-stroke patients.[2,33] However, not all individuals

are capable of operating VR systems due to technological limitations or unfamiliarity. START, with its simplicity, affordability, and user-friendly design, presents an ideal solution for individuals requiring upper-limb rehabilitation. It also serves as a practical therapeutic tool in primary care and community settings, extending the reach of physiotherapists in home-based rehabilitation programs.

Nevertheless, several limitations exist. The START device has not yet been clinically tested on a large-scale population, and expert involvement in the CVI assessment was limited. Furthermore, the current prototype lacks automation features, and ergonomic aspects require further optimization. Therefore, future research should focus on evaluating START's clinical effectiveness through large-scale experimental trials, comparing it with conventional rehabilitation or advanced technological approaches. In addition, involving a larger panel of experts will enhance the reliability and generalizability of validity assessments. Subsequent studies should also include field usability testing and analyses of the device's effectiveness and reliability.

Conclusion

The upper-limb rehabilitation device START (Stroke Therapy Assistance and Recovery Tools) demonstrated a very high level of content validity and strong feasibility for clinical use. The high Content Validity Index (CVI) values indicate that experts assessed START as being well aligned with the rehabilitation needs of post-stroke upper-limb recovery. This study also contributes to the development of neuroplasticity-based rehabilitation concepts by integrating strength, coordination, and sensory training within a single, simplified device. Furthermore, it offers innovation in modified Constraint-Induced Movement Therapy (m-CIMT)–based rehabilitation by combining these three training components—strength, coordination, and sensory stimulation—into a multifunctional, low-cost tool that supports continuous, home-based therapeutic interventions.

For future development, several improvements are recommended: the device should be made lighter to enhance portability, equipped with an automated random light feature in the coordination zone, and refined in terms of ergonomic design to ensure comfort and usability across diverse hand sizes. The implementation of START is expected to facilitate therapy adherence among post-stroke individuals by simplifying exercise routines, thereby promoting independence and improving quality of life. Moreover, START holds potential for broader application not only in home-based rehabilitation but also within rehabilitation centers, community health clinics, and hospitals, expanding its impact on upper-limb functional recovery among stroke survivors.

Author Contribution

Syazana Zahra Umardi: Conceptualization, Methodology, Investigation, Formal Analysis, Validation, Writing Original Draft, Writing Review and Editing
Samiyem: Visualization, Resources, Project Administration, Prototype Development
Arif Pristianto: Supervision, Methodology, Validation, Writing Review and Editing
Farid Rahman: Supervision, Validation, Writing Review and Editing

Acknowledgments

The authors gratefully acknowledge the Physiotherapy Study Program, Faculty of Health Sciences, Muhammadiyah University of Surakarta, for institutional support throughout this study. The authors also thank the physiotherapy experts who participated in the content validation process and provided valuable recommendations for improving the START rehabilitation device.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest regarding the publication of this study.

Funding Sources

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics Statement

This study involved the development and expert validation of a rehabilitation device prototype and did not involve human participants or animal subjects. Therefore, formal ethical approval was not required. All expert validators participated voluntarily and provided informed consent before the evaluation process.

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