King Saud University
Collage of Applied Medical Sciences
Department of Rehabilitation Health Sciences

The Effect of Robotic-Assisted Rehabilitation on Upper Limb Function in Patients with Stroke: A Randomized Controlled Trial

أثر التأهيل بمساعدة الروبوت على وظائف الأطراف العلوية لدى المرضى المصابين بالسكتة الدماغية: تجربة عشوائية مقيدة

A Thesis submitted in Partial Fulfillment of the Requirement for the Master's Degree in Physical Therapy

Submitted by

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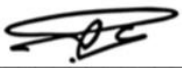

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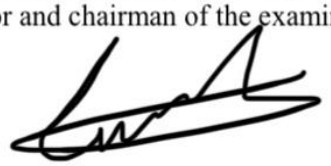

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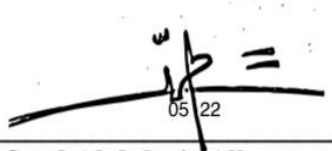

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Abstract

Introduction: Approximately 85% of patients after stroke subsequently suffer from loss of upper limb function, leading to low quality of life and restricted activities of daily living. Upper limb function improvement is the primary rehabilitation goal for such patients, and robotic rehabilitation technologies are increasingly being used in motor and cognitive impairment rehabilitation.

Objective: The purpose of this study is to examine the effect of adding robotic-assisted rehabilitation to conventional rehabilitation on upper limb functions compared to conventional rehabilitation for patients with subacute and chronic stroke.

Methodology: A randomized controlled trial was conducted among 24 patients with stroke, allocated into two groups: (1) robotic-assisted rehabilitation *and* conventional rehabilitation; and (2) conventional rehabilitation only. Both groups received 20 sessions (five times a week for four weeks). All patients were investigated two times, at baseline and post-intervention, using the Jebsen-Taylor Hand Function Test (JTHFT), Functional Independence Measures (FIMs), and JAMAR® Hydraulic hand dynamometer. Independent t-test and Mann-Whitney U test were used to compare between-group differences. A 2×2 (groups by time) mixed-design analysis of variance was used to examine mean differences between control and experimental groups. The Wilcoxon Signed Ranks Test was used to examine within-group differences.

Results: The 24 participating patients were distributed into two groups to evaluate and compare the effects of (1) four weeks of adding robotic-assisted rehabilitation to conventional rehabilitation (experimental group, n=13); and (2) conventional rehabilitation only (control group, n=11) among patients after stroke. Both groups exhibited statistically significant improvements in upper limb function, hand grip power, self-care, transfer, and cognition, as measured with selected outcome measures ($p<0.05$). We found no significant differences between the participants in two groups post-intervention.

Conclusions: Robotic-assisted rehabilitation combined with conventional rehabilitation in the same duration of daily rehabilitation during the subacute and chronic phases has similar effects to conventional rehabilitation alone in terms of upper limb motor function, hand power, and cognition. The outcomes support the use of robotic-assisted rehabilitation among rehabilitation tools for patients after stroke**.**

Dedications

To my dear mother, Munira, for endless encouragement and support throughout my life, and for continued prayers and blessings for me. To my brothers and sisters, for supporting me and being there when I need them

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List of Abbreviations

ADL	Activity of daily living
ANOVA	Analysis of variance
ARAT	Action Research Arm Test
BMI	Body Mass Index
CI	Confidence interval
CNS	Central nervous system
EBP	Evidence-based practice
FIM	Functional Independence Measure
FMA	Fugle-Meyer Assessment
ICH	Intracerebral hemorrhage
JTHFT	Jebsen-Taylor Hand Function Test
KFMC	King Fahad Medical City
MAS	Modified Ashworth Scale
MCID	Minimal clinically important difference
MI	Motricity Index
OT	Occupational therapy
PRM	Physical and Rehabilitation Medicine
PT	Physical therapy
PwS	Patients with stroke
QoC	Quality of care
QoL	Quality of life
RAR	Robotic-assisted rehabilitation

RCT	Randomized controlled trial
ROM	Range of motion
SAH	Subarachnoid hemorrhage
SBAHC	Sultan bin Abdulaziz Humanitarian City
SD	Standard deviation
SNOSE	Sequentially numbered, opaque, sealed envelopes
TCT	Trunk Control Test
ULF	Upper limb function
VR	Virtual reality

Chapter 1

Introduction

1.1. Study Background

Stroke is defined as "a neurological deficit attributed to an acute focal injury of the central nervous system (CNS) by a vascular cause, including cerebral infarction, intracerebral hemorrhage (ICH), and subarachnoid hemorrhage (SAH)".[1] Stroke accounts for an estimated 5 million deaths per year, and a large number of patients with stroke (PwS) complain of physical and cognitive impairments and disabilities.[2] Approximately 85% of Patient after stoke suffer from loss of upper limb function (ULF), leading to reduced quality of life (QoL) and restricted daily functions.[3] More than two-thirds of patients admitted at hospitals due to stroke have a motor impairment such as hemiparesis or hemiplegia, and about 50% of those comprise upper and lower limb impairments, with difficult recovery implications. Most PwS receive multidisciplinary rehabilitation, yet only 8-20% of patients fully recover the functionality of affected limbs post-rehabilitation.[2,4,5]

The loss of ULF fundamentally affects PwS' QoL and social participation,[6] and the improvement of ULF is the primary rehabilitation goal for such patients.[4] Cognitive impairments after stroke can affect patients' functional recovery and QoL, and fundamentally influence rehabilitation plans and long-term prognoses.[7] However, several studies have demonstrated that task-specific, repetitive, and high-intensity training may improve motor function in PwS.[8,9] Also, patients' engagement with rehabilitation programs is important.[10] High-intensity repetitive tasks therapy to improve ULF in PwS can be provided or augmented by robotic devices, which can also improve the upper limb range of motion (ROM) and active movements in PwS.[2]

Robotic rehabilitation technologies are increasingly used in motor and cognitive impairment rehabilitation.[11] A large number of published studies support the use of robotic rehabilitation for PwS as evidence-based practice (EBP) to improve upper limb motor function and activities of daily living (ADLs).[11] In addition, robotic rehabilitation can provide more intensive training and repetitive task-specific training than conventional rehabilitation.[8] Previous studies comparing robotic and conventional rehabilitation found the robotic rehabilitation effect to be greater than that of conventional rehabilitation,[5] while others showed there are no significant differences between robotic and conventional delivery methods.[12,13] However, such variations in the results of studies may be related to the duration, intensity, type of therapy, subject characteristics, and outcome measurements used in trials.[14]

Video game rehabilitation increases the activation of muscle for the upper limb, and gaming in general can make patients' performance more engaged, and reduce non-compliance, and consideration of ancillary compliance factors is considered an important dimension of quality of care (QoC) in modern healthcare services delivery.[15] Game-based exercises are a good option for PwS rehabilitation, leveraging the inherent appeal of video games as a motivating tool for rehabilitation.[16] Many studies suggested involving the use of gaming in upper extremity rehabilitation for PwS.[16] The use of robotic rehabilitation with visual gaming or virtual reality (VR) has been found to improve motivation repetitions and patient engagement with exercises and training.[17,18]

Several studies recommended the use of combining VR and robotic rehabilitation with PwS, to improve ULF and ADLs, having found that matching tasks to visual targets can improve patient training performance.[18,19] Dehem et al. examined the effect of upper limb robotic-assisted therapy in early stroke rehabilitation using one robotic device interaction with a video game combined with conventional therapy.[11] The intervention was delivered over four sessions

a week, over the course of nine weeks. The results showed that robotic-assisted therapy with conventional therapy is more effective than conventional therapy only to improve ULFs.

There are many therapeutic technology companies offering devices for robotic-assisted rehabilitation (RAR), including Tyromotion, which developed the robotic devices Diego®, for arm-shoulder rehabilitation; and Pablo®, for hand-arm rehabilitation).[20]

1.2. Study Rationale

Less than 20% of PwS fully recover their fully ULF.[14] Improved functionality is the most important objective for PwS' rehabilitation, to reduce upper limb disability and enable the resumption of normal life in to the best of the patients' ability.[21] Thus, there is a need for intervention enhancing function recovery for the PwS.[22] Robotic rehabilitation is an emerging and quickly developing treatment avenue, but there are existential variations in the results of robotic rehabilitation in PwS. Systematic reviews have shown differences in results and generally present low-quality evidence.[23] There is a need to conduct high-quality, targeted studies to develop a blueprint for EBP deployments of modern technologies in stroke rehabilitation, and this study seeks to contribute to this emerging research area.

1.3. Research Question

Does adding robotic-assisted rehabilitation to conventional rehabilitation improve ULF in post-stroke patients with subacute and chronic stroke at four weeks follow-up?

1.4. Aim and Objectives

The aim of this study is to examine the effectiveness of adding robotic-assisted rehabilitation to conventional rehabilitation on ULFs. To achieve this aim, it addresses four key objectives, namely to:

- Conduct a randomized controlled trial (RCT) to compare *conventional rehabilitation plus RAR* with *conventional rehabilitation* only for patients with subacute and chronic stroke.
- Conduct comparative analysis of functional independence measures (FIMs): Jebsen-Taylor Hand Function Test (JTHFT) affected hand, motor, self-care, transfer, social cognition, and "total" FIM.
- Compare between-group post-intervention differences.
- Compare within-group differences at baseline and four-week follow-up.

1.5. Hypothesis

Based on the current understanding gleaned from existing literature (as expounded in the following chapter), this study hypothesized that patients who receive robotic-assisted rehabilitation in addition to conventional rehabilitation have better ULF compared to those who receive conventional rehabilitation only. It is important to note that this study seeks to explore the possibility of *augmenting* (and not *replacing*) conventional rehabilitation with RAR.

1.6. Thesis Structure

This introductory chapter explains the background of stroke and existing treatment and rehabilitation services to contextualize the rationale for undertaking this study, whose research question, aim, objectives, and hypothesis are presented. Subsequently, Chapter 2 reviews existing literature pertaining to the definition and prevalence of stroke, the currently supported (EBP) rehabilitation programs for conventional post-stroke therapy, and the emerging scope and potentialities of RAR.

Chapter 3 then expounds the research methodology used to answer the research question, presenting the study design, data collection process (including setting and location), participant

inclusion and exclusion criteria, and sampling and recruitment methods. It also presents the conventional and RAR-assisted interventions used, and the primary and secondary outcome measures and equipment used to gather data, as well as the data analysis procedures. It also explains the ethical considerations undertaken in this project.

Chapter 4 subsequent presents the results of applying the adumbrated methods. It explores the socio-demographic and physiological characteristics of participants, and then unpacks the outcomes of the two studied groups in terms of the FIMs used. Comparative analysis of between-group post-intervention outcomes and within-group differences between baseline and follow-up is presented and described. Chapter 5 discusses these results in relation to existing literature, and concludes the thesis.

Chapter 2

Literature Review

2.1. Stroke Definition and Prevalence

Stroke, a neurological deficit related to CNS-intensive focal injury caused by avascular injury, is considered a major reason for disability and death worldwide.[1] It can also be characterized as a neurological disorder associated with blood vessel blocking, whereby clots occur in the brain, thereby restricting arterial blood flow. The resulting localized increase in blood pressure results in rupture, and the breaking of blood vessels during stroke in the cerebrum causes the sudden death of brain cells (and large parts of the brain) due to the resultant lack of oxygen.[24] The brain is a particularly complex organ that controls the function of the body. In the event of a stroke preventing blood flow from reaching areas of the brain that regulate specific physical functions in the body, the associated body parts will not be able to function as normal.[24]

Stroke is the main cause of limb motor function impairment (e.g., hemiparesis and hemiplegia).[4] Impairment caused by a stroke can be classified into two major types: (1) impairment of body function, such as a significant deviation or loss in neuromusculoskeletal and movement function related to joint mobility, muscle power, muscle tone, and/or involuntary movements; and (2) impairment of body structures, such as a significant deviation in nervous system structure or strangulation. In the case of upper limb impairments requires a thorough assessment of particular needs and capabilities in order to provide appropriate care.[25] Impairment of upper limb motor functions affects individuals' ability to carry out many ADLs, which is likely to decrease independence and increase the care burden (on informal family caregivers in addition to healthcare professionals).[26]

2.2. Rehabilitation Programs

Most rehabilitation programs focus primarily on the lower limbs, in order to enable patients to resume walking and attain greater mobility (e.g., techniques to regain normal gait function), with insufficient attention to upper limb rehabilitation.[27] However, upper limb function improvement is essential (for those affected in the upper limbs) in order to decrease disability in PwS.[21] Motor function recovery refer to restore patients' muscle activation patterns.[21] The fact that training and physical activity can help restore motor function in PwS has long been recognized.[28] Consistent with motor "learning" in healthy adults, this "relearning" process is mediated by neuroplasticity, which is defined as the ability of the CNS to undergo a structural and functional change in response to new experiences.[29]

Active movements of the upper limb can be restored and increased by focusing on neuroplasticity,[30] which is a major component of conventional therapy, which enables the substantial rehabilitation of up to 60% of patients.[27] Updated evidence on the effect of many intervention approaches, such as mirror, contrast-induced movement, VR, and high-intensity repetitive tasks therapies to improve ULFs in PwS note that high-intensity repetitive tasks can be provided or assisted by robotic devices, which can also improve upper limb ROM and active movements.[2]

2.3. Robotic Rehabilitation

Robotic rehabilitation devices are intervention tools that are developed to assist and to train performance for regaining limb functions.[31] A considerable number of studies have analyzed RAR in PwS, examining the effects of robotics rehabilitation alone or in combination with conventional therapy. Also, some recent stroke guidelines have begun to recommend using robots in addition to conventional rehabilitation.[14] Furthermore, a study investigating the effect of new technologies on upper limb motor, functional state, and cognitive outcomes in PwS

concluded that short-term two-week robotic rehabilitation or VR had a positive effect on upper motor recovery.[21]

Sale et al. evaluated the effect of robotic-assisted therapy compared to usual physical therapy (PT) on ULF during the subacute stroke phase over 30 sessions (Five days a week for six weeks).[32] They used the MIT-MANUS/InMotion2 (Interactive Motion technologies, Inc.,MA, USA) robotic device, they measured ULF using Fugl-Meyer Assessment (FMA) and Motricity Index (MI), and they found that robotic-assisted therapy enabled greater functional recovery in motor function than usual PT in early stage of therapy.[32]

Masiero et al. conducted an RCT to investigate early therapy with a novel robotic device that can enhance functional recovery and decrease hemiplegic or hemiparetic upper extremity motor impairment in patients with acute stoke.[33] They used a robotic device NeReBot in 25 sessions starting from one-week post-stroke. They measured ULF using FMA, FIM, Trunk Control Test (TCT), Modified Ashworth Scale (MAS), and Medical Research Council. They concluded that the group receiving robotic therapy in addition to conventional therapy showed greater functional ability improvements and decreased motor impairment compared to the conventional group.[33]

Carpinella et al. conducted a pilot RCT to assess the effects of robotic therapy and compared it to arm-specific PT in PwS.[34] They specifically analyzed arm function and motor strategies derived from upper limb instrumented kinematics, measured by FMA of the upper extremity, MAS, and FIM. They used planar robotic manipulandum (Braccio di Ferro, Celin s.r.l., Italy) for 45 minutes, five times per week, for 20 sessions They concluded that both RAR and arm-specific PT reduced arm impairments, but RAR was more effective in improving motor strategies as well as inducing larger improvements in coordination of shoulder/elbow, with

greater reduction of abnormal trunk movements. The benefits of RAR appeared to be more obvious in chronic patients.[34]

Qian et al. evaluated the training effects of device-assisted treatment for subacute PwS and compared them to the effects of traditional physical treatments, measured by FMA, MAS, the Action Research Arm Test (ARAT), and FIM. They used the EMg-Driven NMES-robot System for 60 minutes, five times a week, over 20 sessions, and concluded that the robotic-assisted (NMES-robot) training was effective for early upper limb rehabilitation for PwS and promoted ADL independence more than traditional PT.[35]

Zengin-metli et al. examined the effects of robotic rehabilitation on ULF, cognitive, and ADL outcomes in patients with subacute stroke.[36] They added robotic rehabilitation to conventional rehabilitation and compared it to conventional rehabilitation only. The intervention duration was the sessions was 30 minutes, five times, for three weeks, using the robotic device Armeo Spring HocomAG Inc. (Volketswill, Switzerland). They concluded that the addition of robotics to conventional rehabilitation had the same effect on motor function improvement and ADL in patients with subacute stroke.[36]

Taveggia et al investigated the effectiveness of robotic-assisted motion and activity in addition to Physical and Rehabilitation Medicine (PRM) for rehabilitation ULF recovery in PwS.[37] They added robotic therapy to conventional treatment and compared it to conventional treatment, using the Armeo Spring robotic device for 1 hour, five days per week, over six weeks. The found that robotics associated with RPM achieved similar outcomes to conventional rehabilitation for the treatment of disability, pain, and spasticity in upper limb impairment among PwS.[37]

Iris et al. conducted a pilot study to evaluate the utility of the set identified devices in clinical practice as well as compared robotic treatment with conventional therapy of the upper limb in PwS.[38] The robotic devices they used encompassed the Amadeo, Diego, and Pablo ones from Tyromotion, and Motore from Humanware (Pisa, Italy). The intervention was applied in 45-minute sessions on five days a week, for 30 sessions. The findings indicated that patients with subacute stroke in a robotic therapy group exhibited greater improvement in the Barthel index, FMA, and de-ambulation outcomes than those receiving conventional therapy.[38]

The same intervention was applied by Aprile et al., who examined the effect of robotic upper limb therapy using the Amadeo, Diego, and Pablo devices from Tyromotion, and the Motore devise from Humanware (Pisa, Italy), and compared outcomes with those receiving conventional therapy in 30 sessions (each lasting 45 minutes), five days per week.[14] They measured by FMA, MI , Medical Research Council, MAS, Neuropathic Pain Diagnostic Questionnaire, Numerical Rating Scale of Pain, Modified Barthel Index, Frenchay Arm Test, ARAT, and the 36-item Short-Form Health Survey. They concluded that robotics-assisted therapy improved ULF and activity, but there was no statistically significant difference in outcomes between subacute stroke patients in the robotic and conventional therapy groups.[14]

2.4. Summary

Stroke continues to be a massive problem of increasing prevalence and impacts on healthcare systems worldwide. A growing body of research has developed and explored the impacts of deploying modern robotics technologies in rehabilitation for various particular symptoms (i.e., impairments) among PwS. While many studies have examined the effect of robotic rehabilitation on ULF in PwS, most of them only used a single robotic device, albeit some did used multiple devices.

Most (though not all) of the reviewed studies found that RAR improved outcomes among PwS relative to conventional therapies. However, it should be noted that none of the reviewed studies sought to *replace* conventional therapy with RAR, and there is consensus that the augmentation of conventional therapy is the underling aim of research in this field.

To the best of our knowledge, no previous study examined the effect of adding RAR on conventional rehabilitation on ULF using two robotic devices Diego® and Pablo® devices (from Tyromotion, Austria) in a four-week intervention program for patients with subacute and chronic stroke (measured by JTHFT). Thus this study seeks to contribute new insights concerning robotic interventions among PwS.

Chapter 3

Methodology

3.1. Study Design

This study undertook an RCT, using parallel experimental and control groups, targeting a [1:1] ratio. An RCT manifests a quantitative epistemology grounded in positivist ontology. An experimental comparison is conducted under controlled conditions, with randomly allocated experimental and comparison groups, whose outcomes are compared to determine the effectiveness of an intervention (in this case, RAR among PwS). RCTs are considered to be the most robust and rigorous methodologies to support EBP with proof of the clinical effectiveness of treatments in clinical practice, with high-quality data supporting generalizable conclusions. They can also be used in subsequent systematic reviews and meta-analyses to generating increasing volumes of high-quality evidence to support decision-makers.[39]

3.2. Setting and Location of Data Collection

The study was conducted at the rehabilitation department at Sultan bin Abdulaziz Humanitarian City (SBAHC) and the rehabilitation department at King Fahad Medical City (KFMC), Riyadh, Saudi Arabia. Fieldwork was conducted from January 2022 to March 2024.

3.3. Sampling and Recruitment

Non-probability convenience sampling method was used to recruit participants eligible for participation. The inclusion and exclusion criteria for participants in this study are shown in Table 1. Eligible patients were inpatients recruited directly from the selected centers. The nature and scope of the study was explained in full verbally and in writing, after which they

were invited to participate. Those who wished to voluntarily participate gave full written informed consent (see section 3.12).

Table 1: Participant inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Male and female	Patients complaining of other neurological or orthopedic conditions affecting upper limb
Aged 18 years old and above	Patients unable to move the upper limb at all
First stroke suffered	Patients having clinically diagnosed psychological disorders
Time of onset from 1 to 24 months	Patients unable to interact with robotic devices due to severe cognitive problems
Patients can understand and follow instructions in Arabic or English	Patients with severe spasticity (Modified Ashworth Scale<2)

The total of 26 eligible participants who initially agreed to take part in this study were distributed equally into two groups: the experimental group (hereinafter "ExG") and the control group (hereinafter "CtG"). Thus, there were 13 patients each in the ExG and CtG, as per the original 1:1 target. However, two patients in the CtG subsequently withdrew, as they discontinued the intervention due to discharge from the hospital. The CONSORT flow diagram for the patient recruitment to completion process is shown in Figure 1.[40]

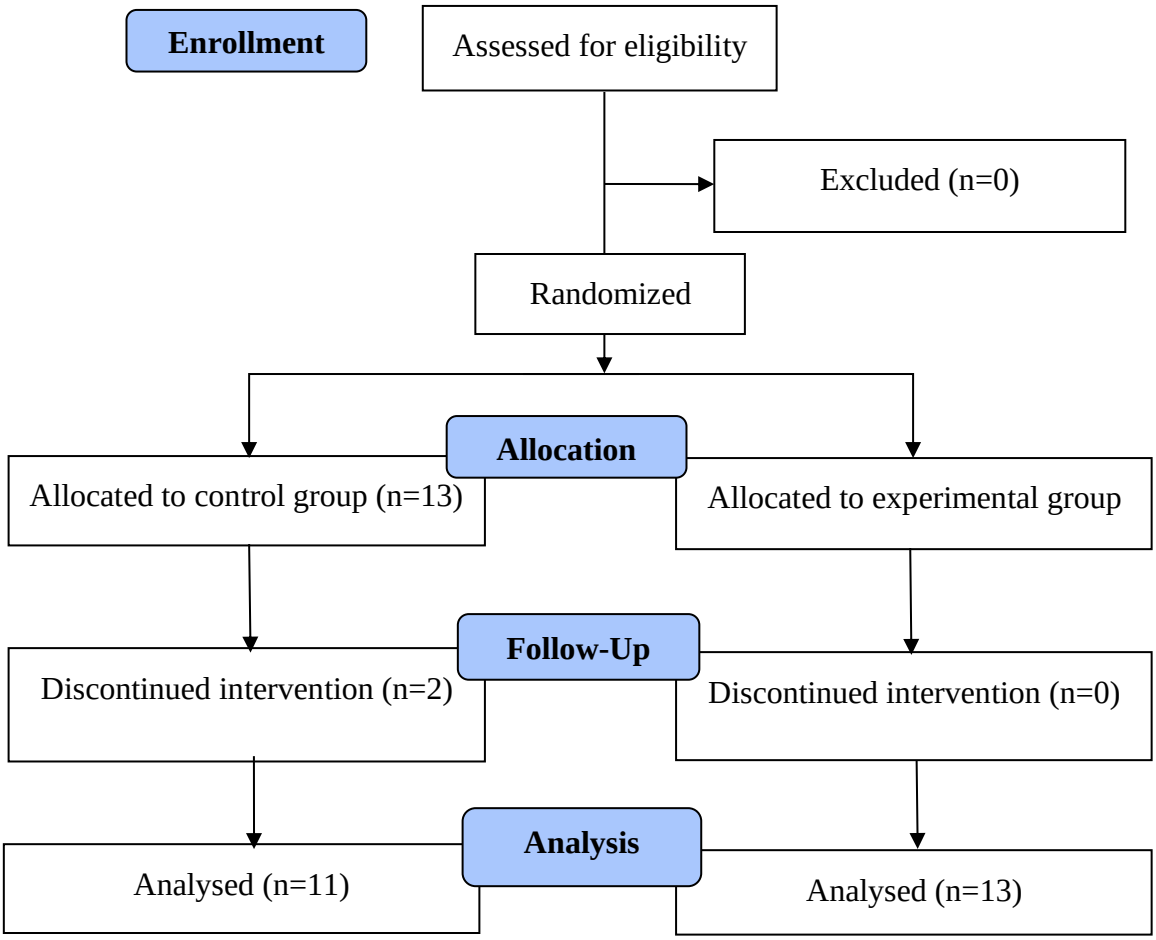

Figure 1: CONSORT patient flow diagram

3.4. General Data Collection

Participants' general data were collected from their medical records (with appropriate permissions) by the investigator. Their socio-demographic data were recorded, including sex, age, weight, height, body mass index (BMI), dominant hand, time of stroke onset, and affected side. The investigator assessed the eligibility and examined spasticity using MAS when participants were recruited. The collection of data concerning specific outcomes related to devices is explained in detail in the following sections.

3.5. Details of Interventions

3.5.1. Overview

The ExG received RAR for the upper limb in addition to conventional therapy, while the CtG received only conventional therapy. For the purpose of randomizing the patients, the block randomization method was used, with a block size of 4.[41] Sequentially numbered, opaque, sealed envelopes (SNOSE) were used for the allocation concealment scheme.[42] Both groups received 20 sessions (on five days a week for four weeks), including two hours of PT and occupational therapy (OT). The study was an open-label trial; patients were not blinded to the intervention allocation, and the investigators were unable to be blinded, because they were assessed patients and performed the intervention. All measures were investigated at the rehabilitation departments in selected centers two times, at the baseline of intervention (T0), and four weeks after the initiation of the intervention (T1).

3.5.2. Conventional Rehabilitation

All patients in both groups received conventional rehabilitation (PT and OT), including upper and lower limb rehabilitation. It should be noted that conventional rehabilitation programs were tailored to the needs of each patient (embodying the principle of beneficence, as per conventional norms), and thus varied slightly in particulars (though not in essence) between participants. The main components of conventional upper and lower limb rehabilitation as delivered in this study are displayed in Table 2.

Table 2: Conventional upper and lower limb rehabilitation therapy components

Conventional Upper Limb Rehabilitation	Conventional Lower Limb Rehabilitation
Active assisted ROM	ROM exercises
Strengthening exercises	Strengthening exercises
Hand function training	Functional training
Reaching exercises	Bed mobility training
Fine motor skills training	Task-specific training
Modalities	Transfer training
	Balance exercises
	Gait training
	Modalities

3.5.3. Robotic-Assisted Rehabilitation

Patients in the ExG received 30 minutes of upper limb rehabilitation with the following devices (explained in more detail in section 3.8):

- A robotic device that allows unsupported 3-dimensional movement of shoulder, elbow, and wrist joints (Pablo®, from Tyromtion, Austria).
- A robotic device that allows 3-dimensional movement of the shoulder joint with supported arm weight (Diego®, from Tyromotion, Austria).

Both devices aim to increase ULF, ROM, and muscle power. During training, patients perform motor and cognitive tasks that interact with visual and auditory feedback from devices by video games. The therapeutic program used is as follows:

- Pablo®: includes 1-dimensional and 2-dimensiona; game-based exercises (“highway”, and “chicken and worm”). Interaction with the game is based on grasping handle sensors with variable power as well as movements of elbow and wrist joints.

- Diego®: includes a game-environment (VR) exercises ("box and blocks", "hanging up the laundry", and "breaststroke"). Interaction with the game is based on the movements of shoulder and elbow joints.

Each device has more than one game with similar exercises and purposes. The therapist adapted the workspace and difficulty according to the patient's ability. During robotic training, each patient was supervised by one therapist. Both devices were used in all sessions, each device for 15 minutes, with five minutes' rest between the use of each of the two devices.

3.5.4. Duration of Treatment

The CtG and ExG received the rehabilitation therapies with durations displayed in Table 3.

Table 3: Duration of therapy components

Rehabilitation Type	Control Group	Experimental Group
Conventional lower limb rehabilitation	60	60
Conventional upper limb rehabilitation	60	30
Robotic-assisted rehabilitation	-	30

3.6. Primary Outcome Measure: Jebsen-Taylor Hand Function Test (JTHFT)

JTHFT developed by Jensen, and Taylor in 1969, is used widely for hand motor function assessment.[43] It has been demonstrated to have good validity, reliability, and responsiveness, and normative data for the test are available for all ages and genders of PwS.[43–46] The JTHFT is scored by times using a stopwatch to complete seven tasks, including: writing sentences, turning over cards, picking up small objects and placing them in a can, stacking checkers, moving large light cans, and moving heavy cans.[43] In this study, a sum time of seven tasks was used. The specific JAMAR® hand function test was used in this study.

3.7. Secondary Outcome Measures

3.7.1. Functional Independence Measure (FIM)

FIM is an outcome measure commonly used in stroke rehabilitation to assess function level, developed by the American Academy of Physical Medicine and rehabilitation in 1984. It is a valid, reliable and responsive outcome measure to PwS.[47,48] It includes 18 items over the motor and cognitive sub-scales, 13 items for motor (self-care, sphincter control, locomotion, and transfer), and five items for cognitive (communication and social cognition) dimensions. Each FIM item is scored from 1 to 7, ranging from 1 = "[require] total assistance" to 7 = "complete independence". The total score for FIM ranges between 18 and 126.[49,50]

3.7.2. JAMAR® Hydraulic Hand Dynamometer

The JAMAR® Hydraulic Hand Dynamometer is a gold standard outcome used to measure handgrip power. It is a valid, reliable and responsive outcome measurement for assessing grip power among PwS.[51] Patients were asked to sit with their shoulders in a neutral position with their arms at their sides and elbows flexed 90 degrees, with their wrists in a mild ulnar deviated position. After the subjects were positioned with the Dynamometer, they were asked to squeeze as hard as possible. Three trials were performed, and the outcomes were used to calculate the grip power (i.e., the mean of the grip score for the three trials).[52]

3.7.3. Modified Ashworth Scale (MAS)

MAS is a modified version of the Ashworth scale used in rehabilitation to assess muscle tone (spasticity). It is a valid, reliable, and responsive outcome measure to assess muscle tone in PwS.[53–55] MAS scores range from 0 to 4, where 0 means "no increase in muscle tone", 1 means "slight increase muscle tone, manifested by either a catch and release or minimal resistance at the end of the ROM", 1+ means "slight increase in muscle tone, manifested by a catch followed by minimal resistance throughout the remainder (less than half) of the ROM", 2 means "more

marked increase in muscle tone but the limb is easily flexed", 3 means "considerable increase in muscle tone, passive movement difficult", and 4 means "limb is rigid in flexion or extension". It is based on muscle resistance in response to passive movement provided by the investigator.[54] MAS was used as a screening outcome measure during recruitment.

3.8. Equipment

In this study, we used two robotic systems for upper limb rehabilitation, as described below.

3.8.1. Pablo® (from Tyromotion, Austria)

Pablo is a robotic system that uni-manual or bi-manual three-dimensional movement device, based on two sensors, and is able to record hand movement and forces to provide assistance. The therapist can control either force or motion in response to which the patient must flex and extend the finger, as well as undertaking movement of the shoulder, elbow, and wrist. Possible movements include shoulder abduction/adduction, elbow extension/flexion, forearm supination/pronation, and wrist dorsal extension/palmar flexion. The movement was performed through two additional tools in this study: multi-board and multi-ball. All the movements were unassisted.[7,14]

3.8.2. Diego® (from Tyromotion, Austria)

Diego is a robotic system that is uni-manual and bi-manual, which allows three-dimensional movement devices, and movements of the shoulder joint, with arm weight support. The devices can apply to unilateral and bilateral of upper limbs. They consist of two arm units that are suspended above the patient and allow for separate arm training. Two ropes pull the arm of the patient up at the wrist and elbow.[7,15] For patient safety, Diego has an emergency stop button (used in emergency cases, such as patient discomfort or distress, to stop the device).[20]

In both devices, patients can perform motor and cognitive tasks, and the devices provide training with visual games (i.e., video games) to improve patient satisfaction and compliance. The functional exercises based on video games are available on robotic devices. The interactive games improve function through the support of assistive forces provided by robotic devices without an external assistant.[7]

3.9. Data Analysis

The distribution of data was examined before analysis using the Shapiro-Wilk test. The data statistically be treated to show the means and standard deviations (SDs) of age, height, weight, BMI%, and time of stroke onset. To compare data on descriptive demographic characteristics, the Chi-square test was used. Differences between the ExG and CtG were examined using separate parametric and non-parametric test based on data distribution and homogeneity of variance. Mann-Whitney U was used to compare between-group differences in hand grip power, cognitive FIM, and communication FIM. T-tests for independent samples were used to compare between-group differences of JTHFT affected hand, self-care, transfer, motor, social cognition, and total FIM. A 2×2 (groups by time) mixed-design analysis of variance (ANOVA) was used to examine the mean differences between ExG and CtG. The Wilcoxon Signed Ranks Test was used to compare within-group references, with the level of significance at $P>0.05$. All analysis was conducted using SPSS Statistics for Windows, Version 25.0 (Chicago, USA).

3.10. Sample Size Estimation

The sample size needed in the current study was estimated using the statistical software G*Power 3.1.9.4 with the following combination: ANOVA repeated measure, within-between interaction, effect size (f) of 0.30, an alpha level of 0.05, power (1-β) of 0.80, with two groups

and 2 measurements and, non-sphericity correlation (Є) of 1. The estimated sample size was thus 24 patients, which was achieved.[56]

3.11. Ethical Approval

Prior to conducting any fieldwork, ethical approval was sought and obtained from SBAHC (No. 61-2022-IRB) (Appendix A) and KFMC (No. 23-178) (Appendix B), and the Deanship of Graduate Studies gave approval to commence the study (Appendix C). The nature and scope of the study was explained in full verbally and in writing in the participant information sheet (Appendix D), after which eligible participants were invited to participate. It was stressed that participation was entirely voluntary, and that participants could decline or subsequently withdraw from the study at any time without giving a reason, and that their healthcare services and statutory rights would not be affected at all by such choices. They were assured that all of their responses and all data collected in this study would be reported anonymously, with no personally identifying information. All eligible patients signed the written consent form before enrolling in this study, at SBAHC (Appendix E) and KFMC (Appendix F).

Chapter 4

Results

4.1. Socio-Demographic and Physiological Characteristics

From the total of 26 eligible participants who initially agreed to take part in this study (13 patients in the ExG and 13 in the CtG, as per the original 1:1 target), two patients in the CtG withdrew as they discontinued intervention due to discharge from the hospital; nevertheless, the study still had the required 24 participants to attain statistical power, as explained in the previous chapter. The mean and SD of the general characteristics are shown in Table 4.

Table 4: General characteristics of participants

	Control (mean±SD)	**Experimental (mean±SD)**	**P value**
Age (years)	53.45±17.45	57.85±10.58	0.46
Height (cm)	169.91±8.42	167.77±9.13	0.56
Weight (kg)	79.22±12.86	78±11.56	0.81
BMI (kg/m^2)	27.42±3.75	27.90±4.83	0.79
Onset time (months)	4.32±3.4	8.61±7.49	0.09

Table 5 shows the socio-demographic descriptive statistics concerning the participants. It can be seen that the majority in each group were male (ExG n=10; CtG n=9), and were receiving treatment at SBAHC (ExG n=11; CtG n=9). More than half of patients in the ExG were high school educated (n=6), while most of those in the CtG were university educated (n=7). The most dominant hand in patients in both groups was the right (ExG n=12; CtG n=9), and almost all patients in both groups were married (ExG n=10; CtG n=8) and all participants were living with their families. The vast majority of participants had experienced the ischemic stroke type (ExG n=10; CtG n=9). Moreover, more than half of patients suffered from left-hand

impairment (ExG n=7; CtG n=8). The general characteristics data were comparable, and there were no statistically significant differences between groups (P<0.05) (Table 4).

Table 5: Socio-demographic descriptive statistics (n=24)

Characteristics		**Control (n=11)**	**Experimental (n=13)**
Sex	Male	9	10
	Female	2	3
Hospital	SBAHC	9	11
	KFMC	2	2
Education	Primary	2	4
	Secondary	0	0
	High school	2	6
	Bachelor	7	2
	Postgraduate	0	1
Dominant hand	Right	9	12
	Left	2	1
Marital status	Single	3	1
	Married	8	10
	Divorced	0	1
	Widower	0	1
Living status	Alone	0	0
	With family	11	13
	Other	0	0
Stroke type	Ischemic	9	10
	Hemorrhage	2	3
Affected hand	Right	3	6
	Left	8	7

4.2. Study Variables

Chi-square testing revealed no statistically significant differences for sex (P=0.769) or stroke type (P=0.77). Moreover, Shapiro-Wilk test to examine the assumptions of normal distribution revealed no statistically significant differences in each group at baseline for most measures (P>0.05), with the exceptions of hand grip power, cognitive FIM, and communication FIM, for which statistically significant differences were observed (P<0.05). This indicates that some data violated the assumptions of normal distributions (Table 6 shows descriptive statistics for outcome measures at pre- and post-intervention).

Table 7 and Table 8 compare baseline data between the two groups. Baseline data that met the assumptions was tested using an independent t-test. It can be seen that there were no statistically significant differences between the groups in terms of their scores for JTHFT affected hand (t(22)= -0.104, P=0.92), motor FIM (t(22)= 1.509, P=0.15), self-care FIM (t(22)= 0.853, P=0.40), transfer FIM (t(22)= 1.593, P=0.13), social cognition FIM (t(22)= 0.757, P=0.46), and total FIM (t(22)= 1.433, P=0.17).

Baseline data that violated the assumptions were tested using the Mann-Whitney U test. No statistically significant differences were observed between groups in terms of hand grip power (u=65.000, p= 0.70), cognitive FIM (u=70.500, p= 0.95), or communication FIM (u=56.000, p= 0.30).

Table 6: Shapiro-Wilk normality test scores

Variables	Groups	Time	Shapiro-Wilk
Age	Control	-	0.63
	Experimental	-	0.30
Weight	Control	-	0.06
	Experimental	-	0.10
Height	Control	-	0.25
	Experimental	-	0.63
BMI	Control	-	0.33
	Experimental	-	0.17
Hand grip power	Control	Pre	0.001
		Post	0.08
	Experimental	Pre	0.000
		Post	0.001
JTHFT affected hand	Control	Pre	0.19
		Post	0.15
	Experimental	Pre	0.60
		Post	0.30
Motor FIM	Control	Pre	0.25
		Post	0.35
	Experimental	Pre	0.43
		Post	0.11
Self-care FIM	Control	Pre	0.25
		Post	0.34
	Experimental	Pre	0.38
		Post	0.46
Transfer FIM	Control	Pre	0.05
		Post	0.12
	Experimental	Pre	0.23
		Post	0.07

Table 6: Shapiro-Wilk normality test scores

Variables	Groups	Time	Shapiro-Wilk
Cognitive FIM	Control	Pre	0.012
		Post	0.000
	Experimental	Pre	0.05
		Post	0.001
Communication FIM	Control	Pre	0.000
		Post	0.000
	Experimental	Pre	0.001
		Post	0.000
Social cognition FIM	Control	Pre	0.18
		Post	0.001
	Experimental	Pre	0.06
		Post	0.001
Total FIM	Control	Pre	0.83
		Post	0.16
	Experimental	Pre	0.51
		Post	0.12

Table 7: Descriptive statistics for outcome measures (Median (Interquartile Range))

	Experimental		Control	
	Pre	Post	Pre	Post
JTHFT affected hand	77.08±45.99	57.21±37.67	79.19±53.72	60.86±47.23
Motor FIM	48±16.14	67.08±18.40	36.73±20.46	61.82±23.31
Self-care FIM	19.54±7.71	29.15±9.82	16.73±8.43	28.64±10.41
Transfer FIM	13.62±5.14	16.46±4.23	9.91±6.27	15.18±5.62
Social cognition FIM	17.69±3.03	19.31±2.39	16.64±3.80	10.09±2.91
Total FIM	81.38±17.81	99.38±19.71	69±24.45	94.36±26.66

Table 8: Descriptive statistics for outcome measures (Mean±SD)

	Experimental		Control	
	Pre	**Post**	**Pre**	**Post**
Hand grip power	2 (2.3)	3 (3.6)	3.10 (4.5)	5.50 (11.6)
Cognitive FIM	30 (9)	35 (7)	32 (8)	35 (3)
Communication FIM	14 (3)	14 (1)	14 (1)	14 (0)

4.3. Comparative Analysis of Functional Independence Measures

The studied variables were compared using ANOVA. The results are shown in Table 9, and the identified relationships between them are discussed below.

Table 9: Comparison between variables using 2×2 (groups by time) ANOVA

Variables	**Interaction**	**Time Main Effects**	**Group Main Effects**
JTHFT affected hand	F (1,22) =0.42 p=0.84	F (1,22) =26.22 p=<0.001	F (1,22) =0.02 p=0.88
Motor FIM	F (1,22) =1.13 p=0.30	F (1,22) =61.24 p=<0.001	F (1,22) =1.22 p=0.28
Self-care FIM	F (1,22) =0.67 p=0.42	F (1,22) =58.62 p=<0.001	F (1,22) =0.23 p=0.64
Transfer FIM	F (1,22) =2.61 p=0.12	F (1,22) =29.29 p=<0.001	F (1,22) =1.49 p=0.23
Social cognition FIM	F (1,22) =1.19 p=0.29	F (1,22) =27.91 p=<0.001	F (1,22) =0.29 p=0.60
Total FIM	F(1,22) =1.59 p=0.22	F (1,22) =55.16 p=<0.001	F (1,22) =1.03 p=0.32

4.3.1. JTHFT Affected Hand

There was no statistically significant impact of the intervention on JTHFT affected hand score (F (1,22) =0.042, P=0.88), but there was a statistically significant difference between scores at T0 and T1 (F (1,22) =26.218, P<0.001). Participants required less time to perform JTHFT affected hand at T1 compared to T0, as indicated by the effect size (Cohen's d= 1.07 (95 CI: 0.56 to 1.57)), with no statistically significant impact associated with group interaction (F (1,22) =0.042, P=0.84) (Figure 2).

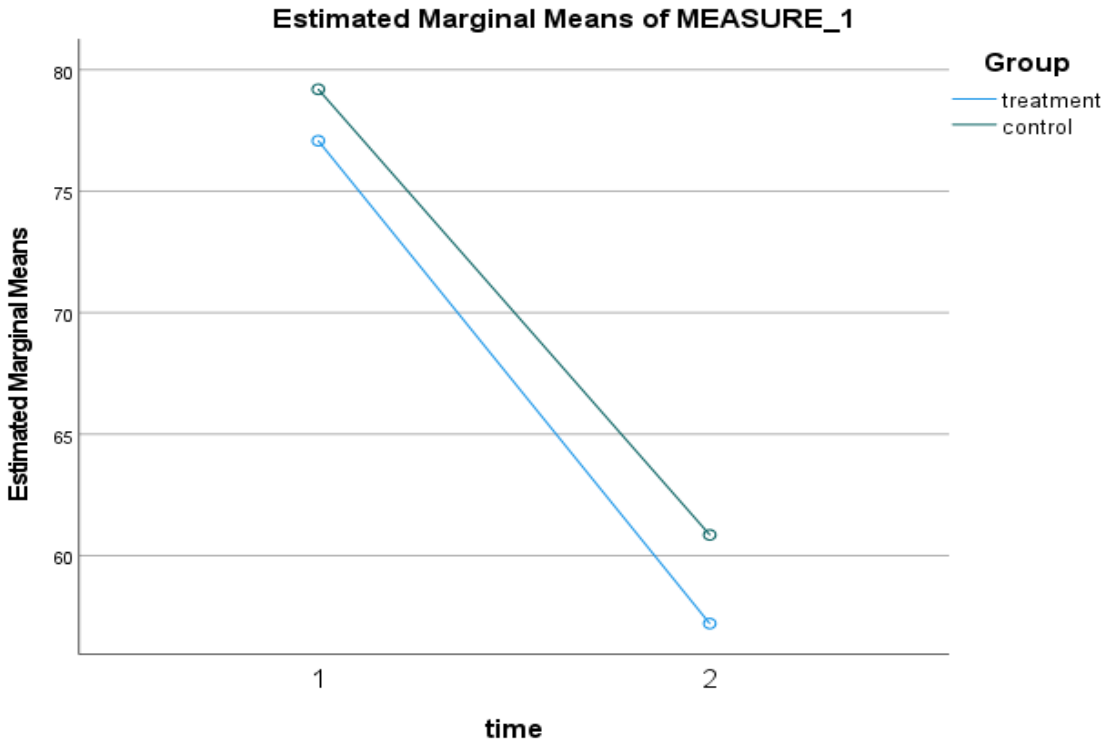

Figure 2: JTHFT test pre- and post-intervention primary and secondary outcomes

4.3.2. Motor FIM

There was no statistically significant impact of the intervention on motor FIM sub-scale score (F (1,22) =1.217, P=0.28), but there was a statistically significant difference between scores at T0 and T1 (F (1,22) =61.237, P<0.001). Participants improved at T1 compared to T0, as indicated by the effect size (Cohen's d= -1.58 (95 CI: -2.18 to -0.97)), with no statistically significant impact associated with group interaction (F (1,22) =1.135, P=0.30) (Figure 3).

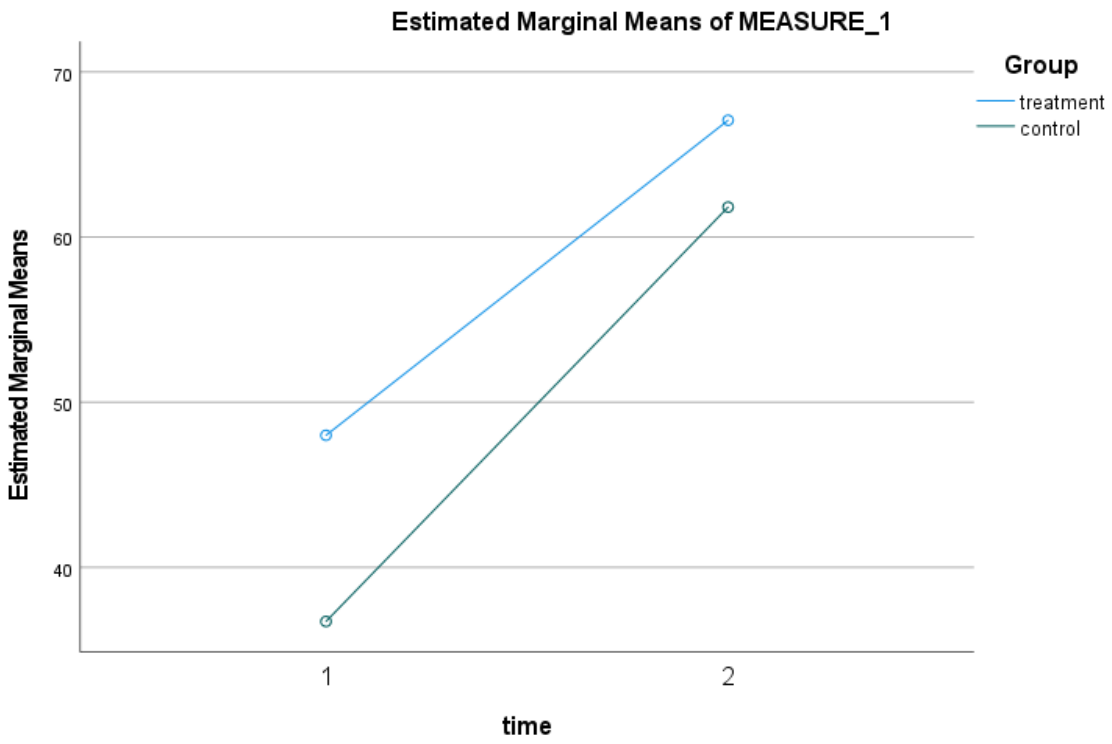

Figure 3: Motor FIM test pre- and post-intervention primary and secondary outcomes

4.3.3. Self-Care FIM

There was no statistically significant impact of the intervention on self-care FIM domain score (F (1,22) =0.231, P=0.64), but there was a statistically significant difference between scores at T0 and T1 (F (1,22) =58.622, P<0.001). Participants improved at T1 compared to T0, as indicated by the effect size (Cohen's d= -1.57 (95 CI: -2.16 to -0.96)), with no statistically significant impact associated with group interaction (F (1,22) =0.666, P=0.42) (Figure 4).

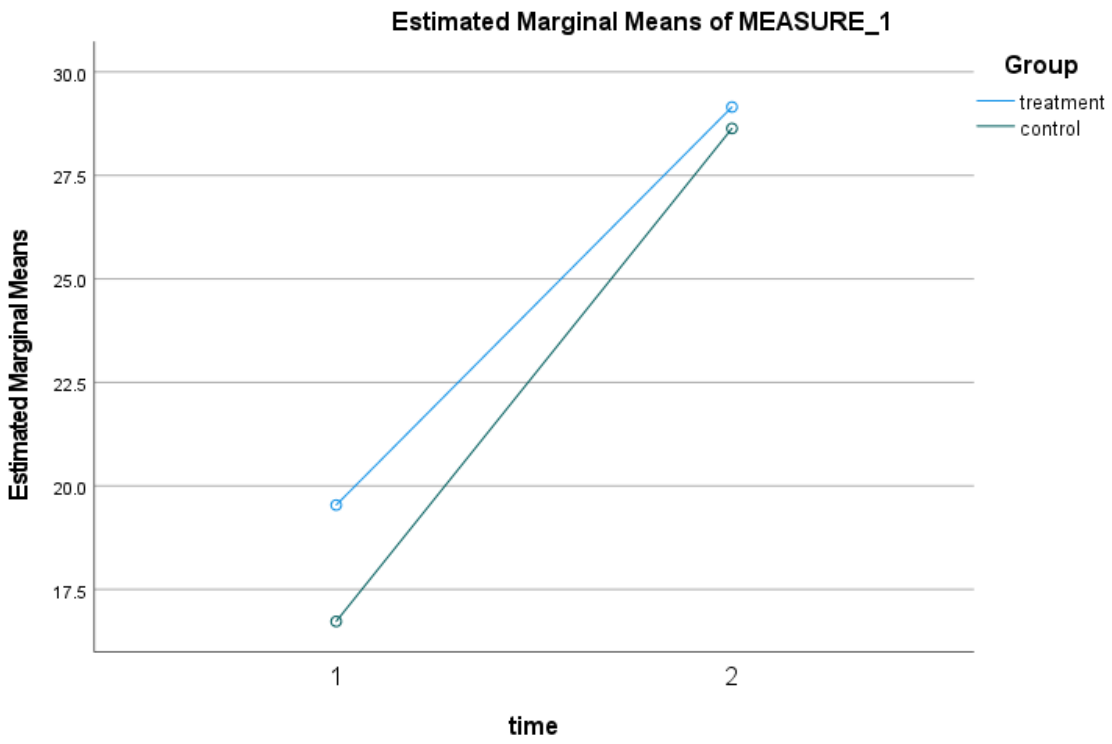

Figure 4: Self-care FIM test pre- and post-intervention primary and secondary outcomes

4.3.4. Transfer FIM

There was no statistically significant impact of the intervention on transfer FIM domain score (F (1,22) =1.491, P=0.23), but there was a statistically significant difference between scores at T0 and T1 (F (1,22) =29.203, P<0.001). Participants improved at T1 compared to T0, as indicated by the effect size (Cohen's d= -1.04 (95 CI: -1.54 to -0.54)), with no statistically significant impact associated with group interaction (F (1,22) =2.609, P=0.12) (Figure 5).

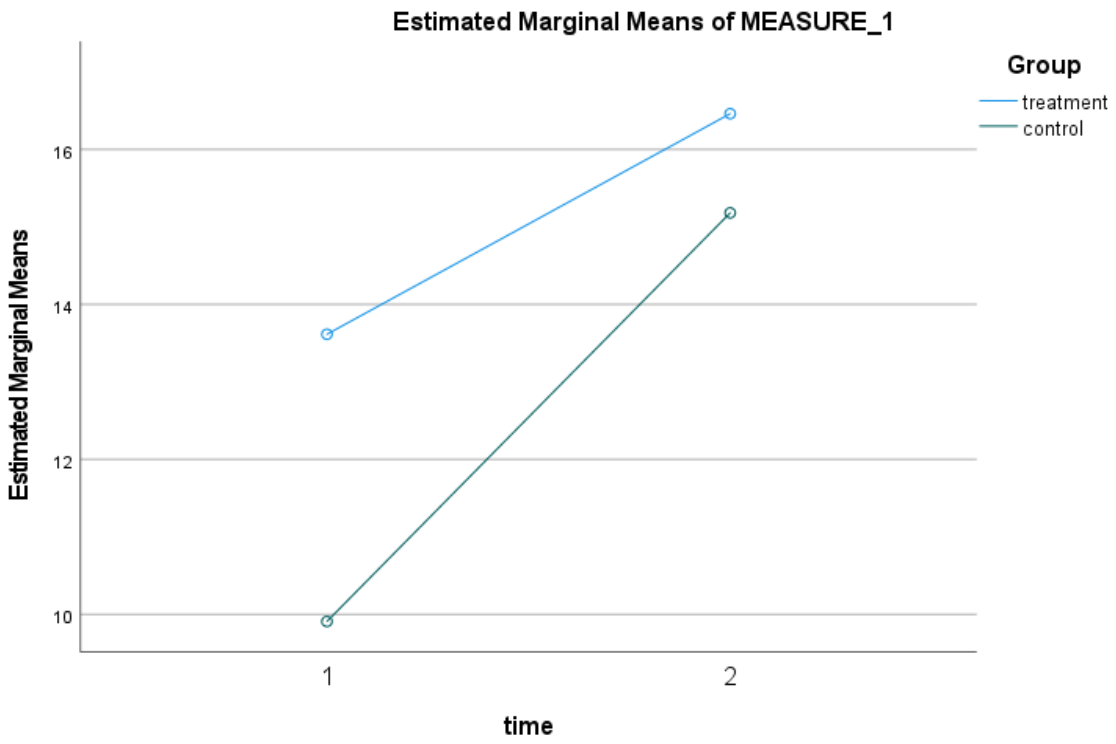

Figure 5: Transfer FIM test pre- and post-intervention primary and secondary outcomes

4.3.5. Social Cognition FIM

There was no statistically significant impact of the intervention on social cognition FIM domain score (F (1,22) =0.287, P=0.60), but there was a statistically significant difference between scores at T0 and T1 (F (1,22) =27.907, P<0.001). Participants improved at T1 compared to T0, as indicated by the effect size (Cohen's d= -1.06 (95 CI: -1.55 to -0.55)), with no statistically significant impact associated with group interaction (F (1,22) =1.186, P=0.29) (Figure 6).

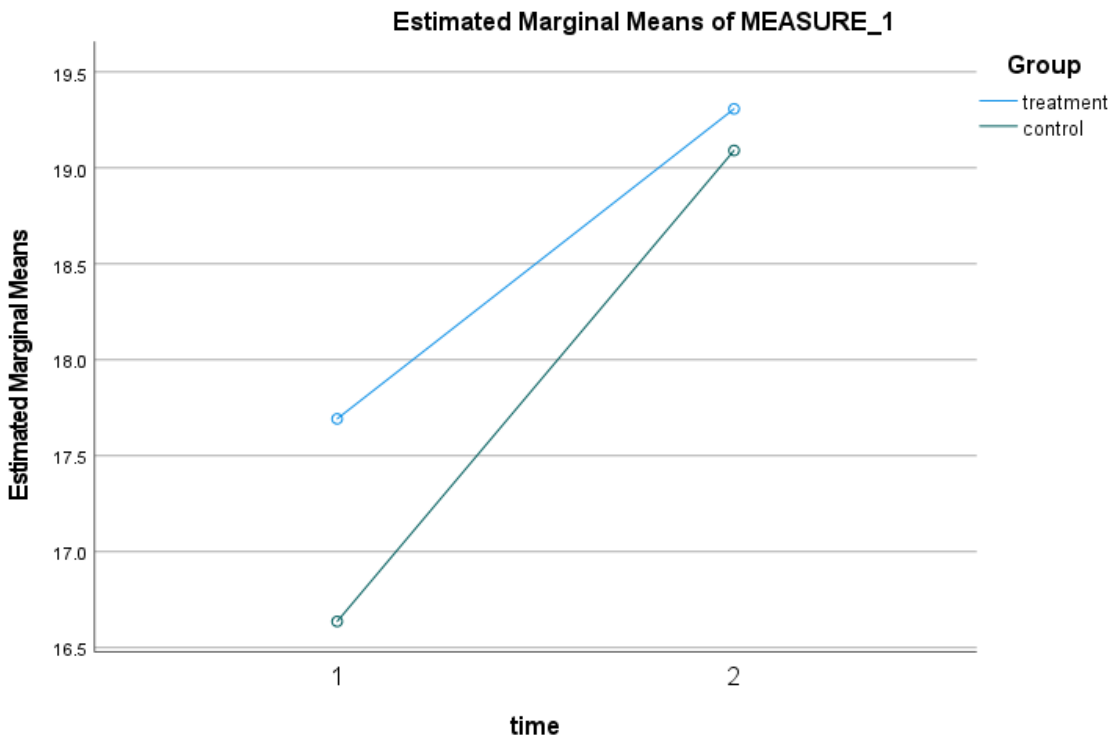

Figure 6: Social Cognition FIM test pre- and post-intervention primary and secondary outcomes

4.3.6. Total FIM

There was no statistically significant impact of the intervention on the total FIM score (F (1,22) =1.028, P=0.32), but there was a statistically significant difference between scores at T0 and T1 (F (1,22) =55.161, P<0.001). Participants improved at T1 compared to T0, as indicated by the effect size (Cohen's d= -1.48 (95 CI: -2.06 to -0.89)), with no statistically significant impact associated with group interaction (F (1,22) =1.591, P=0.22) (Figure 7).

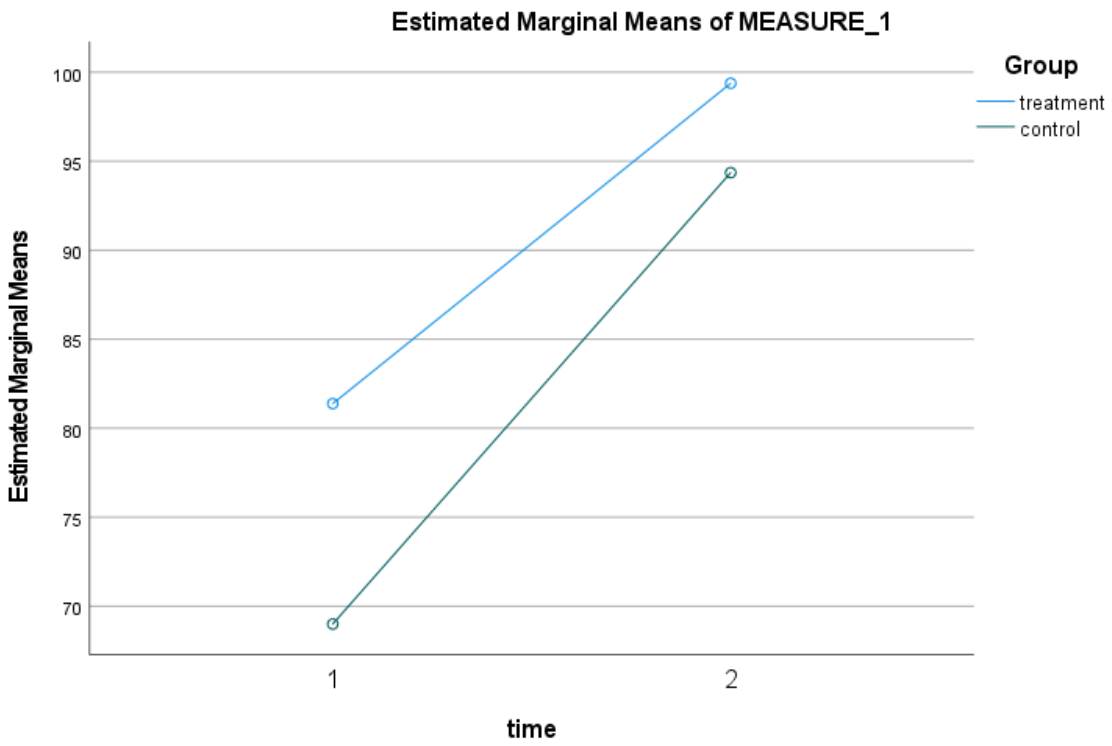

Figure 7: Total FIM test pre- and post-intervention primary and secondary outcomes

4.4. Comparative Analysis

Mann-Whitney U and Wilcoxon Signed Ranks tests were conducted to compare variables. The results are shown in Table 10, and the identified relations are discussed below.

Table 10: Comparison between variables using Mann-Whitney U test and Wilcoxon signed ranks test

Variables	Between group comparisons		Within group comparisons	
			Control	Experimental
Hand grip power	Pre	u=65.000, p=0.70	Z= - 2.552 p=0.01	Z= - 2.803 p=0.005
	Post	u=42.000, p=0.09		
Cognitive FIM	Pre	u=70.500, p=0.95	Z= - 2.384 p=0.02	Z= - 2.527 p=0.01
	Post	u=70.000, p=0.92		
Communication FIM	Pre	u=56.000, p=0.30	Z= - 1.633 p=0.10	Z= - 1.841 p=0.07
	Post	u=62.000, p=0.40		

4.4.1. Between-Group Post-Intervention Differences

For the non-parametric data, the Mann-Whitney U test was used for between-group differences post-intervention. The salient findings of this testing revealed that:

- Post-intervention hand grip power was not significantly different between groups (u=42.000, p= 0.09).
- Post-intervention cognitive FIM sub-scale scores were not significantly different between groups (u=70.000, p= 0.92).
- Post-intervention communication FIM domain scores were not significantly different between groups (u=62.000, p= 0.40).

4.4.2. Within-Group Differences

Wilcoxon Signed Rank test was used for testing within group differences. The salient findings of this testing revealed that:

- Hand grip power was significantly improved at post-intervention compared to baseline in the CtG as measured with the JAMAR hand grip dynamometer (Z= - 2.552, p= 0.01),

and was significantly improved at post-intervention compared to baseline in the ExG (Z= - 2.803, p= 0.005).

- Cognitive was significantly improved at post-intervention compared to baseline in the CtG as measured with cognitive FIM sub-scale score (Z= - 2.384, p= 0.02), and was significantly improved at post-intervention compared to baseline in the ExG (Z= - 2.527, p= 0.01).
- Communication was not significantly improved at post-intervention compared to baseline in the CtG as measured with communication FIM domain score (Z= - 1.633, p= 0.10), and was not significantly improved at post-intervention compared to baseline in the ExG (Z= - 1.841, p= 0.07).

Chapter 5

Discussion and Conclusion

5.1. Main Outcomes

PwS typically have severe impairments to their upper limb motor function and cognition, and they require appropriate rehabilitation programs in order to improve motor function, which thereby improves their QoL and diverse personal psycho-social and professional outcomes (e.g., enabling the resumption of normal social activities and returning to work).[57] The majority of PwS have impaired ULF, and have difficulty in performing ADLs independently.[9] To improve the functional ability of the upper limb in PwS, many rehabilitation techniques have been developed,[18] but it is difficult to empirically measure the effect of rehabilitation programs on PwS, and studies are lacking on effective techniques for EBP to enable patients to regain ULF.[21]

This study examined the effect of adding RAR to conventional rehabilitation on ULFs compared to solely using conventional rehabilitation techniques for PwS. We hypothesized that patients who would receive RAR and conventional rehabilitation would have better ULF compared to those who received only conventional rehabilitation, and tested this by studying FIMs to undertake comparative analysis. The participants (24 PwS) were assigned into two groups: 13 in the ExG and 11 in the CtG. All patients were relatively older adults (with mean ages of 57.58 and 53.45 years in the ExG and CtG, respectively). The majority of patients were male in both groups (76.92% ExG, 81.81% CtG). In the present study, the effect of four weeks of adding RAR to conventional rehabilitation was evaluated and compared to conventional rehabilitation only in PwS. We found no significant differences between the participants in

both groups post-intervention in the studied ULF, hand grip power, self-care, transfer, cognitive, and communications outcomes.

The mean differences in JTHFT affected hand between pre- and post-intervention were 19.87 seconds (ExG) and 18.33 seconds (CtG), with minimal clinically important difference (MCID) was reported for healthy people as 6.32 seconds for the dominant hand and 10.12 seconds for non-dominant hand.[58] Mean differences in total FIM score between pre- and post-intervention were 18 (ExG) and 25.36 (CtG), with CtG matching MCID (22).[59] The motor sub-scale FIM scores were 19.08 (ExG) and 31.09 (CtG), with both groups matching the MCID (17).[59]

Several studies have evaluated the efficacy of RAR compared to conventional rehabilitation. However, the majority of the studies examined the effect of RAR in conjunction with conventional rehabilitation. Moreover, some studies evaluated the effects of RAR alone compared to conventional rehabilitation. While such works cannot be compared with the current study directly, due to studying diverse and different populations, using varying particular techniques and outcome measures, most of them found significant improvements in ULFs in RAR similar to conventional rehabilitation.[9,14,60] Some studies found significant differences in ULFs post-intervention, but most of them were in the early stroke phase of rehabilitation.[11,33]

Variation between previous studies in intensity, duration of treatment, patient characteristics, type of treatment, and outcome measures were used, following recent meta-analysis.[5,14] Most previous studies in this field examined the effects of one robotic rehabilitation device compared to conventional rehabilitation, but most available robotic devices are targeted to act on a limited range of joints. Ideally, robotic devices that enable the treatment of the whole upper limb (from shoulder to hand) should be used.[14] Moreover, some studies examined the effects of four robotic rehabilitation devices,[14,38] which could lead to limiting the patient's ability to engage

with robotic rehabilitation and feel fatigued. In the current study two robotic rehabilitation devices was used to cover whole upper limb joint and functions, and to ensure patient engagement with the robotic rehabilitation devices.

Hand grip power, as measured with the JAMAR hand grip dynamometer, revealed no significant differences between both the studied groups, contrary to a recent study which found significant differences between the RAR group and the conventional rehabilitation group in hand strength as measured with the MI.[14] The MI outcome measure is used to measure hand strength that does not focus on the hand grip.

The current study's results affirm those of most previous works on RAR and conventional rehabilitation in terms of achieving improved ULF in patients with subacute and chronic stroke in similar improvements. A previous systematic review examined the effect of robotic therapy compared to usual care in motor control, functional independence, QoL, and upper limb performance of PwS, and found the same improvements in both groups, with no statistically significant differences between the robotic therapy group and the usual care group (i.e., equivalent to the ExG and CtG in this study).[61]

5.2. Strengths, Limitations, and Implications

This study shows the real effectiveness of RAR combined with conventional rehabilitation in patients after subacute and chronic stroke recruited in rehabilitation centers, reflecting the intrinsic utility of the methods adopted to effectively answer the research question, and achieve the research objectives.

Nevertheless, this study has several limitations, notably in (1) using a medium effect size, (2) using a short term of intervention (i.e., four weeks), and (3) not using blinding for the allocation of patients and investigators for intervention and control groups. Consequently, it is advised to

conduct future studies with a smaller effect size, longer-term intervention programs, with at least a single-blinded trial. Additionally, most of the participants in each group were recruited from SBAHC (eleven and nine in the experimental and control groups, respectively); while this increases homogeneity, it would be preferable to include a larger sample of patients being treated at diverse rehabilitation centers across Saudi Arabia.

The results of the current study support the use of RAR combined with conventional rehabilitation in the same duration of daily rehabilitation during the subacute and chronic phases. This EBP recommendation is based on the similar effects of this treatment to conventional rehabilitation alone in terms of upper limb motor function, hand power, and cognition outcomes. This means that we can use RAR as a useful ancillary tool of rehabilitation for PwS. However, we need further studies with a small effect size to confirm the results of the current study and support clinical decision makers to adopt particular RAR for tangible clinical outcomes to improve QoC and patient outcomes.

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Appendix A: Sultan Bin Abdulaziz Humanitarian City Ethical Approval

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY

Date: 09/01/2022
IRB No.: 61-2022-IRB

To: Dr. Abdulrahman Alsubiheen
PI: "The Effect of Robotic-Assisted Rehabilitation on Upper Limb Function in Patients with Stroke: Open Label Randomized Controlled Trial"
King Saud University
E-mail: aalsubiheen@ksu.edu.sa

Subject:	Approval for Research No. 57/MSc/2022
Study Title:	"The Effect of Robotic-Assisted Rehabilitation on Upper Limb Function in Patients with Stroke: Open Label Randomized Controlled Trial"
Study Code:	57/MSc/2022
Date of Approval:	06/01/2022
Date of Expiry:	05/03/2023
Board approval:	All members except absentees

Dear Dr. Abdulrahman Alsubiheen,

Your Project has been approved and you have the permission to conduct this study following your submitted documents as follow:

1. Curriculum Vitae for the PI researcher
2. Letter from the researcher requesting SBAHC participation in the clinical study
3. Research proposal according to SBAHC IRB Guidelines
4. SBAHC Informed Consent Template (English/Arabic)
5. Research Obligatory Agreement. Available upon the completion of the other requirements

You are required to obey by the rules and regulations of the Government of Saudi Arabia, the SBAHC IRB Policies and procedures and the ICH-GCP guidelines. You have to note that this approval mandate responding to IRB's periodic request and surveillance result. Drawing your attention to the following:

- Amendment of the project with the required modification to providing Periodical report for this project specially when study extension is required or expiry before study completion

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY
لجنة أخلاقيات البحوث الطبية
Institutional Review Board (IRB)

- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the IRB as soon as possible
- Any serious unexpected adverse events should be reported immediately within 24 hours.
- Personal identifying data should only be collected when necessary for research.
- Secondary disclosure of personal identifiable data is not allowed.
- Monitoring: projects may be subject to an audit by the IRB at any time.
- The PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years.
- Data should be stored securely so that a few authorized users are permitted access to the database.

The IRB registered with the IRB KACST Registration No. H-01-R-090. It is authorized to conduct the ethical review of clinic studies and operates in accordance with ICH-GCP Guidelines and all applicable national/local and institutional regulations and guidelines which govern Good Clinical Practices.

For Future Correspondence, please quote the project number and project title above and you are requested to keep IRB informed about your study progress and submit project progress report every six (6) months. A final report should be provided upon completion of the study.

Wish you a success in your research project.

Yours sincerely,

Prof. Khalid Al-Rubeaan
Chairman-IRB
Sultan Bin Abdulaziz Humanitarian City

Appendix B: King Fahad Medical City Ethical Approval

مدينة الملك فهد الطبية
King Fahad Medical City

IRB Registration Number with KACST, KSA: H-01-R-012
IRB Registration Number with OHRP/NIH, USA: IRB00010471
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

May 23, 2023
IRB Log Number: 23-178
Department: Physical Therapy, Rehabilitation
Category of Approval: FULL

Dear Abdulaziz Alarfaj, Dr. Abdulrahman Alsubiheen, Abdulaziz Aljabrei,

I am pleased to inform you that submission dated April 9, 2023 for the study titled '**The effect of Robotic-Assisted Rehabilitation on Upper Limb Function in Patients with Stroke: Open Label Randomized Controlled Trial (RCT)**' was reviewed at the IRB meeting held on May 10, 2023 and was approved according to Good Clinical Practice guidelines.

Please be informed that in conducting this study, you as the Principal Investigator are required to abide by the applicable rules and regulations of the Government of Saudi Arabia (Royal decree 7/B/9512), the KFMC/IRB policies and procedures (CPP 1432-91), and the most recent version of the ICH Good Clinical Practice guidelines. Further, you are required to submit a Progress report every 6 months starting from the date of approval. Approvals are for 1 year and are renewable on submission of satisfactory 6-monthly reports. The approval of this proposal will automatically be **suspended on May 23, 2024** pending the acceptance of the end-of-year Progress Report. You also need to notify the IRB as soon as possible in the case of:

8. Any amendments to the project protocol, CRF, ICF, IB, and other related documents.
9. Sponsor visits, reviews, and notifications that should be brought to the attention of the IRB Chair.
10. Termination of the study.
11. Any serious unexpected adverse events within two working days (CPP 1432-91).
12. Any protocol violations or protocol deviations (CPP 1432-91).
13. Any event or new information that may affect the benefit/risk ratio of the proposal.
14. Any conflict of financial and non-financial interest (CPP 1435-23).

Please observe the following specific KFMC/IRB policies:

11. **Human Research Subject Protection** Training certification shall be submitted to IRB before start of the study.
12. **Consent**: The following KFMC/IRB policies shall be observed (1432-92: Guidelines and Procedures of Informed Consent for Clinical Research; 1435-68Re-Consenting in IRB Approved Research Studies; 1435-15 Informed Consent for Vulnerable Participants in Approved IRB Research Projects). Full disclosure to the participant and assurance of confidentiality and voluntary consent should be done. The participant shall write his/name and date and then sign The consent process

Saudi Arabia - Riyadh
King Fahad Medical City
Faculty of Medicine
Phone: 0112889999

المملكة العربية السعودية - الرياض
Institutional Review Board
Approved
Date: 23 MAY 2023

should be documented in the medical record and a copy of the consent form shall be kept in the medical record as well as the research file.

13. **Privacy and confidentiality**: The following KFMC/IRB policies shall be observed (1433-08 IRB Protected Health Information (PHI) for Research Subjects). Personal identifying data should only be collected when necessary for research. The data collected should only be used for this proposal. Data should be stored securely so that a few authorized users are permitted access to the database; secondary disclosure of personal identifiable data is not allowed.
14. **Drug and device trials: Permission must be obtained from the Saudi Food and Drug Administration before starting clinical trials** (1435-20 Registration of Clinical Trials with the Saudi Food and Drug Administration).
15. **Saudi Clinical Trial Registry:** Clinical trials require approval by SFDA before commencing data collection. This approval can be before, after or parallel to IRB approval. In addition, the trial must be registered at the Saudi Clinical Trials Registry at https://sctr.sfda.gov.sa/.
16. **The KFMC Investigational Drug Service (IDS)** clearance must be obtained and kept in the medical record and the research file (1432-431 Handling of Investigational Drugs).
17. **Sending biological specimens to laboratories outside the Kingdom must follow the guidelines** Article 6.4 of the Implementing Regulations of the Law of Ethics of Research on Living Creatures of 1437H-2015. A copy is available on request.
18. **Overseas genetic testing** of any specimens must have prior approval by KFMC IRB (1432-86 Regulations on Sending Human Tissue Abroad for Research Purposes).
19. **A research alert** must be entered by the principal investigator in the online hospital electronic medical record system.
20. **Publication:** You are required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

We wish you every success in your research endeavor.

Sincerely yours,

Institutional Review Board
Approved
23 MAY 2023

Dr. Hussam Sakkijha, FCCP, FACP, Diplomat, ABSIM
Chairman Institutional Review Board--IRB
Consultant, Critical Care, Pulmonary & Sleep Medicine
Adult ICU Department
Critical Care Services Administration
King Fahad Medical City
P.O. Box. 59046, Riyadh 11525
Kingdom of Saudi Arabia
(+966) 11 288 9999 Ext: 15789
Mobile #: 053-941-7297
E-mail: hsakkijha@kfmc.med.sa

Appendix C: Deanship of Graduate Studies Statement

وزارة التعليم العالي
جامعة الملك سعود
وكالة الجامعة للدراسات العليا والبحث العلمي
عمادة الدراسات العيا

إفادة

تفيد عمادة الدراسات العليا بجامعة الملك سعود بأنه تم اعتماد المقترح البحثي

للطالب / عبدالعزيز عبدالرحمن الجبري رقم جامعي / 442105310

كلية / كلية العلوم الطبية التطبيقية قسم / قسم التأهيل الصحي

الدرجة العلمية / ماجستير رقم الهوية/الإقامة / 1079681225

بعنوان

أثر التأهيل بمساعدة الروبوت على وظائف الأطراف العلوية لدى المرضى المصابين بالسكتة الدماغية تجربة عشوائية مقيدة

The Effect of Robotic Assisted Rehabilitation on Upper Limb Function in Patients with Stroke Randomized Controlled Trial RCT

نوع الاشراف	المرتبة العلمية	الاسم	الرقم الوظيفي
المشرف	أستاذ مشارك	عبدالرحمن محمد عبدالرحمن السبيهين	37850

الموفقات	رقم الجلسة	تاريخ الجلسة
موافقة القسم	8	1443/07/27
موافقة الكلية	11	1443/08/11
موافقة عمادة الدراسات العليا	32	1443/08/17

تاريخ الإصدار / 1445/08/20

الرقم التسلسلي / 10,267

ملحوظة:

معتمد من عمادة الدراسات العليا

Appendix D: Participant Information Sheet

يقوم المريض بتعبئة هذا النموذج

To be filled by the patient

الرجاء إكمال جميع المعلومات المطلوبة **التاريخ:**

Participant name:	اسم المشارك:
Age:	العمر:
Gender: ☐ Male ☐ Female	الجنس: ☐ ذكر ☐ انثى
Handedness: ☐ Right ☐ Left ☐ Ambidextrous	أي يد تعتبر المفضلة للقيام بأي عمل: ☐ اليمنى ☐ اليسرى ☐ كلتا اليدين
Social status: ☐Married ☐Single ☐Divorced ☐ Widowed	الحالة الاجتماعية: ☐ مطلق/ة ☐ متزوج/ة ☐ أعزب/عزباء ☐ أرمل/ة
Occupation:	الوظيفة:
المستوى التعليمي: Education level:	

فوق الجامعي Postgraduate ☐	جامعي University ☐	ثانوي High school ☐	متوسط Secondary ☐	إبتدائي Primary ☐

Living: ☐Alone ☐ With family ☐ Other (specify)……	السكن: أخرى (حدد)..... ☐ مع العائلة ☐ منفرد ☐

Appendix E: Sultan Bin Abdulaziz Humanitarian City Participant Consent Form

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY
RESEARCH & SCIENTIFIC CENTER

INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *
إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)*
(اشطب ما لا ينطبق)*

Patient's Nameplate:

Title of Proposal: The Effect of Robotic-Assisted Rehabilitation on Upper Limb Function in Patients with Stroke: Randomized Controlled Trial (RCT)	**عنوان البحث :** أثر التأهيل بمساعدة الروبوت على وظائف الأطراف العلوية لدى المرضى المصابين بالسكتة الدماغية: تجربة عشوائية مقيدة
Part I – Research Participant Information Sheet: You are invited to participate in a scientific research project	**الجزء الأول – معلومات للمشارك في البحث:** **ندعوك للمشاركة في بحث علمي**
A. Purpose of the Research is to increase general knowledge about	**أ. الغرض من البحث هو زيادة المعرفة عن**
the effect of adding robotic-assisted to conventional rehabilitation on upper limb functions comparing to conventional rehabilitation for patients with stroke.	**أثر إضافة التأهيل بمساعدة الروبوت الى العلاج التأهيلي الاعتيادي على وظائف الأطراف العلوي ومقارنته بالعلاج التأهيلي فقط لمرضى السكتات الدماغية**
B. Description of the Research:	**ب. وصف البحث:**
Randomized controlled trial, we will compare between two groups. The experimental group will receive robotic rehabilitation plus the conventional and control group will receive conventional rehabilitation only. Four weeks duration of the trial	تجربه عشوائية مقيدة ، يتم فيها مقارنة مجموعتين ، المجموعة التجريبية ستتلقى برنامج تأهيل بمساعدة الروبوت بالإضافة الى البرنامج التأهيلي الاعتيادي ، المجموعه المتحكمه ستتلقى برنامج تأهيلي فقط مدة التجربه أربعة أسابيع
D. Potential Benefits:	**د. الفوائد المحتملة:**
Increase upper limb function	**زيادة في وظائف الأطراف العلوية**
H. Compensation / Treatment: In the event of injury resulting from participation in the research study, Sultan Bin Abdulaziz Humanitarian City will make available to you, including admission, if required, its hospital facilities and professional attention. Financial compensation from SBAHC is not available.	**ح. التعويضات / العلاج:** في حالة حدوث أي ضرر لا قدر الله من جراء مشاركتك بهذه الدراسة ستتكفل مدينة سلطان بن عبدالعزيز للخدمات الإنسانية بتقديم العناية الطبية اللازمة أو التنويم في المستشفى إذا لزم الأمر ولكن لا تمنح المدينة أي تعويضات مالية.

For Official Use Only
INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *
(Cross out the not applicable)*

From: _____
To _____
RAC# _____

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)*
(اشطب ما لا ينطبق)*

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY
RESEARCH & SCIENTIFIC CENTER

INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

Patient's Nameplate:

I. Voluntary Participation: Participation in this study is voluntary. You will suffer no penalty nor loss of any benefits to which you are otherwise entitled should you decide not to participate. Withdrawal from this research study will not affect your ability to receive alternative methods of medical care available at (you will be informed about). Significant new findings that may come up during the course of the research study which might be reasonably expected to affect your willingness to continue to participate in the research study.	**ط. المشاركة التطوعية:** المشاركة في هذه الدراسة تطوعية وإذا قررت عدم المشاركة فانك لن تتعرض لأي مضايقات أو لفقدان حقك المشروع في المعالجة ، كما أن قرارك بالانسحاب من الدراسة لن يؤثر علي تلقيك لخدمة علاجية بديلة متوفرة في (مدينة سلطان بن عبدالعزيز للخدمات الانسانية). سيتم إبلاغك إن ظهرت من خلال سير البحث نتائج جديدة هامة قد تستدعي اعادتك النظر في رغبتك بالاستمرار في هذه الدراسة0
J. Confidentiality: Your identity and medical record, as a participant in this research study, will remain confidential with respect to any publications of the results of this study. Furthermore, your medical record may be reviewed by the SBAHC Institutional Review Board or the agency sponsoring this research in accordance with applicable laws and regulations.	**ي. السرية:** كمشارك في هذه الدراسة ستكون هويتك ومحتويات ملفك الطبّي سرية في جميع المنشورات المتعلقة بنتائج الدراسة، ويمكن الاطلاع عليه من قبل لجنة أخلاقيات البحوث أو الجهة الداعمة للدراسة في حدود النظم والقوانين المطبقة بهذا الخصوص
K. Contact Person(s): You may call the, Office of Research & Scientific Center at 562 0000, extension 1708, 8828 for general questions concerning research at or research subjects' rights. For any specific questions with regard to this study, or in the event of a research-related injury, please contact the PI Dr. Abdulrahman Alsubiheen telephone # 0562290178 Ext. _____, Pager # _____. You have the right to receive a signed copy of the consent form.	**ك. الأشخاص الذين يمكن الاتصال بهم:** يمكنك التواصل مع مركز الأبحاث على هاتف رقم 5620000 على التحويلة 1708 أو 8828 للإجابة على استفسارتك المتعلقة بالبحث أو بحقوق المشارك. وفي حالة وجود أسئلة محدّدة تتعلّق بهذا البحث أو في حالة حدوث أي إصابات بسبب الدراسة، نرجو الاتصال على الباحث الدكتور عبدالرحمن السبيهين على هاتف رقم ٠٥٦٢٢٩٠١٧٨، تحويلة رقم _____ أو جهاز نداء رقم _____. من حقك الاحتفاظ بنسخة موقعة من هذا الإذن

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(Cross out the not applicable)*

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

From: _____

To _____

RAC# _____

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY
RESEARCH & SCIENTIFIC CENTER

INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *
إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)*
(اشطب ما لا ينطبق)*

Patient's Nameplate:

PART II - Authorization for Administration of certain drugs, use of devices or performance of certain procedures to:	**الجزء الثاني: تفويض باستعمال علاج أو جهاز أو إجراء طبي:**
Patient Name: _____ MRN: _____	اسم المريض: _____ رقم الملف الطبي : _____
1. a I authorize Dr. Abdulrahman Alsubiheen and his/her associates at Name the hospital to administer the following (drugs, use the following devices or perform the following procedures)* during my treatment (or the treatment of the person named above for whom I am a legal representative)* **Robotic devices**	1-أ بهذا أفوض الدكتور: عبد الرحمن السبيهين أو أحد المشاركين معه في (مستشفى)باستعمال (الدواء أو الجهاز أو الإجراء الطبي)* التالي - خلال معالجتي الطبية (أو معالجة الشخص المذكور أعلاه والذي أمثله شرعاً كولي أمره)* **التأهيل بجهاز الروبوت**
1. I understand that the above-mentioned (drugs, devices or procedures) * are being studied to determine the extent to which they may be of value in treating my illness or condition (or the illness or condition of such patient named above, as the case may be).	2. أفهم بأن (الدواء ، أو الجهاز ، أو الإجراء)* المذكور أعلاه سيتم دراسته لمعرفة إلى أي حد قد يكون مفيداً لمعالجة الحالة التي أعاني منها (أو المرض والحالة التي يعاني منها المريض الذي أتولى أمره).

INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

Patient's Nameplate:

2. I acknowledge that I have (read, or had explained to me in a language I understand) the attached Research Participant Information sheet and that Dr. _____ has explained to me the nature and purposed of the (drugs, devices or procedures)* described in the Research Participant Information Sheet as well as any benefits reasonably to be expected, possible alternative methods of treatment, the attendant discomforts and risks reasonably to be expected and the possibility that complications from both known and unknown causes may arise as a result thereof. I have had the opportunity to ask any questions I had with respect to such (drugs, devices or procedures) * and all questions I asked were answered to my satisfaction.	3. أقر بأنني قد (قرأت أو قد شرحت لي بلغة أفهمها) جميع المعلومات المتعلّقة بالمشاركة بالبحث والمرفقة، وأن الدكتور/ _____ قد أوضح لي ماهية وطبيعة (الدواء أو الجهاز أو الإجراءات)* المذكورة في نموذج المعلومات للمشارك والغرض منها والفوائد المرجوة منها والطرق العلاجية البديلة لها والمخاطر والانزعاجات المتوقع حدوثها وكذلك احتمال حدوث مضاعفات لأسباب معروفة أو غير معروفة نتيجة لذلك. كما أنه قد أتيحت لي الفرصة الكافية لعرض الأسئلة فيما يتعلّق باستخدام (الدواء أو الجهاز أو الإجراء الطبي)* وتلقيت الإجابات الكافية عنها.
3. I understand that I am entitled for reimbursement for expenses incurred as a result of my participation in this study	4. من المفهوم لديّ بأنني قد استحق تعويضاً عن المصروفات التي قد أتكبدها جراء مشاركتي في هذه الدراسة.
4. I voluntarily accept the risks associated with the use of the above-mentioned drugs, devices or the performance of the above-mentioned procedures with the knowledge and understanding that the extent to which they may be effective in my treatment (or the treatment of the patient named above, has not been established, that there may be side effects and complications from both known and unknown causes and that these drugs, devices, or procedures may not result in cure or improvement.	5. إنني وبمحض إرادتي أقبل المخاطر المتعلقة باستخدام الدواء أو الجهاز أو الإجراءات المذكورة في هذا الإذن مع علمي وفهمي التام بأنه لم يتم بعد إثبات مدى فائدتها في(علاجي/ أو للشخص الذي أتولى أمره)*. وأنه قد تكون هناك مضاعفات وآثار جانبية متوقعة ولأسباب معروفة أو غير معروفة. إن هذه الأدوية أو الأجهزة أو الإجراءات الخاصة قد لا تؤدّي إلى تحسّن حالتي أو الشفاء التام منها.

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(Cross out the not applicable)*

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

From: _____

To _____

RAC# _____

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY
RESEARCH & SCIENTIFIC CENTER

INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

Patient's Nameplate:

5. I understand that I am free to withdraw this consent and discontinue experimental treatment with the above-mentioned drugs, devices or procedures at any time. The consequences and risks, if any, which might occur in the event I decide to discontinue such treatment have been explained to me. I understand that such withdrawal will not affect my ability to receive any medical care made necessary by the performance of such studies or to which I might be otherwise entitled.	6. وأفهم أن لي مطلق الحرية بسحب موافقتي وقطع المعالجة بهذا (الدواء/الجهاز/أو الإجراء التجريبي)* في أي وقت. وقد شرحت لي جميع العواقب والمخاطر المترتبة على انسحابي من الدراسة (إن وجدت). كما أفهم بأن انسحابي من هذه الدراسة لن يؤثر على حقي في تلقّي العناية الطبية اللازمة (كنتيجة للمشاركة في هذه الدراسة). أو التي تمنح للمشاركين بالدراسة أو التي أستحقها في الأحوال العادية.

CONSENT Subject: The research and procedures have been explained to me. I have been allowed to ask any questions and all my questions have been answered. I have read the consent and have had time to think about participating. I can ask any additional questions I may think of later. I may refuse to participate in the study, and I may quit being in the study at any time without any penalty and without affecting my health care. I have been given permission for the study doctor and sponsor to use and disclose my personal health information. I will receive a signed copy of this consent form. I agree to participate in this study. My agreement is voluntary. I do not have to sign this form if I do not want to be part of this research study.	**الموافقة** المشارك: تم توضيح البحث والإجراءات لي وقد سُمح لي بطرح أي سؤال وتمت الإجابة على جميع أسئلتي. قرأت الموافقة وفكرت في المشاركة ويمكنني طرح أي أسئلة إضافية فيما بعد. قد أرفض المشاركة في الدراسة وقد أنسحب منها في أي وقت دون عقوبة ولن يؤثر ذلك على رعايتي الصحية. أسمح لطبيب الدراسة والراعي باستخدام معلوماتي الصحية الشخصية والكشف عنها. سأستلم نسخة موقعة من نموذج الموافقة. أوافق على المشاركة في هذه الدراسة وموافقتي هي تطوعًا مني وليس مطلوبًا مني التوقيع على هذا النموذج إذا لم أرغب بالمشاركة في هذه الدراسة البحثية.
Subject Signature:	**توقيع المشارك:**
Date:	**التاريخ:**
Time: ☐ AM ☐ PM	**الوقت:** ☐ صباحًا ☐ مساءً

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(Cross out the not applicable)*

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

From: _____

To _____

RAC# _____

مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY
RESEARCH & SCIENTIFIC CENTER

INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)*

(اشطب ما لا ينطبق)*

Patient's Nameplate:

Person Obtaining Consent:	**الشخص الذي يحصل على الموافقة:**
I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.	لقد وضحت طبيعة الدراسة والغرض منها والمخاطر المتعلقة بها، كما أجبت على الأسئلة وسوف أجيب عليها بأقصى استطاعتي. سأسلم نسخة موقعة من نموذج الموافقة للمشارك.
Signature of Person Obtaining Consent:	**توقيع الشخص الذي يحصل على الموافقة:**
Date:	**التاريخ**
Time: ❑ AM ❑ PM	**الوقت:** ❑ صباحًا ❑ مساءً
Principal Investigator: Dr. Abdulrahman Alsubiheen	**الباحث المسؤول:** د. عبدالرحمن السبيهين
Signature of Principal Investigator:	**توقيع الباحث المسؤول:**
Date:	**التاريخ:**
Time: ❑ AM ❑ PM	**الوقت:** ❑ صباحًا ❑ مساءً

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INFORMED CONSENT FOR RESEARCH INVOLVING THE ADMINISTRATION OF (DRUGS, USE OF DEVICES OR PERFORMANCE OF PROCEDURES) *

(Cross out the not applicable)*

From: _____

To _____

RAC# _____

إذن ناف للجهالة بالموافقة على المشاركة في الأبحاث التي تتطلّب استعمال (دواء/جهاز/ أو إجراءات خاصة)* (اشطب ما لا ينطبق)*

Appendix F: King Fahad Medical City Participant Consent Form

وزارة الصحة مدينة الملك فهد الطبية King Fahad Medical City	**Institutional Review Board** **Consent Form for Full Review Studies**

IRB Log Number:			**رقم البحث العلمي:**
Subject or Study Number:			**اسم المشارك:**
Medical Record Number:		اثر التأهيل بمساعدة الروبوت على وظائف الأطراف العلوية لدى المرضى المصابين بالسكتة الدماغية:تجربة عشوائية مقيدة	**عنوان البحث العلمي:**
Study Title:	The Effect of Robotic-Assisted Rehabilitation on Upper Limb Function in Patients with Stroke: Open Label Randomized Controlled Trial (RCT)		
اثر التأهيل بمساعدة الروبوت على وظائف الأطراف العلوية لدى المرضى المصابين بالسكتة الدماغية:تجربة عشوائية مقيدة			**عنوان البحث العلمي:**
Principal Investigator:	Abdulaziz Suliman Alarfaj	عبدالعزيز سليمان العرفج	**الباحث الرئيس:**
Address:	Riyadh	الرياض	**العنوان:**
Telephone:	0544793465	0544793465	**رقم الهاتف:**

A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, and how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form and will be given a copy for your records. Throughout this consent form, "you" will refer to you or your child, as appropriate.	**سيشرح لك عضو من فريق البحث محتويات هذه الدراسة وتأثيرها عليك. و يصف هذا الإقرار إجراءات الدراسة ، والمخاطر والفوائد من المشاركة ، وكيفية الحفاظ على سرية المعلومات. الرجاء اخذ الوقت الكافي في طرح الأسئلة لكي تتخذ قرارك ما إذا كنت ستشارك أم لا. وهذه الموافقة تسمى الموافقة المستنيرة. إذا قررت المشاركة في هذه الدراسة ، سيطلب منك التوقيع على هذا الإقرار وستعطي نسخة لسجلاتك. وطوال هذا الإقرار اللفظ "أنت" سوف يشير إليك أو إلى طفلك ، حسب الاقتضاء.**

Why is this study being done (objectives)?	**لماذا تجري هذه الدراسة(الاهداف)؟**
The purpose of this study is to examine the effect of adding robotic-assisted to conventional rehabilitation on upper limb functions comparing to conventional rehabilitation for patients with stroke.	يؤمل من خلال هذا البرنامج زيادة وظائف الأطراف العلويه للمريض.

How many people will take part in this study?	**وكم عدد المشاركين في هذه الدراسة؟**
50	50

What will happen if I take part in this study?	**ماذا سيحدث إذا شاركت في هذه الدراسة ؟**
Will improve and increase upper limb function	بعد مشيئة الله سوف تزيد وظائف الأطراف العلوية للمريض

Study location:	**موقع الدراسة:**

Rehabilitation department in King Fahad medical city, Riyadh Kingdom of Saudi Arabia.	قسم إعادة التأهيل بمدينة الملك فهد الطبية بالرياض بالمملكة العربية السعودية.

What is expected of me during the study?	ما هو متوقع من خلال دراسة لي؟
Cooperation and adherence to the instructions provided by the treating specialist.	التعاون والالتزام بالتعليمات المقدمة من قبل الاخصائي المعالج.

How long will I be in the study?	ما هي مدة المشاركة في هذه الدراسة؟
4 weeks	٤ اسابيع

Can I stop being in this study?	هل أستطيع إنهاء المشاركة ؟
Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or you've decided to stop. He or she will tell you how to stop your participation safely. No one will try to get you to change your mind.	نعم. يمكنك أن تقرر التوقف في أي وقت. فقط اخبر الطبيب إذا قررت التوقف. ليوضح لك كيفية إنهاء مشاركتك بأمان. لا أحد سيحملك علي تغيير رأيك.

Are there risks if I stop being in this study?	هل هناك مخاطر متوقعة إذا أنهيت المشاركة في الدراسة ؟
No, there isn't any risks.	لا، لا يوجد أي أخطار.

What side effects or risks can I expect from being in the study?	ما هي المخاطر أو الآثار الجانبية التي يمكن حدوثها من جراء المشاركة في الدراسة؟
There isn't any risk or side effects	لا يوجد أي مخاطر او اثار جانبيه

Are there benefits to taking part in the study?	هل هناك فوائد من المشاركة في الدراسة ؟
Taking part in this study may or may not make your health better. While doctors hope the intervention will be more effective effects than the standard (usual) treatment, there is no proof of this yet.	قد تؤدي المشاركة في هذه الدراسة إلى تحسين صحتك أو عدم تحسينها. بينما يأمل الأطباء أن يكون التدخل أكثر فاعلية من العلاج القياسي (المعتاد) ، فلا يوجد دليل على ذلك حتى الآن.

What other options are there?	ما هي الخيارات الأخرى ؟
Instead of being in this study, you have these options: Continuation of the rehabilitation program provided by the hospital itself without adding the other program.	لديك خيارات أخري بدلا عن المشاركة في الدراسة: الاستمرار على برنامج التأهيل المقدم من قبل المستشفى نفسه دون إضافة البرنامج الأخر.

What happens if I am injured because I took part in this study?	ماذا يحدث لو أنني تعرضت للإصابة بسبب المشاركة في هذه الدراسة؟
It is important that you tell Abdulaziz Suliman Alarfaj if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at 0544793465 . If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by KFMC or the study sponsor, depending on a number of factors. KFMC and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board (IRB) at extension 26913.	من المهم أن تبلغ عبدالعزيز سليمان العرفج إذا كنت تظن انك قد تعرضت للإصابة بسبب مشاركتك في هذه الدراسة. يمكنك أن تبلغ الطبيب شخصيا أو الاتصال به علي 0544793465 . في حال تعرضك للإصابة سيكون والعلاج متاحا. ستقدم لك مدينة الملك فهد الطبية تكاليف العلاج، ويتوقف ذلك على عدد من العوامل. عادة لا تقدم مدينة الملك فهد الطبية أو ممول الدراسة أي شكل آخر من أشكال التعويض عن الضرر. وللحصول على مزيد من المعلومات عن هذا الموضوع، يمكنك الاتصال بمكتب المؤسسي استعراض المجلس (IRB) علي الرقم 26913.

What are the costs of taking part in the study?	وما هي تكاليف المشاركة في الدراسة؟
You will not be charged for any study activities.	لن تتحمل تكاليف أي من أنشطة الدراسة.

Will I be paid for my taking part in this study?	هل سأتقاضى اجر نظير المشاركة في هذه الدراسة ؟

☐ In return for your time, effort and travel expenses, you will be paid _____ for taking part in this study. ☒ You will not be paid for taking part in this study.	☐ في مقابل وقتك، جهدك ونفقات السفر سيدفع لك _____ ، للمشاركة في هذه الدراسة. ☒ أو، لن يكون هناك اجر.

Will my medical information be kept private?	**هل سيتم الحفاظ علي المعلومات الطبية الخاصة بي بسرية ؟**
We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.	سنبذل قصارى جهدنا للتأكد من أن المعلومات الشخصية في سجلك الطبي تحظى بالسرية. ومع ذلك ، لا يمكننا أن نضمن الخصوصية التامة. يمكن أن يفصح عن معلوماتك الشخصية إذا اقتضى الأمر وذلك بموجب القانون. لن يتم الإفصاح عن اسمك أو المعلومات الشخصية إذا تم نشر نتائج هذه الدراسة نشرت أو عرضت في الاجتماعات العلمية.

What are my rights if I take part in this study?	**ما هي حقوقي إذا وافقت على المشاركة في هذه الدراسة ؟**
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from KFMC. Dr. Abdulrahman Alsubiheen may use information that was collected prior to your leaving the study. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.	قرار المشاركة في هذه الدراسة من اختيارك. لك حرية اختيار المشاركة في هذه الدراسة أو لا .كما يمكنك إنهاء المشاركة في أي وقت. مهما كان قرارك ، لن يكون هناك أي عقوبة و لن تفقد أي من الفوائد العادية الخاصة بك. ترك الدراسة لن يؤثر علي الرعاية الطبية المقدمة لك من مدينة الملك فهد الطبية. الدكتور عبدالرحمن السبيهين قد يستخدم المعلومات التي تم جمعها قبل أن تترك لدراسة. ونحن سوف نبلغك بكل المعلومات والمستجدات أو التغييرات في الدراسة التي يمكن أن تؤثر على صحتك أو على استعدادك لمواصلة الدراسة. وفي حالة الإصابة الناتجة عن هذه الدراسة ،بتوقيع هذا الإقرار, لن تفقد أيا من الحقوق القانونية في طلب التعويض.

Who do I call if I have questions or problems?	**بمن يمكنني الاتصال إذا كانت لدي أي أسئلة أو مشاكل ؟**

Institutional Review Board

Consent Form for Full Review Studies

Before you agree to be in this study, you will talk to a study team member qualified to tell you about this study. You can ask questions about any aspect of the research. If you have further questions about the study, you may ask them at any time. You may call the principal investigator at 0562290178	قبل أن توافق على المشاركة هذه الدراسة ،ستتحدث إلى احد أعضاء فريق دراسة المؤهلين ليخبرك عن هذه الدراسة . يمكنك أن تطرح الأسئلة حول أي جانب من جوانب البحث. إذا كان لديك المزيد من الأسئلة عن الدراسة ،يمكنك السؤال في أي وقت. يمكنك الاتصال الباحث الرئيس علي الرقم 0562290178 .

CONSENT:

Subject/Guardian (if the subject is minor):

The research and procedures have been explained to me. I have been allowed to ask any questions I have at this time. I can ask any additional questions I may think of later. I may quit being in the study at any time without affecting my health care.

I will receive a signed copy of this consent form.

I agree to participate in this study. My agreement is voluntary. I do not have to sign this form if I do not want to be part of this research study.

إقرار بالموافقة:

المشارك:

لقد تم شرح البحث والإجراءات لي. وسمح ي بأن اسأل أي سؤال لدي في هذا الوقت. ويمكنني أن اسأل أي أسئلة إضافية في وقت لاحق. ويمكنني إنهاء المشاركة في الدراسة في أي وقت دون يؤثر ذلك علي الرعاية الصحية المقدمة لي.

سأحصل علي نسخة موقعة من هذا الإقرار بالموافقة.

إنا اقر بالموافقة على المشاركة في هذه الدراسة. موافقتي طوعية, ولست بحاجة إلى التوقيع على هذا الإقرار إذا كنت لا أريد المشاركة في هذه الدراسة البحثية.

Subject Signature: _____ **توقيع المشارك:** _____

Date: _____ **التاريخ:** _____

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص **الوقت:** _____

Witness Signature: _____ **توقيع الشاهد:** _____

Date: _____ **التاريخ:** _____

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص **الوقت:** _____

Person Obtaining Consent:

I have explained the nature and purpose of the study and the risks involved. I have answered and will answer questions to the best of my ability. I will give a signed copy of the consent form to the subject.

الشخص الحاصل على الموافقة:

لقد شرحت طبيعة الدراسة والغرض منها وما تنطوي عليه من مخاطر. وقد أجبت وسأجيب علي الأسئلة على أفضل قدر من استطاعتي. سأعطي نسخة موقعة من الإقرار بالموافقة إلي المشارك المذكور أعلاه.

Signature of Person Obtaining Consent: _____ **توقيع الشخص الحاصل علي الإقرار بالموافقة:** _____

Date: _____ **التاريخ:** _____

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص _____ :الوقت

Principal Investigator: **الباحث الرئيس:**

Signature of Principal Investigator: _____ _____ :توقيع الباحث الرئيسي

Date: _____ _____ :التاريخ

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص _____ :الوقت

Stamp Stamp

[STOP! Do not use the following signature lines unless third party consent is being requested.]

[قف! لا تستخدم خطوط التوقيع التالية إلا إذا طلبت موافقة طرف ثالث]

AND/OR: **و / أو:**

Legally Authorized Representative Signature: _____ _____ :الممثل المخول قانونا

Date: _____ _____ :التاريخ

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص _____ :الوقت

Person Obtaining Consent: _____ _____ :الشخص الحاصل على الموافقة

Date: _____ _____ :التاريخ

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص _____ :الوقت

OR **أو**

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

الشخص المعني بالدراسة غير قادر على الموافقة بنفسه لأنه / إنها قاصر. من خلال التوقيع أدناه، أنت تعطي إذنك لطفلك بان يضمن في هذه الدراسة.

Parent or Legal Guardian: _____ _____ :الأبوين أو الوصي قانونا

Date: _____ _____ :التاريخ

Time: _____ ☐ AM ☐ PM ☐ م ☐ ص _____ :الوقت

ملخص البحث

Arabic Abstract

مشكلة البحث: يعاني ما يقرب من ٨٥% من المرضى بعد الإصابة بالسكتة الدماغية من فقدان وظيفة الطرف العلوي، مما يؤدي إلى انخفاض جودة الحياة وتقييد الوظائف اليومية. إن تحسين وظيفة الطرف العلوي هو الهدف الأساسي لإعادة التأهيل للمرضى بعد السكتة الدماغية. يعد إعادة التأهيل باستخدام الروبوت أحد تقنيات إعادة التأهيل التي يتم استخدامها بشكل متزايد في إعادة تأهيل الإعاقة الحركية والإدراكية.

الأهداف: الغرض من هذه الدراسة هو دراسة تأثير إعادة التأهيل بالطريقة التقليدية بإضافة مساعدة الروبوت على وظائف الطرف العلوي مقارنة بإعادة التأهيل التقليدية للمرضى الذين يعانون من السكتة الدماغية تحت الحادة والمزمنة.

طريقة البحث: تم تصميم الدراسة كتجربة مراقبة عشوائية. ٢٤ شخصا يعانون من السكتة الدماغية. تم تقسيمهم إلى مجموعتين، مجموعة تتلقى إعادة التأهيل التقليدي بالإضافة إلى المساعدة الروبوتية، ومجموعة تتلقى إعادة التأهيل التقليدي فقط. تلقت كلا المجموعتين ٢٠ جلسة (٥ مرات في الأسبوع لمدة اربع اسابيع). تم فحص جميع المرضى مرتين قبل البدء بالتأهيل وبعد الانتهاء من التأهيل باستخدام مقياس جيبسن تايلور لوظائف اليد و مقياس الاستقلال الوظيفي ومقياس قوة اليد الهيدروليكي. تم استخدام اختبار تي لعينتين مستقلتين واختبار مان ويتني لمقارنة الاختلافات بين المجموعة. تم استخدام اختبار تحليل التباين الثنائي 2×2 (المجموعات حسب الوقت) لفحص متوسط الفروق بين المجموعتين. تم استخدام اختبار ويلكوكسون لفحص الاختلافات داخل المجموعة.

النتائج: تم توزيع ٢٤ مريضًا على مجموعتين ١٣ مجموعة تجريبية ، ١١ مجموعة مراقبة، وتم تقييم تأثير أربعة أسابيع من إضافة المساعدة الروبوتية إلى إعادة التأهيل التقليدية مقارنة بإعادة التأهيل التقليدية فقط على المرضى بعد السكتة الدماغية. تتمتع كلا المجموعتين بتحسينات كبيرة في وظيفة الطرف العلوي، وقوة قبضة اليد، والرعاية الذاتية، والتنقل، والإدراك. لم نجد فروق ذات دلالة إحصائية بين كلا المجموعتين بعد العلاج.

الاستنتاج: إن المساعدة الروبوتية جنبًا إلى جنب مع إعادة التأهيل التقليدي في نفس مدة إعادة التأهيل اليومي خلال المراحل تحت الحادة والمزمنة لها تأثيرات مماثلة لإعادة التأهيل التقليدي وحده في الوظيفة الحركية للطرف العلوي، وقوة اليد، والإدراك. وهذا يعني أنه يمكننا استخدام المساعدة الروبوتية كأداة لإعادة تأهيل المرضى بعد السكتة الدماغية.

جامعة الملك سعود

كلية العلوم الطبية التطبيقية

قسم علوم التأهيل الصحي

أثر التأهيل بمساعدة الروبوت على وظائف الأطراف العلوية لدى المرضى المصابين بالسكتة الدماغية: تجربة عشوائية مقيدة

قدمت هذه الرسالة استكمالاً لمتطلبات درجة الماجستير في تخصص العلاج الطبيعي بقسم علوم التأهيل الصحي في كلية العلوم الطبية التطبيقية

إعداد:

عبدالعزيز عبدالرحمن الجبري

طالب ماجستير في تخصص العلاج الطبيعي

الرقم الجامعي: ٤٤٢١٠٥٣١٠

اشراف:

د.عبدالرحمن بن محمد السبيهين

تاريخ المناقشة: ٠٧-٠٥-٢٠٢٤م