THE EFFECTIVENESS OF SINGLE JOINT HYBRID ASSISTIVE LIMB (HAL-SJ) ROBOTIC EXOSKELETON THERAPY IN IMPROVING FUNCTIONAL OUTCOMES AMONG WORKERS WITH WRIST FRACTURES: A RANDOMIZED CONTROLLED TRIAL

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KEBERKESANAN EKSOSKELETAL ROBOTIK SINGLE JOINT HYBRID ASSISTIVE LIMB (HAL-SJ) DALAM MENINGKATKAN KEFUNGSIAN DI KALANGAN PEKERJA YANG MENGALAMI KEPATAHAN TULANG PERGELANGAN TANGAN: PERCUBAAN KAWALAN RAWAK

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TESIS YANG DIKEMUKAKAN UNTUK MEMPEROLEH
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KUALA LUMPUR
2026

DECLARATION

I hereby declare that the work in this thesis is my own except for quotations and summaries which have been duly acknowledged.

11 August 2025

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ABSTRAK

Teknologi robotik telah dibangunkan untuk pemulihan kefungsian motor. Penggunaan robot sedemikian telah menunjukkan hasil yang menggalakkan berbanding dengan dos terapi klinikal biasa yang setara. Kebelakangan ini, intervensi robotik telah dicadangkan untuk digunakan dalam pemulihan ortopedik bagi masalah kefungsian anggota atas, terutamanya yang berkaitan dengan tangan dan pergelangan tangan. Kajian ini bertujuan untuk menentukan keberkesanan gabungan terapi konvensional dan terapi robotik HAL-SJ dalam memulihkan fungsi pergelangan tangan selepas kepatahan tulang, berbanding dengan terapi konvensional secara tunggal. Kajian ini dijalankan di Pusat Rehabilitasi PERKESO. Tiga puluh lapan individu yang mengalami kepatahan tulang pergelangan tangan telah diagihkan secara rawak mudah kepada dua kumpulan, iaitu kumpulan kawalan (terapi konvensional) dan kumpulan intervensi (gabungan terapi konvensional dan intervensi robotik HAL-SJ). Kedua-dua kumpulan kawalan dan intervensi menjalani sesi terapi cara kerja dan fisioterapi harian (masing-masing selama 90 minit) sebanyak lima hari seminggu bagi tempoh masa empat minggu. Kumpulan intervensi turut menerima sesi terapi robotik HAL-SJ selama 60 minit sebagai tambahan kepada rawatan konvensional. Penilaian hasil termasuk skor *Disabilities of the Arm, Shoulder and Hand* (DASH) *Outcome Measure*, tahap kesakitan, kekuatan genggaman dan cubitan, julat pergerakan pergelangan tangan dan jari aktif, *Purdue Pegboard Test*, *Box and Block Test*, dan *Lam Assessment of Stages of Employment Readiness* (LASER). Penilaian dilakukan pada permulaan dan selepas intervensi selama empat minggu. Analisa statistik menggunakan *repeated measure* ANOVA menunjukkan kemajuan yang signifikan dalam semua hasil penilaian bagi kedua-dua kumpulan ($p<0.001$) dan mengesahkan keberkesanan terapi. Hasil kajian telah menunjukkan perbezaan ketara dalam skor DASH ($p<0.001$), tahap kesakitan ($p<0.001$), kekuatan genggaman ($p<0.001$), kekuatan cubitan ($p<0.001$), julat pergerakan aktif pergelangan tangan ($p<0.001$), julat pergerakan aktif jari ($p<0.001$), *Purdue Pegboard Test* ($p<0.001$), dan *Box and Block Test* ($p<0.001$) selepas empat minggu intervensi dalam kedua-dua kumpulan, menunjukkan bahawa kedua-dua program terapi dalam kumpulan kawalan dan intervensi adalah berkesan dalam meningkatkan tahap kefungsian dan prestasi fizikal. Walau bagaimanapun, tiada perbezaan yang signifikan diperhatikan berkaitan tahap kefungsian dan prestasi fizikal antara kumpulan kawalan dan intervensi. Kesediaan bekerja dalam kumpulan intervensi meningkat, dengan peningkatan peserta di peringkat tindakan LASER daripada 18.4% kepada 34.2%, manakala bilangan peserta dalam kumpulan kawalan kekal pada 13 orang (34.2%). Kajian ini boleh dianggap sebagai titik permulaan untuk memperkenalkan intervensi robotik dalam pemulihan kepatahan tulang pergelangan tangan. Sebagai kesimpulan, kajian ini menyokong manfaat pelengkap terapi robotik HAL-SJ untuk digabungkan dalam pemulihan konvensional kepatahan pergelangan tangan, di samping menjadi asas bagi penyelidikan dan pelaksanaan dalam tetapan klinikal pada masa depan.

ABSTRACT

Robotic technologies have been developed for motor rehabilitation. Such robots have shown favourable results compared to equivalent doses of usual clinical therapy. Recently, robotic interventions have been suggested for application in orthopaedic rehabilitation for upper extremity disorders, especially those related to the hand and wrist. This study aims to determine the effectiveness of combined conventional therapy and HAL-SJ robotic therapy in restoring wrist functionality following fractures, compared to the standard conventional therapy alone. This trial was conducted at PERKESO Rehabilitation Centre. Thirty-eight individuals with wrist fractures were allocated through simple randomization into two groups, i.e., the control group (conventional therapy) and the intervention group (combination of conventional therapy and robotic HAL-SJ intervention). Both control and intervention groups underwent daily occupational and physiotherapy sessions (90 minutes each), five days a week for four weeks. The intervention group additionally received a 60-minute session of HAL-SJ robotic therapy alongside conventional treatment. Outcome measures included the Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure score, pain, grip and pinch strength, wrist range of motion fingers active range of motion, Purdue Pegboard Test, Box and Block Test, and the Lam Assessment of Stages of Employment Readiness (LASER). Assessments were performed at baseline and after the four-week intervention. Statistical analysis using repeated measure ANOVA revealed significant improvements across all outcome measures in both groups ($p<0.001$), confirming the effectiveness of the therapies. The results showed that there were significant differences in DASH score ($p<0.001$), pain intensity ($p<0.001$), grip strength ($p<0.001$), pinch strength ($p<0.001$), wrist active range of motion ($p<0.001$), fingers active range of motion ($p<0.001$), Purdue Pegboard Test ($p<0.001$), and Box and Block Test ($p<0.001$) after four weeks of interventions in both groups, indicating that both the therapy programmes in the control and intervention groups were effective in improving the functional level and physical performance. However, no significant differences were observed regarding functional level and physical performance between the control and intervention groups. Notably, work readiness in the intervention group improved, with increased participants at the action stage of LASER from 18.4% to 34.2%, while the number of participants in the control group remained at 13 (34.2%). This work can be considered as the starting point for introducing robotic interventions in wrist fracture rehabilitation. This study supports the complementary benefits of incorporating HAL-SJ robotic therapy into conventional wrist fracture rehabilitation, laying the groundwork for future research and implementation in clinical settings.

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LIST OF ABBREVIATIONS

ADL	activities of daily living
ANZCTR	Australian New Zealand Clinical Trials Registry
AOTA	American Occupational Therapy Association
AROM	active range of motion
BBT	Box and Block Test
CAC	Cybernic Autonomous Control
CVC	Cybernic Voluntary Control
DASH	Disabilities of the Arm, Shoulder and Hand Outcome Measure
DIPJ	distal interphalangeal joint
DRF	distal radius fracture
DRUJ	distal radioulnar joint
DTM	dart throwing motion
ECRB	extensor carpi radialis brevis
ECRL	extensor carpi radialis longus
FCR	flexor carpi radialis
FCU	flexor carpi ulnaris
GSR	grip strength ratio
HAL	Hybrid Assistive Limb
HAL-SJ	Single Joint Hybrid Assistive Limb
IADL	instrumental activities of daily living
ICF	International Classification of Functioning, Disability and Health
ICC	intraclass correlation coefficients
LASER	Lam Assessment on Stages of Employment Readiness
MCID	minimal clinically important difference
MCPJ	metacarpophalangeal joint
OT	occupational therapy
ORIF	open reduction and internal fixation

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PERKESO	Pertubuhan Keselamatan Sosial (Social Security Organization)
PL	palmaris longus
PIPJ	proximal interphalangeal joint
PPT	Purdue Pegboard Test
PROMs	patient rated outcome measures
PRWE	Patient-Rated Wrist Evaluation
PT	physiotherapy
RCJ	radiocarpal joint
RCT	randomized controlled trial
ROM	range of motion
SDC	smallest detectable change
UCJ	ulnocarpal joint
VAS	visual analogue scale
WRFQ	Work Role Functioning Questionnaire
WORQ	Work Rehabilitation Questionnaire

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OPERATIONAL DEFINITIONS

Wrist	Made up of the distal ends of the radius and ulna, the eight carpal bones, and the proximal bases of the five metacarpal bones
Wrist joint	A multi-joint system that includes the radiocarpal joint (RCJ), ulnocarpal joint (UCJ), and distal radiuoulnar joint (DRUJ)
Wrist fractures	Individual or combined fractures of the distal radius, distal ulna, distal radioulnar, radiocarpal joint; including extraarticular fracture, partial articular fracture, and/or complete articular fracture
Functional outcomes	Objective indicators of an individual's upper extremity and hand functions as measured by using the Disabilities of the Arm, Shoulder and Arm (DASH) Outcome Measure
Pain	Intensity of pain perception as measured by using the Visual Analogue Scale (VAS)
Work Readiness	The readiness of an individual to return to work as measured by using the Lam Assessment on Stages of Employment Readiness (LASER)
Grip Strength	Force or power generated by the muscles of the hand and forearm when gripping, squeezing, or holding an object as measured by the hand dynamometer
Pinch Strength	Force generated between the thumb and the fingers when pinching an object as measured by the pinch gauge
Active Range of Motion	The amount of movement an individual can achieve at a joint using their own muscle strength, without any external assistance as measured by the goniometer

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Manual Dexterity	Ability to skilfully use the hands to grasp and manipulate, with the involvement of gross hand movements and hand-eye coordination as measured by the Box and Block Test (BBT)
Fine Dexterity	Ability to perform precise, small movements using the fingers and hands as measured by the Purdue Pegboard Test (PPT)

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CHAPTER I

INTRODUCTION

1.1 INTRODUCTION

The primary goal of occupational therapy (OT) is to enable people to participate in the activities of daily living (ADLs), including the ability to work (Desiron et al. 2011).

Work-related hand injuries contributed to 24.9% of all industrial accidents in Malaysia's emergency departments and orthopedic clinics (Al-Husuny et al. 2012). Approximately 98.6 % of workers with traumatic hand injuries returned to work after a median absence of 45.5 days (Oberfeld et al. 2015).

The wrist joint has high activity frequencies and functional requirements (Weimer et al. 1999). The distal radius is a crucial support foundation for the wrist joint, which is a multi-joint system that includes the radiocarpal joint (RCJ), ulnocarpal joint (UCJ), and distal radioulnar joint (DRUJ) (Berger 1996; Mehta et al. 2024). It consists of eight carpal bones interposed between the forearm (distal radius and ulna) and the bases of the metacarpals (Berger 1996; Calfee et al. 2010). The carpal bones are categorized as proximal and distal rows based on their kinematics during wrist motions (Berger 1996; Kijima & Viegas, 2009; Calfee et al. 2010). The proximal row consists of the scaphoid, lunate, triquetrum, and pisiform, while the distal row consists of the trapezium, trapezoid, capitate, and hamate (Berger, 1996; Kawamura & Chung, 2007; Kijima & Viegas, 2009; Calfee et al. 2010). The DRUJ consists of the ulna head, the sigmoid notch region of the distal radius, the DRUJ capsule, and the triangular fibrocartilage complex (TFCC) (Berger, 1996; Kawamura & Chung, 2007). The wrist joint complex primarily provides two degrees of freedom, enabling flexion-extension and radial-ulnar deviation. Additionally, limited axial rotation occurs through the

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integration of wrist and forearm movements. The system achieves three functional degrees of freedom When combined with forearm pronation and supination, allowing precise hand positioning for object manipulation (Berger 1996; Kapandji 2007).

Based on the anatomical structures, wrist fractures may include fractures that affect the distal ends of the radius, ulna, and carpus. A distal radius fracture (DRF), commonly known as a wrist fracture, is defined by the involvement of the metaphysis of the distal radius. The fracture may or may not involve the RCJ, DRUJ, and/or the distal ulna (Mauck & Swigler 2018). Traditionally, DRFs have been described using eponyms, e.g., Colles, Smith, Barton, and Chauffeur. During the last half of the twentieth century, several classification systems for DRFs have emerged which include the AO Foundation/Orthopaedic Trauma Association (AO/OTA) system (Kleinlugtenbelt et al. 2017; Mulders et al. 2017; Wæver et al. 2018), the Frykman system (Meena et al. 2014; Kleinlugtenbelt et al. 2017; Mulders et al. 2017; Wæver et al. 2018), the Melone system (Meena et al. 2014; Mulders et al. 2017), the Fernandez system (Meena et al. 2014; Kleinlugtenbelt et al. 2017; Mulders et al. 2017), and the Older system (Wæver et al. 2018). According to Wæver et al. (2018), the AO/OTA classification system seems to be most reliable for routine use, while the study by Mulders et al. (2017) found high consensus among both surgeons and residents for defining the AO/OTA classification as the preferred classification system.

According to the fracture and dislocation classification compendium by the AO Foundation/Orthopaedic Trauma Association (AO/OTA) (2018), the distal end segment fractures for both the radius and ulna bones are classified into three types, namely extra-articular fracture, partial articular fracture, and complete articular fracture. The distal end segment radius and ulna fractures are further classified into nine and three groups, respectively. The nine groups of distal end segment radius fractures include radial styloid avulsion fracture, simple fracture, wedge or multi-fragmentary fracture, sagittal fracture, dorsal rim (Barton's) fracture, volar rim (reverse Barton's, Goyrand Smith II's) fracture, simple articular and metaphyseal fracture, metaphyseal multi-fragmentary fracture, articular multi-fragmentary fracture, and simple or multi-fragmentary metaphyseal fracture. Meanwhile, the three groups of distal end segment ulna fractures

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include extra-articular, styloid process fracture, simple fracture, and multi-fragmentary fracture.

The incidence of DRF is increasing worldwide, with one-sixth of the fractures treated in emergency rooms appearing to be related to distal radius (Mitchlovitz et al. 2001; MacIntyre & Dewan 2016). The majority of patients had some degree of disability one year after DRF, with 16% having moderate to very severe disability and not working (Moore & Leonardi-Bee 2008). Patients who have high self-reported pain/disability and occupational demand at baseline have an average of 9.2 weeks of work loss following DRF (MacDermid et al. 2007). Hand injury costs have brought a cumulative economic impact to patients and their families, employers, and society (Dias & Garcia-Elias 2006). As the incidence of DRFs rises, the short- and long-term costs become apparent (Nellan et al. 2012).

Stiffness and pain (Egol et al. 2014) are common complications of DRFs. Loss of range of motion (ROM) is typically due to periarticular connective tissue changes after fractures, joint injuries, and immobilization (Mitchlovitz et al. 2004). Decreased wrist flexion and/or extension after trauma or surgery can be a challenging problem (McGracth et al. 2008). The goal of restoring motion is to reduce impairments and enhance functional performance for ADLs, work, and leisure.

The rehabilitation program following DRFs involves three phases: the immobilization phase, the mobilization phase, and the strengthening phase. The fundamental goals throughout these three phases include effective edema control, pain management, ROM, strength, and functional restorations (Mitchlovitz et al. 2001). The most frequently used therapeutic interventions following DRFs include compressive wrap with retrograde massage, heat/cold modalities, joint mobilization, electrical stimulation, continuous passive motion (CPM), soft-tissue mobilization, ultrasound, splinting, ROM and strengthening exercises, and functional training (Mitchlovitz et al. 2001). The commonly used nonsurgical interventions for ROM restoration after fracture, fracture/dislocation, joint injury, or other soft tissue injuries include home exercise programs and clinic-based programs such as splinting and casting, joint mobilization, CPM, and therapeutic exercises (Mitchlovitz et al. 2004).

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Improper rehabilitation programs after wrist injury may significantly impair the overall function of the upper extremity (Garcia-Elias & Folgar 2006). Both injury and patient factors can impact the management and outcomes after DRF. Although optimal strength, ROM, and function are achievable within 3-6 months of conservative or surgical management (MacDermid et al. 2007), some patients require longer to complete the rehabilitative phase. According to Moore and Leornardi-Bee (2008), there are 11% of patients endure residual moderate to very severe pain one year following DRF, with 16% still experiencing ongoing disability. This scenario signifies that there is a significant association between patient characteristics and the level of pain and disability among the DRF population.

Concerning the employability issues of workers with wrist fractures, Lam et al. (2010) advocated that matching treatment to the patient's stage of employment readiness is a more effective approach to service provision. A timely and goals-oriented treatment-matching approach in the work program will deliver better cost-effectiveness, employment, and service quality outcomes. The Lam Assessment on Stages of Employment Readiness (LASER) has been used in the treatment-matching endeavor by assessing the patient's stages of employment readiness based on Prochaska's State of Change theory that consists of three stages, namely the Pre-Contemplation, Contemplation, and Action stages (Chan et al. 2006; Lam et al. 2010).

The application of robotic technology in facilitating upper limb movement and functional recovery training is extensive in the field of neurorehabilitation (Riener et al. 2005; Riener 2007; Wagner et al. 2011; Lo & Xie 2012; Ren et al. 2013; Maciejasz et al. 2014; Borboni et al. 2016; Zhang et al. 2017; Hsieh et al. 2018; Ferreira et al. 2018) but limited in the field of orthopedic rehabilitation, particularly in hand therapy practice. Given the current concepts of robotic intervention are focused on providing motor control/learning, practice-induced neuroplasticity, intensity, and task-specific training, Hakim et al. (2017) have suggested the application of robotic intervention in orthopedic rehabilitation with upper extremity disorders, especially those related to hand and wrist.

Various types of robotic devices that can be used for upper limb rehabilitation, subject to their respective mechanical designs (i.e., end-effector-based or exoskeleton-

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based) and types of assistance provided (i.e., active, passive, haptic, or coaching) (Maciejasz et al., 2014). The Single Joint Hybrid Assistive Limb (HAL-SJ) is one of the robotic devices that can be used for upper limb rehabilitation. Hybrid Assistive Limb (HAL) is a cyborg-type robot that can expand, augment, and support physical capability to enhance and upgrade human capabilities based on the frontier science "Cybernics". Cybernics is a new domain of interdisciplinary research centered on cybernetics, mechatronics, and informatics that integrates neuroscience, robotics, systems engineering, information technology, "kansei" engineering, ergonomics, physiology, social science, law, ethics, management, economics, etc. (Sankai 2010).

The HAL is a hybrid control system comprising a 'Cybernic Voluntary Control (Bio-Cybernic Control)' and 'Cybernic Autonomous Control (Cybernic Robot Control)'. Using the two types of algorithms as complementary controls, the cybernic control system can provide suitable physical support to wearers with various conditions, including healthy and physically challenged persons. The Cybernic Voluntary Control provides physical supports/actions according to the operator's voluntary intention caused by the bioelectrical signals, including muscle activity. The power units of HAL generate power assist torque by amplifying the wearer's joint torque estimated from his/her bioelectrical signals, and the support motions are consequently controlled. Bioelectrical signals, including myoelectricity, are useful and reliable information to estimate a human's motion intentions because the signals are measured just before corresponding visible muscle activities. Thus, the wearer receives physical support directly from an unconscious interface using the bioelectrical signals. On the contrary, the Cybernic Autonomous Control autonomously provides a desired functional motion generated according to the wearer's body constitution, conditions, and purposes of motion support (Sankai 2010).

The upper limb HAL-SJ is a wearable movement support robot that detects bioelectrical signals on the skin surface and assists joint movements by controlling and operating an actuator placed outside the respective joint (Otsuka et al. 2011; Kubota et al. 2018). Upper limb rehabilitation using the elbow joint HAL-SJ robotic therapy has been applied to promote elbow functions among neurological patients. A functional imaging study had shown cortical neuroplasticity activity associated with elbow

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movements among post-stroke patients following 20 sessions of elbow joint HAL-SJ intervention for the paretic arm in two weeks (Saita et al. 2016). In addition, studies have proved the safety and feasibility of the upper limb HAL-SJ application for the upper limb rehabilitation of quadriplegia patients (Kubota et al. 2018; Shimizu et al. 2017). The upper limb HAL-SJ is also proven safe and effective for rehabilitation following traumatic brachial plexus injury (Kubota et al. 2017). A newly developed wrist joint attachment to the HAL-SJ is currently available. It can assist the wrist joint's voluntary articulatory movements, including wrist flexion and extension, as well as forearm supination and pronation.

Robotic technologies have been developed for motor rehabilitation, and such robots have shown favorable results compared to equivalent doses of usual clinical therapy (Lo et al. 2010; Novak 2018). Compared to manual therapy, robotic intervention for rehabilitation has the potential for a greater impact on impairment due to easy deployment, its applicability across a wide range of motor impairment, its high measurement reliability, and the capacity to deliver high-dosage and high-intensity training protocols for a longer duration, irrespective of the skills, and fatigue level of the therapist (Huang & Krakauer 2009). Based on the understanding that the amount and intensity of exercise and the quality of motor learning are positively associated with rehabilitation outcomes as aforementioned and the fact that HAL-SJ is a newly developed robotic intervention device that shares similarities with the therapeutic features provided by other robotic devices, the application of the HAL-SJ is hypothesized to provide a similar positive outcome for wrist fractures. Investigating the outcome of HAL-SJ among upper limb injured workers, especially those with wrist fractures, shall give further evidence of the effectiveness and usability of robotic interventions in the field of hand therapy and upper limb rehabilitation.

1.2 RESEARCH JUSTIFICATION

Upper limb robotic interventions have shown promising results and positive evidence in the functional recovery of the neurological population. Based on current motor learning concepts, practice-induced neuroplasticity, and muscle plasticity, robotic interventions can provide highly repetitive, intensive, and task-specific training

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required for functional restoration. There are vast studies on the clinical applications of robotic interventions for neurological rehabilitation. However, robotic interventions in orthopedic rehabilitation, especially for the wrist and hand, remain inadequately explored. This study aims to determine the effectiveness of robotic interventions in improving the functions and the recovery period following DRF.

1.3 PROBLEM STATEMENT

Most patients who recovered from wrist fractures, particularly the DRF, have some residual disability or pain. MacDermid et al. (2003) found that at one year following DRF, of 129 patients, there were still 46% of them experienced a certain extent of difficulty with usual activities, ranging from very severe to mild. Although most of the recovery following a DRF occurred within six months after a conventional hand therapy regime, most of the patients can still be expected to experience minimal pain and disability still. DRF cases can take up to a few months and one or two years to achieve maximal functional improvement (Michlovitz et al. 2001). The residual disability or pain, along with the long functional recovery period following DRF, may impact the socioeconomics of a person, family, and society significantly (Dias & Garcia-Elias 2006; MacDermid et al.2007). With the advancement in rehabilitation technology, robotic intervention has shown positive outcomes in neurological rehabilitation program for the past decades. However, there is a lack of published evidence about the usability and effectiveness of robotic intervention in orthopedic rehabilitation programs, especially in hand therapy.

1.3.1 Conceptual Framework

Establishing outcome assessments within a widely recognized theoretical framework is essential for clinical measurement (Goldhahn et al. 2014). Such a framework should clearly outline relevant domains for evaluation. The International Classification of Functioning, Disability and Health (ICF), published by the World Health Organization (WHO) in 2002, as a universally applicable health model, provides a suitable structure for assessing diverse conditions, including wrist fractures.

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The International Classification of Functioning, Disability, and Health (ICF), introduced in 2001, provides a comprehensive framework for assessing health and disability. It comprises three interrelated domains: Body Structure/Function, Activity, and Participation. These domains interact dynamically rather than linearly and are influenced by personal and environmental factors (WHO 2001). The ICF integrates perspectives from the body, individual, and society, organizing health-related aspects into two primary components: body functions and structures as well as activities and participation (Goldhahn et al. 2014). Importantly, the relationships among impairments, activity limitations, and participation restrictions are bidirectional and context-dependent which can be mediated by environmental and personal factors (Goldhahn et al. 2014). Increasingly adopted as a global standard, the ICF is widely endorsed as a suitable framework for evaluating the DRF health outcomes (Harris et al. 2005; Goldhahn et al. 2014).

In alignment with the ICF framework, the World Health Organization (WHO) has recently developed ICF Core Sets specific to hand conditions (ICF Research Branch 2010). These include a Comprehensive Core Set comprising 117 ICF categories, designed to support detailed, multidisciplinary assessments, and a Brief Core Set of 23 categories, intended for use by individual healthcare professionals in clinical settings. The selected categories reflect key aspects of functioning relevant to hand conditions, encompassing emotional function, sensory functions (e.g., touch, pain, response to temperature and stimuli), joint mobility and stability, muscle power, voluntary movement control, and skin's protective functions. These core sets facilitate standardized, function-oriented evaluation and planning of care for individuals with hand-related impairments (ICF Research Branch 2010).

Of the 15 most commonly used outcome measures in DRF studies, seven measures were categorised in both the Body Function/ Structure and Activity/Participation domains of the ICF, including the DASH, ROM, grip, pain, PRWE, Gartland and Werley Score (GWS), Short Form 12 or 36, Mayo Wrist Score (MVS), patient satisfaction, EuroQol- 5 Dimension Questionnaire (EQ-5D), Castaing Score (CS), Green and O'Brien Score (GOBS), pinch, Canadian Occupational Performance Measure (COPM), and Michigan Hand Questionnaire (MHQ) (Norton et

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al. 2022). The DASH, ROM, and grip were the most commonly used measures; each was used almost twice as much as the other measures (Norton et al. 2022).

This study applies the ICF framework to systematically assess the health impact of wrist fractures and the effectiveness of robotic therapy by using the HAL-SJ device in rehabilitation. The ICF enables a structured evaluation of outcomes across key domains, emphasizing objective measures such as body functions, activities, and participation, and contextual factors like personal and environmental influences.

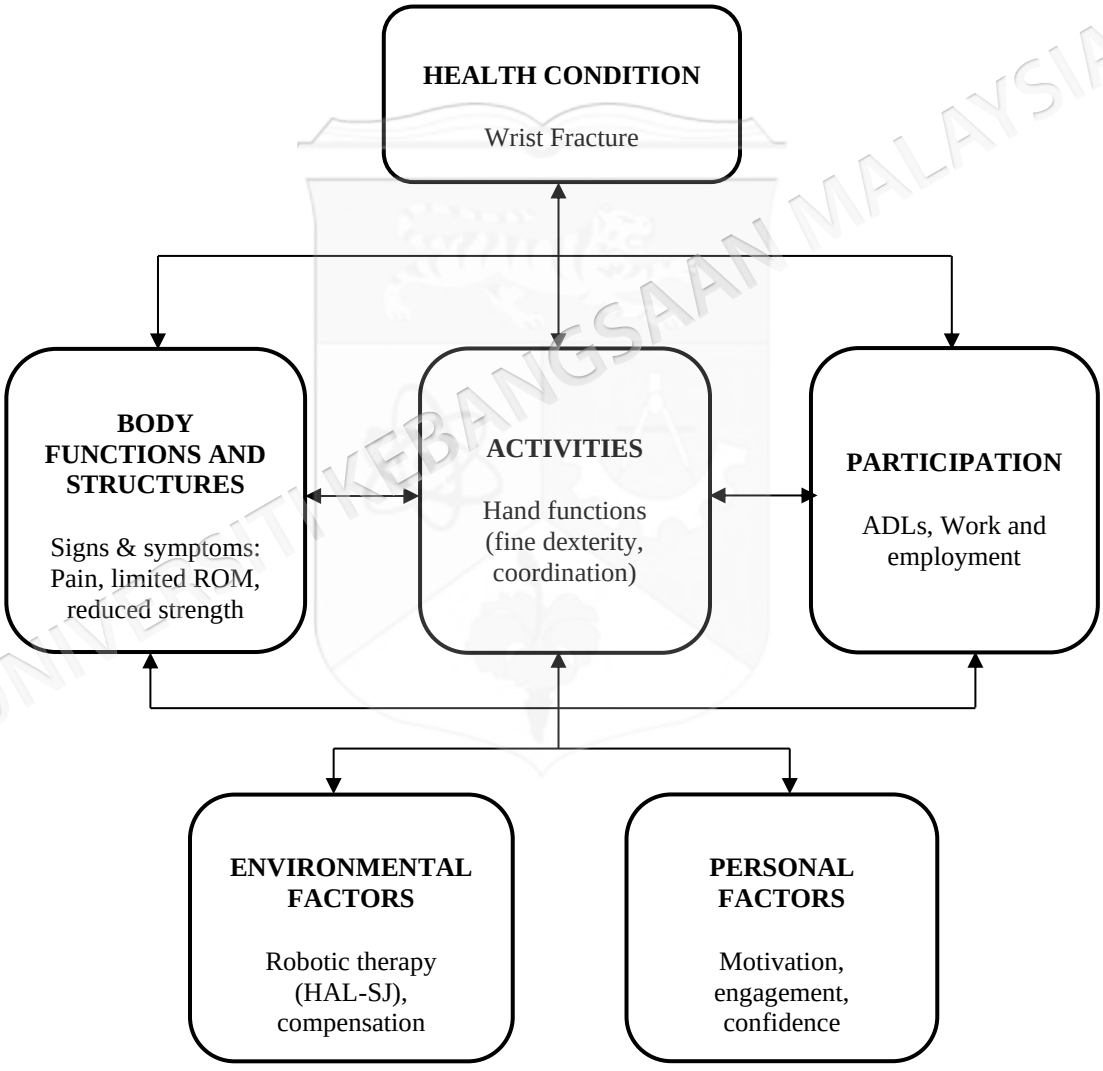

Figure 1.1 International Classification of Functioning, Disability and Health model applied to the present study

Robotic therapy with HAL-SJ provides repetitive, task-specific training that targets neuromuscular and biomechanical deficits among patients with wrist fractures.

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The ICF framework defines body functions as the physiological functions of body systems and body structures as anatomical parts of the body such as organs, limbs, and their components. In the context of wrist fractures, these two components are central to understanding the nature and extent of impairment and serve as the biomedical foundation for rehabilitation planning. A wrist fracture most commonly involves disruption of the distal radius and/or ulna, with possible involvement of the carpal bones, ligaments, and surrounding soft tissues. Under the ICF framework, the fracture represents an impairment of body structures. These structural impairments directly affect body functions, particularly neuromusculoskeletal and movement-related functions. Common functional impairments following wrist fractures include pain, reduced joint mobility, decreased muscle strength, impaired coordination, diminished grip and pinch strength, and altered proprioception. These impairments underlie the basis for activity limitations and participation restrictions observed during recovery. Comprehensive rehabilitation must therefore address both structural healing and restoration of physiological function to optimize overall functioning and return-to-work outcomes. Using the ICF framework, improvements can be evaluated regarding ROM, grip and pinch strength, and pain, which are directly linked to ICF codes such as b710 (mobility of joint functions) and b730 (muscle power functions). Additionally, beyond the domains of body functions and body structures, the ICF framework enables comprehensive measurements of individual activities and participation in ADLs, returning to work, hobbies, or social interactions. Some of the examples of these functional outcomes are coded under d440 (fine hand use), d445 (hand and arm use), d850 (remunerative employment) or d920 (recreation and leisure).

The following table shows the listing of ICF codes that are associated with this study:

Table 1.1 ICF Codes Listing

ICF Codes	Description
b280	Sensation of pain
b710	Mobility of joint functions
b730	Muscle power function
b760	Control of voluntary movement functions
d230	Carrying out daily routine
d430	Lifting and carrying objects

to be continued…

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…continuation	
d440	Fine hand use
d445	Hand and arm use
d5	Self care
d6	Domestic life
d840-d859	Work and employment
e198	Products and technology, other specified
e355	Health professionals
e580	Health services, systems and policies

In the ICF framework, environmental factors refer to the physical, social, and attitudinal environment in which people live and conduct their lives. These factors can either facilitate or hinder a person's functioning and recovery. In the rehabilitation of wrist fractures, robotic therapy systems can serve as key facilitators in several ways, including the provision of assistive technology for rehabilitation (code: e115), improving accessibility of services by supplementing therapist time (code: e580), and supporting clinicians (code: e355). At the level of body functions and structures, robotic technology supports recovery by enabling controlled, repetitive, and task-specific movements of the wrist and hand. Wrist fractures are often associated with impairments such as reduced range of motion, decreased grip strength, joint stiffness, and impaired coordination. Robotic devices provide precise movement guidance, adjustable resistance, and real-time feedback, thereby promoting motor relearning and neuromuscular recovery. At the level of activity and participation, robotic interventions facilitate the reacquisition of functional tasks, such as grasping, lifting, manipulating tools, and performing fine motor activities, thereby enbaling safer and earlier reintegration into functional and occupational roles.

Within the ICF framework, personal factors in workers with wrist fractures encompass demographic characteristics, occupational background, psychological attributes, lifestyle behaviors, and socioeconomic conditions. Although these factors are not formally coded in the ICF classification system, they significantly influence recovery of body function, performance of activity, and participation in work. A comprehensive rehabilitation approach must therefore incorporate assessment of personal factors to facilitate individualized intervention planning and optimize return-to-work outcomes. While robotic devices themselves are environmental supports, their effectiveness in workers with wrist fractures is significantly shaped by personal

characteristics that determine acceptance, adherence, and responsiveness to such technology. The applications of robotic therapy in the rehabilitation of wrist fractures can positively influence these personal elements by enhancing motivation and engagement while supporting the patients self-efficacy and confidence. Thus, the integration of robotic rehabilitation into post-fracture care should not only focus on the device's technological capabilities but also consider the individual worker's personal characteristics to optimize functional recovery and return-to-work outcomes.

1.4 RESEARCH QUESTION

Does a combined conventional therapy with HAL-SJ robotic therapy provide greater effectiveness in improving functional level, physical performance, and work readiness among workers with wrist fractures after 4 weeks of intervention compared to conventional therapy alone?

1.5 RESEARCH OBJECTIVE

1.5.1 General Objective

The research aimed to determine the effectiveness of HAL-SJ robotic therapy in improving functional level, physical performance, and work readiness among workers with wrist fractures after 4 weeks of intervention.

1.5.2 Specific Objectives

a. Specific objective 1: To determine the effectiveness of HAL-SJ robotic therapy on functional level among workers with wrist fracture after 4 weeks of intervention.

b. Specific objective 2: To determine the effectiveness of HAL-SJ robotic therapy on physical performance in terms of pain level, wrist and fingers ROM, grip and pinch strength as well as hand dexterity among workers with wrist fracture after 4 weeks of intervention.

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c. Specific objective 3: To determine the effectiveness of HAL-SJ robotic therapy on work readiness among workers with wrist fracture after 4 weeks of intervention.

1.6 HYPOTHESIS

There are eight hypotheses proposed in this study.

a. **Hypothesis 1:** A 4-week combined conventional therapy and HAL-SJ robotic therapy provides greater functional level improvement among workers with wrist fractures as compared to those receiving conventional therapy alone during the same intervention period as measured by the Disabilities of the Arm, Shoulder, and Hand (DASH) Outcome Measure.

b. **Hypothesis 2:** A 4-week combined conventional therapy and HAL-SJ robotic therapy provides greater improvement of physical performance in terms of pain, wrist and fingers range of motion,grip and pinch strength, as well as finger fine and gross dexterity among workers with wrist fractures as compared to those who only receive standard conventional therapy in the same intervention period as measured by the Visual Analgoue Scale (VAS), goniometer, Jamar dynamometer, B&L Engineering pinch gauge, Purdue Pegboard Test (PPT) and Box and Block Test (BBT) respectively.

c. **Hypothesis 3:** A 4-week combined conventional therapy and HAL-SJ robotic therapy provides greater improvement in work readiness among workers with wrist fractures as compared to those who only receive standard conventional therapy in the same intervention period as measured by the Lam Assessment on Stages of Employment Readiness (LASER).

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CHAPTER II

LITERATURE REVIEW

2.1 WRIST FUNCTIONAL ANATOMY

According to Viegas (2001), the wrist is a complex structure composed of eight carpal bones intricately connected by ligaments and capsules. These bones are linked to one another, the metacarpals distally and the radius and ulna proximally, enabling the smooth and stable movement known as the "wrist joint." Literature has defined the wrist as the crucial bridge between the forearm and hand, made up of the distal ends of the radius and ulna, the eight carpal bones, and the proximal bases of the five metacarpal bones (Berger 1996; Eathorne 2005; Kijima & Viegas 2009; Kawamura & Chung 2007).

The distal radius is a crucial support foundation for the wrist joint, which is a multi-joint system that includes the RCJ, ulnocarpal joint (UCJ), and DRUJ (Berger 1996; Mehta et al. 2024). The wrist joint facilitates the efficient transfer of forces, particularly during weight-bearing activities involving both upper limb's open and closed chain movements (Mehta et al. 2024; Eathorne 2005). The articular complex of the wrist provides two primary degrees of freedom. Beyond the fundamental movements of flexion, extension, radial deviation, and ulnar deviation, the wrist joint also enables limited rotation along its length, a combination of these motions, and independent forearm rotation. When combined with pronation and supination (the rotation of the forearm along its long axis), it allows three degrees of freedom, positioning the hand at any angle to grasp or hold an object (Berger 1996; Kapandji 2007).

The RCJ and UCJ are anatomically adjacent joints between the distal radius,

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ulna, and the proximal carpal row, facilitating normal wrist flexion-extension and ulnar-radial deviation active range of motion (AROM). The DRUJ is a pivot or trochoid joint formed at the ulnar sigmoid notch, where the distal radius articulates with the head of the ulna. This joint is supported by strong volar and dorsal DRUJ capsular ligaments, and the TFCC, which provide stability and facilitate its movement. The DRUJ plays a key role in wrist function, particularly in activities that involve pronation and supination of the forearm (Berger 1996; Eathorne 2005; Mehta et al. 2024).

The eight irregularly shaped carpal bones are divided into proximal and distal rows based on their kinematic behavior during global wrist motion. The proximal row consists of the scaphoid, lunate, triquetrum, and pisiform, and the distal row consists of the trapezium, trapezoid, capitate, and hamate. The scaphoid spans these two rows and is the key to maintaining wrist stability (Berger 1996; Eathorne 2005; Kawamura & Chung 2007). The proximal carpal row bones are called an intercalated segment because they lack tendon insertions and rely entirely on mechanical forces from surrounding articulations for movement. In contrast, the distal row of carpal bones is tightly connected through strong intercarpal ligaments, with motion between them considered negligible. Similarly, the rigid ligamentous connection between the trapezium and capitate with the index and middle metacarpal bones, along with the absence of motion between these bones, allows the distal row to function as part of a fixed hand unit that moves in response to the musculotendinous forces from the forearm (Kuo & Wolfe 2008; Kijima & Viegas 2009).

The ligaments of the wrist play a crucial role in guiding and restricting the complex movement of the carpal bones about the forearm bones, metacarpals, and adjacent carpal bones (Berger 2001). According to Taleisnik (1976), wrist ligaments can be extrinsic and intrinsic. Extrinsic ligaments connect the distal radius and ulna to the carpal bones, while intrinsic ligaments originate and insert within the carpal bones themselves (Taleisnik 1976; Kawamura & Chung 2007). The extrinsic wrist ligaments are classified into palmar and dorsal radiocarpal, ulnocarpal, intercarpal, and midcarpal groups. The palmar radiocarpal ligament complex includes the radioscaphocapitate, long radiolunate, radioscapholunate, and short radiolunate ligaments. The ulnocarpal ligaments consist of the ulnolunate, ulnotriquetral, and ulnocapitate ligaments.

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Dorsally, the radiocarpal joint is supported by the dorsal radiocarpal ligament. Palmar ligaments connecting the proximal and distal carpal rows include the scaphotrapeziotrapezoid, scaphocapitate, triquetrocapitate, and triquetrohamate ligaments. Interosseous ligaments are divided into proximal and distal rows, with dorsal and palmar subdivisions, connecting specific carpal bones like the scapholunate, pisotriquetral, trapezocapitate, and capitohamate (Berger 1996; Berger 2001; Eathorne 2005).

The muscles acting on the wrist joint originate from the forearm, as there are no intrinsic muscles of the wrist (Eathorne 2005; Eschweiler et al. 2022). All of the tendons that influence wrist motion insert distally, crossing the wrist joint and inserting on the hand or fingers (Eschweiler et al. 2022), except the flexor carpi ulnaris (FCU), which inserts into the pisiform (Kapandji 2007). These muscles can be categorized into flexor-extensor, ulnar-radial deviator, and pronator-supinator groups (Eathorne 2005). The primary wrist flexors from the anterior side of the forearm are the flexor carpi radialis (FCR), (FCU, and the palmaris longus (PL) (Eathorne 2005; Kapandji 2007; Eschweiler et al. 2022). Meanwhile, wrist extension occurs through the action of the posterior forearm muscles consisting of the extensor carpi radialis longus (ECRL), extensor carpi radialis brevis (ECRB), and extensor carpi ulnaris (ECU) (Eathorne 2005; Kapandji 2007; Eschweiler et al. 2022). Ulnar deviation occurs through the contraction of the FCU and ECU muscles, while radial deviation is primarily driven by the contraction of the ECRL and FCR muscles, with additional contribution from the ECRB and thumb extensors and abductors (Eathorne 2005). Pronation and supination primarily occur at the proximal radioulnar joint (PRUJ) and DRUJ. Supination, being the more powerful movement, is mainly driven by the biceps brachii, which is most effective when the elbow is flexed and involves a combined effort from both the supinator and biceps brachii muscles. Pronation, in contrast, is primarily achieved through the action of the pronator teres and pronator quadratus muscles, with the FCR contributing when the wrist is flexed (Eathorne 2005).

2.2 WRIST FUNCTIONAL RANGE OF MOTION AND DAILY ACTIVITIES

In a study aimed at identifying the wrist range of motion necessary for performing

activities of daily living, Ryu et al. (1991) reported an average maximum range of 60° extension to 78° flexion (total arc of 138°) and 21° radial to 38° ulnar deviation (total arc of 59°), based on goniometric measurements. They concluded that 60° of extension, 54° of flexion, 40° of ulnar deviation, and 17° of radial deviation were required to complete all 24 assessed activities. However, they noted that most tasks could still be performed with 40° of extension and flexion (approximately 70% of the full range of motion), though not all were achievable.

Furthermore, Ryu et al. (1991) provided detailed insights into the wrist ROM required for functional activities. They reported that performing all 24 activities of daily living (ADLs) necessitated 60° of extension, 54° of flexion, 40° of ulnar deviation, and 17° of radial deviation. Specifically, personal care and hygiene tasks such as combing hair, perineal care, dental care, buttoning and unbuttoning, neck tie/scarf, as well as tying and untying shoe laces required 42° of extension to 54° of flexion and 40° of ulnar to 15° of radial deviation. Work-related functions, i.e., turning a doorknob or key and using a steering wheel, demanded over 40° of wrist extension, while inserting vertical screws required 43° of flexion, and inserting horizontal screws needed 31° of ulnar deviation. The lowest ROM requirements were associated with handwriting, needing only 14° of extension-flexion and 12° of radioulnar deviation. Conversely, the greatest extension (60°) and radial deviation (17°) were needed for rising from a chair using armrests. Diet and food preparation tasks were among those requiring the least wrist ROM, i.e., 42° extension to 37° flexion and 40° ulnar to 12° radial deviation.

The earlier study by Palmer et al. (1985) reported a smaller arc of functional wrist motions. It appeared that the functional range of wrist motion is between 5° of flexion, 30° of extension, 10° of radial deviation, and 15° of ulnar deviation, based on the evaluation of 52 tasks that were performed by normal subjects in a standardized manner in which a triaxial electrogoniometer was used. The 52 tasks were categorized into personal hygiene, culinary, other ADLs, carpentry, housekeeping, mechanics, secretary and surgeon.

Nelson et al. (1994) extended the work of Palmer et al. by analyzing the wrist range of motion (ROM) required for various daily tasks. Their findings indicated that

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perineal hygiene involved the greatest degree of wrist flexion (50°), followed by hair combing (38°) and jar opening (35°). Wrist extension was most pronounced when holding a telephone (51°), wringing a washcloth (49°), and pouring from a pitcher (46°). The highest radial deviation occurred during perineal hygiene (12°), with typewriter paper loading (11°) and hair combing (10°) also requiring significant movement. Tasks requiring the most ulnar deviation included turning a faucet (40°), opening a jar (39°), and turning a doorknob (36°). Collectively, these data defined an average maximal "envelope" of wrist motion: 50° flexion, 51° extension, 12° radial deviation, and 40° ulnar deviation.

However, not all tasks contributed significantly to defining this range. Eight out of 24 activities required less than 75% of the maximum ROM in all four directions, and 14 required less than 90%. Only 10 activities matched or closely approached (within 10%) the maximal ROM values. These included combing hair, perineal hygiene, wringing a washcloth, turning food with a spatula, pouring from a pitcher, opening a jar, operating a faucet, using a telephone, loading typewriter paper, and turning a doorknob. Table 2.1 summarizes the wrist ROM required in 24 ADLs that Nelson et al. (1994) studied.

Table 2.1 Wrist Range of Motion in Activities of Daily Living

	Radial Deviation			**Ulnar Deviation**			**Flexion**			**Extension**		
Activities	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg	Max	Min	Avg
Comb hair	18	-3	10.4	44	8	29.9	74	14	38.4	55	32	42.2
Tailbone	24	-3	11.6	37	12	24.3	65	28	49.8	66	-5	37.8
Washcloth	15	-6	6.4	50	17	34.4	74	9	28.3	65	25	49.2
Button	14	-5	6.3	40	7	19.1	35	-5	20.3	47	10	29.4
Tie shoe	15	2	7.5	31	13	22.7	56	-2	17.9	45	17	29.3
Use knife	17	-18	-7.1	37	16	26.4	32	-25	2.9	37	-5	15.0
Use fork	16	-9	-0.1	37	12	23.7	22	-20	-4.8	55	28	38.6
Spatula	2	-25	-12.1	45	25	37.2	44	8	25.4	53	12	28.9
Drink cup	11	-10	0.5	45	18	32.8	6	-27	-11.0	44	19	31.8
Picher	12	-3	6.1	42	17	31.2	36	-15	5.3	61	29	46.6
Can opener	18	-15	4.2	33	16	25.3	10	-22	-5.7	53	22	41.3
Stir bowl	18	-30	5.4	43	10	33.8	56	15	32.5	56	-8	21.6
Open jar	25	-10	6.9	47	32	39.6	57	24	35.3	52	12	34.8
Turn faucet	18	-2	9.0	51	27	40.0	50	18	26.3	59	-4	29.6
Turn page	17	-19	0	45	6	27.5	52	-17	17.7	40	8	28.3
Write name	13	-18	0.9	38	-8	11.6	10	-50	-20.0	54	14	33.9
Use phone	17	-3	9.2	32	15	24.7	10	-19	-3.2	63	37	51.1

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Dial "O"	17	-23	0	38	11	24.6	30	-5	10.8	54.7	7	28.8
Typewriter	17	7	11.4	46	18	29.3	42	0	22.0	50	10	36.2
Steer wheel	11	-2	4.7	45	28	34.9	35	-9	9.2	65	17	39.3
Door knob	11	-25	-8.3	44	26	36.3	20	-18	-1.1	54	24	41.2
Turn key	5	-22	-9.4	47	19	34.6	10	-36	-1.7	45	14	33.5
Screwdriver	-12	-25	-18.0	45	18	34.8	25	-9	2.5	45	23	33.4
Throw ball	18	-5	6.2	37	13	24.6	31	6	16.4	64	30	48.1

A more recent study by Gates et al. (2016) further quantified the wrist ROM necessary to perform ADL, reporting that 38° of flexion, 40° of extension, 38° of ulnar deviation, and 28° of radial deviation were sufficient to complete all tasks assessed. Notably, every task tested could be accomplished within a range of 38° flexion and 40° extension. The activities that demanded the most extensive wrist motion were donning pants and performing perineal care. When donning pants, participants typically extended the wrist up to 40° and radially deviated by 25° while pulling the pants upward, followed by 38° of flexion and 35° of ulnar deviation during zipper closure. This task also involved numerous wrist sub-movements as participants repositioned the pants. During perineal care, the greatest radial deviation (28°) occurred in the ipsilateral wrist during wiping, while the contralateral wrist exhibited peak ulnar deviation (38°) when retrieving toilet paper. These findings suggest that several ADLs engage nearly the full functional ROM of the wrist, reinforcing the importance of restoring this capacity during rehabilitation. Table 2.2 presents the mean wrist ROM requirements for upper limb ADLs according to the study by Gates et al. (2016).

Table 2.2 Mean Wrist Range of Motion Required for Activities of Daily Living

Activities	**Flexion**	**Extension**	**Ulnar Deviation**	**Radial Deviation**
Donning and zipping pants	38	40	35	25
Perineal care—ipsilateral limb	34	38	34	28
Perineal care—contralateral limb	16	32	38	12
Hand to back pocket	28	15	35	7
Deodorant—ipsilateral limb	11	27	23	12
Deodorant—contralateral limb	9	21	24	4
Box off ground	11	19	33	5
Box off shelf—head height	11	31	34	10
Box off shelf—fixed height	10	33	32	12
Can off shelf—head height	6	32	30	13

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Can off shelf—fixed height	10	31	29	10
Drinking from a cup	8	33	23	11

A recent study by Wei et al. (2025) highlighted the significance of ulnar extension as the most functionally essential direction of wrist motion in daily activities. This finding suggests that rehabilitation protocols can be more effectively tailored by prioritizing improvements in ROM in directions most critical to functional performance. By focusing therapeutic efforts on movements like ulnar extension while de-emphasizing less impactful motions, clinicians may enhance functional outcomes more efficiently and with reduced overall intervention demands (Wei et al. 2025).

The studies had provided quantitative characterizations of the wrist motions required to complete different activities of daily living. Understanding the wrist functional ROM is essential in making clinical decisions and setting treatment goals in OT practice.

2.3 TYPES OF WRIST FRACTURES

Various classification systems have been developed to categorize fractures of the distal radius and ulna, each emphasizing different aspects such as the mechanism of injury, fracture morphology, the extent of comminution, and involvement of the articular surface (Hanel et al. 2002). Historically, some of the earliest and most recognized eponymous fractures include Colles', Barton's, Smith's, and Hutchinson's (also known as Chauffeur's) fractures (Hanel et al. 2002; Meena et al. 2014; Goldfarb et al. 2001; Acosta-Olivo 2017; Saxton et al. 2021; Mehta et al. 2024).

2.3.1 Colles' Fracture

Colles' fractures were first described by Abraham Colles in 1814 at the Royal College of Surgeons in Dublin (Saxton et al. 2021; Acosta-Olivo 2017). They are defined as transverse, extra-articular fractures of the distal radial metaphysis, typically exhibiting dorsal comminution, dorsal angulation, dorsal displacement (including dorsal tilt and shift), and radial shortening. A pronounced dorsal angulation may result in the

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characteristic "dinner fork" deformity. Associated fractures of the ulnar styloid process are frequently observed (Saxton et al. 2021; Goldfarb et al. 2001; Meena et al. 2014).

Colles' fractures are the most prevalent type of DRF and commonly occur following a fall on an outstretched hand with the wrist in dorsiflexion (Saxton et al. 2021; Goldfarb et al. 2001). The injury mechanism involves tension forces along the volar aspect of the wrist, particularly through the proximal carpal row, most notably the lunate and scaphoid. These forces are transmitted dorsally to the distal radius, resulting in an extra-articular fracture with dorsal displacement of the distal fragment. The fracture generally remains extra-articular to the RCJ and is proximal to the DRUJ (Saxton et al. 2021).

2.3.2 Smith's Fracture

Smith's fracture, first described in 1847 by Irish surgeon Robert William Smith, is also referred to as a reverse Colles' fracture (Saxton et al. 2021; Goldfarb et al. 2001; Meena et al. 2014; Acosta-Olivo 2017). It is typically defined as a transverse, extra-articular fracture of the distal radius, characterized by volar displacement or angulation of the distal fragment (Saxton et al. 2021; Goldfarb et al. 2001; Acosta-Olivo 2017). The fracture may sometimes extend into the RCJ, involving the articular surface (Saxton et al. 2021).

Smith's fractures generally occur in younger individuals and are associated with higher-energy mechanisms of injury. Common causes include a fall onto a volar-flexed wrist (Goldfarb et al. 2001) or a direct impact to the dorsal aspect of the wrist (Saxton et al. 2021).

2.3.3 Barton's Fracture

Barton's fracture was first described in the 19th century by American orthopedic surgeon John Rhea Barton (Saxton et al. 2021). It is classified as a shear-type, intra-articular fracture of the distal radius, typically involving dorsal displacement of the carpal bones and hand along with a fragment of the distal radial articular surface (Goldfarb et al. 2001; Meena et al.,2014; Saxton et al. 2021). The most common

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mechanism of injury is a fall onto an outstretched, pronated wrist, which generates compressive forces transmitted through the hand and wrist to the articular surface of the radius. This force causes a triangular fragment of the distal radius to shear off and displace dorsally.

In contrast, a reverse Barton's fracture involves volar displacement of the articular fragment of the distal radius. Like the dorsal variant, the carpal bones remain attached to the displaced fragment and follow its volar displacement (Saxton et al. 2021). Both types are inherently unstable due to joint surface involvement and are typically managed surgically to restore anatomical alignment and wrist function.

2.3.4 Hutchinson's Fracture (Chauffeur's Fracture)

Hutchinson's fracture, also known as a Chauffeur's fracture, is an oblique, intra-articular fracture of the distal radius that includes the radial styloid process within the fracture fragment. The size of the fracture fragment can vary, and displacement is often influenced by intercarpal ligamentous attachments, particularly involving the scapholunate ligament. The injury typically results from shear or translational forces transmitted through the scaphoid or scapholunate joint during forced dorsiflexion and abduction or from direct trauma to the dorsal aspect of the wrist (Goldfarb et al. 2001; Saxton et al. 2021).

The fracture was first described by British surgeon Jonathan Hutchinson in 1866. The eponym "Chauffeur's fracture" emerged in the early 20th century, referring to wrist injuries sustained by drivers using hand-crank starters to ignite car engines. Unexpected backfire from the crank could cause sudden wrist hyperextension, leading to radial styloid fracture. Anatomically, the fracture extends obliquely from the distal articular surface proximally through the lateral cortex of the distal radius, separating the radial styloid from the main radial shaft. These fractures are frequently unstable and require surgical stabilization (Saxton et al. 2021).

Although Colles', Smith's, Barton's, and Chauffeur's fractures primarily involve the distal radius and/or wrist joint, there are other complex forearm fractures such as Essex-Lopresti (McGlinn et al. 2013) and Galeazzi fractures (Sebastian &

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Chung 2010; Alajmi 2020) that disrupt the anatomical and biomechanical functions of the DRUJ. The Essex-Lopresti injury is characterized by a radial head fracture, disruption of the interosseous membrane (IOM), and concomitant dislocation of the DRUJ (Essex-Lopresti 1951; McGlinn et al. 2013; Giannatos et al. 2022). Galeazzi fracture-dislocations involve a fracture of the distal third of the radius, accompanied by a dislocation of the DRUJ. British surgeon Sir Astley Cooper initially described this injury pattern in 1822; it was later named after Italian surgeon Ricardo Galeazzi, who in 1934 published a detailed series of 18 cases outlining the injury's mechanism, frequency, and management strategies (Sebastian & Chung 2010; Alajmi 2020).

2.4 REHABILITATION FOR WRIST FRACTURES

The Cochrane review by Handoll and Elliot (2015) and the systematic review by Handoll et al. (2003) concluded that current evidence from randomized controlled trials (RCTs) remains insufficient to determine the comparative effectiveness of various interventions used in the rehabilitation of adults with DRF.

Although definitive guidelines are lacking, a widely accepted phased approach to DRF rehabilitation is applied in nonoperative and operative management. Rehabilitation typically progresses through distinct phases, beginning with early protective mobilization, followed by wrist mobilization, and culminating in a strengthening phase that continues until patients transition to an independent home exercise program (Smith et al. 2004; Brehmer & Husband 2014; Coughlin et al. 2021; Mehta et al. 2024).

Regarding the timing of rehabilitation initiation following DRF, strong evidence supports the early commencement of therapy. Specifically, it is recommended that clinicians initiate AROM exercises for the hand, wrist, and shoulder, in conjunction with light daily activities, within the first three weeks postoperatively. This early intervention has been shown to significantly improve short-term outcomes (up to three months) related to pain, wrist AROM, grip strength, and functional performance, as well as long-term outcomes (≥ six months) in wrist AROM and grip strength (Mehta et al. 2024).

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2.4.1 Protective Phase

The early protective phase usually begins immediately after a surgical intervention or the application of a cast or splint, aiming to prevent joint stiffness that may compromise functional recovery (Chung et al 2006; Brehmer & Husband 2014; Quadlbauer et al. 2017; Mehta et al. 2024). During this phase, wrist immobilization is achieved using a cast or splint, and wrist ROM is generally restricted (Smith et al. 2004; Chung et al. 2006; Brehmer & Husband 2014; Quadlbauer et al. 2020; Mehta et al. 2024). However, movement of uninvolved joints is actively encouraged (Brehmer & Husband 2014; Kuo et al. 2013; Smith et al. 2004). In a randomized trial, Kuo et al. (2013) demonstrated that patient education promoting self-directed active or passive ROM of the digits, elbow, forearm, and shoulder significantly improves fine motor function, specifically enhancing finger and thumb workspace, as well as pinch and grip strength without increasing the risk of deformity.

Bruder et al. (2017), in a systematic review, found that initiating mobilization and exercise after a shorter period of immobilization may enhance patient outcomes by increasing activity participation and reducing impairment. However, whether these benefits stem primarily from the reduced immobilization duration or the earlier commencement of exercise remains unclear. Evidence suggests that shorter immobilization periods and early active mobilization contribute to decreased pain, swelling, edema, and other factors that may otherwise lead to scar tissue formation and restricted ROM. This evidence highlights the significance of immobilization duration as a key factor influencing short-term functional recovery following DRF. Furthermore, reducing immobilization length facilitates using both hands in daily tasks, potentially improving quality of life and allowing for greater exercise engagement due to more normalized hand function (Quadlbauer et al. 2020).

2.4.2 Mobilization Phase

The wrist mobilization phase typically begins once the orthopaedic surgeon confirms satisfactory fracture healing, allowing for safe loading across the affected distal radius (Mehta et al. 2024; Kooner & Grewal. 2021). The primary focus of the wrist mobilization phase is to manage pain and edema while optimizing both active and

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passive ROM at the wrist, as well as in the hand, elbow, and shoulder (Smith et al. 2004; Brehmer & Husband 2014; Wollstein et al. 2019; Kooner & Grewal 2021; Mehta et al. 2024). For patients managed conservatively, this phase usually begins after a cast immobilization period of 4 to 6 weeks (Lozano-Calderón et al. 2008; Karagiannopoulos et al. 2013; Coughlin et al. 2021; Kooner & Grewal. 2021; Mehta et al. 2024).

In contrast, for patients who have undergone surgical interventions, early active rehabilitation protocols are appropriate with specific surgical methods of distal radius fixation, including the external fixation, dorsal plating, and volar plating (Smith et al. 2004). Volar fixed-angle plating allows an early active motion program emphasizing the early restoration of wrist extension (Smith et al. 2004). Studies had shown that for patients who have undergone surgical repair with volar plating internal fixation, mobilization might start as early as immediately following surgery within the first two weeks (accelerated rehabilitation approach) (Quadlbauer et al. 2020; Quadlbauer et al 2017; Sørensen et al. 2020; Tomruk et al. 2020; Deng et al. 2021; Smith et al. 2004; Chung et al. 2006; Lozano-Calderón et al. 2008; Brehmer & Husband 2014; Smith et al. 2004) or at 4 to 6 weeks (delayed-standard rehabilitation approach) (Lozano-Calderón et al. 2008; Brehmer & Husband 2014; Wollstein et al. 2019) following surgery, depending on fracture stability and healing progress. However, studies have not consistently demonstrated superior outcomes with early mobilization protocols. Multiple trials have reported no significant improvements in ROM or DASH scores between early and delayed mobilization groups (Sørensen et al. 2020; Lozano-Calderón et al. 2008; Andrade-Silva et al. 2019). Deng et al. (2021) revealed that early mobilization (immobilization period ≤ 2 weeks) resulted in a significantly better DASH score than late mobilization (immobilization period > 2 weeks) at 6 weeks (mean difference of 10.15 points) postoperatively. Nevertheless, their study revealed that although early mobilization had significantly better DASH, PRWE, grip strength, and wrist ROM outcomes at earlier stages, both early mobilization and late mobilization had similar clinical outcomes during the long-term follow-up period at 12 weeks and ≥ 1 year (Deng et al. 2021). This lack of observed benefit may stem from insufficient aggressive early mobilization programs, particularly in terms of early weight-bearing activity (Sørensen et al. 2020). In contrast, Brehmer and Husband (2014) advocate for a more intensive rehabilitation approach. Their findings suggest that initiating ROM

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exercises as early as three to five days following volar open reduction internal fixation (ORIF) for DRFs, along with the introduction of strengthening at two weeks postoperatively, may promote an earlier return of functions and potentially allow for an earlier return to daily, work, and sports activities (Brehmer & Husband 2014).

For patients treated with wrist external fixation or dorsal plating, initial rehabilitation emphasizes pain, edema management, and digital ROM exercises (Smith et al., 2004). During this early phase, pin site care is critical, and active wrist movement is not possible due to the rigid, locked configuration of the external fixator, which spans the wrist joint. However, patients are encouraged to engage in active, active-assisted, and passive ROM exercises for the uninvolved joints, including the shoulder, elbow, and digits (Smith et al. 2004). Once the external fixator is removed, rehabilitation shifts toward restoring wrist mobility. The interventions a gradual progression of active, active-assisted, and passive motion techniques, with particular attention to wrist extension, radial deviation, and supination (Smith et al. 2004). Similarly, for patients with dorsal plating, early rehabilitation involves a protective static splint, during which active motion of uninvolved joints and the resumption of ADLs are encouraged. Following sufficient bony healing, wrist-specific exercises are initiated, emphasizing on active wrist flexion to address potential scarring of the dorsal wrist capsule (Smith et al. 2004).

2.4.3 Manual Therapy Techniques

Manual therapy techniques, including joint and soft tissue mobilization, have demonstrated positive effects on functional outcomes during the wrist mobilization phase following DRF (Tomruk et al. 2020; Mitsukane et al. 2015; Bruder et al. 2013; Knygsand-Roenhoej & Marib 2011; Mehta et al. 2024). Early application of Mulligan's mobilization with movement (MVM) techniques targeting the RCJ, UCJ, DRUJ, and PRUJ has significantly improved outcomes in patients treated with volar plating. These improvements include enhanced DASH and PRWE scores, reduced pain, increased wrist extension, flexion, radial deviation, ulnar deviation, supination, and grip strength (Tomruk et al. 2020). Complementing these findings, Reid et al. (2020) provided additional support for MWM as an effective adjunct to ROM exercises and patient

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education. Their randomized trial among non-operatively treated DRF patients demonstrated that the inclusion of MWM resulted in statistically and clinically significant improvements in QuickDASH scores, supination, wrist extension, and flexion at both 4-week and 12-week follow-up intervals. Additionally, Mitsukane et al. (2015) found that repetitive wrist extension exercises promoted greater activation of the wrist extensor muscles during grasping tasks, thereby contributing to enhanced grip strength. Conversely, earlier work by Kay et al. (2000) found no added benefit of passive mobilization techniques when combined with exercise and advice in patients treated with pins and/or plaster casts. These findings suggest that manual therapy interventions such as MWM, accessory joint mobilizations, oscillatory techniques, and sustained stretching should be considered as part of a multimodal rehabilitation approach. These interventions should be applied based on individual tolerance and fracture stability to support short-term improvements in wrist pain, AROM, and upper limb functional outcomes in operatively and non-operatively managed DRF cases (Mehta et al. 2024).

2.4.4 Edema and Scar Management

Effective management of hand and wrist edema is considered an important component in the early phases of DRF rehabilitation, regardless of whether the injury is managed operatively or non-operatively (Chung et al. 2006; Brehmer & Husband 2014; Miller-Shahabar et al. 2018; Kooner & Grewal. 2021; Mehta et al., 2024). Various interventions have been utilized to control edema, including compression garments or gloves, manual lymphatic drainage techniques, upper-limb elevation, intermittent pneumatic compression, and other therapeutic modalities (Härén & Wiberg 2006; Knygsand-Roenhoej & Maribo 2011; Miller-Shahabar et al. 2018; Alkner et al. 2018; Mehta et al. 2024). An RCT by Miller-Shahabar et al. (2018) demonstrated that the combined use of compression gloves (20-30 mmHg worn 10 hours/day) with standard rehabilitation significantly improved outcomes in terms of pain, swelling, wrist and finger ROM, and the ability to perform daily activities, compared to routine rehabilitation alone. Furthermore, manual techniques such as manual edema mobilization or manual lymphatic drainage have effectively reduced subacute swelling in the hand and upper limb (Härén & Wiberg 2006; Knygsand-Roenhoej & Maribo

2011). Härén and Wiberg (2006) emphasized that manual lymphatic drainage may be critical for timely rehabilitation progress, as persistent edema can delay recovery. Similarly, Knygsand-Roenhoej and Maribo (2011) found that manual edema mobilization reduced subacute swelling more effectively than conventional edema management techniques and required fewer treatment sessions. In contrast, Alkner et al. (2018) reported that intermittent pneumatic compression initiated four weeks after volar plate fixation provided no significant therapeutic advantage, and their findings do not support its routine application in postoperative DRF rehabilitation.

Besides that, following surgical wound healing, scar management techniques, including skin mobilization and deep massage, play an important role in minimizing tendon adherence at the skin level, further supporting optimal wrist function during rehabilitation (Smith et al. 2004).

2.4.5 Splinting and Orthosis Management

Using wrist splints or orthoses is a complementary component within the multimodal rehabilitation framework for DRF. The primary objective of splinting or orthotic intervention is to restore physiological joint motion by promoting permanent viscoelastic elongation of shortened or contracted soft tissues surrounding the wrist joint (Mehta et al. 2024). Patients with posttraumatic joint stiffness following DRF have demonstrated significant improvements in wrist and forearm ROM by using static progressive splinting (Lucado et al. 2008). In their study, Lucado et al. (2008) reported mean increases of 18.6° in wrist extension, 11.4° in flexion, 20.0° in forearm pronation, and 14.5° in supination among DRF patients presenting with stiffness-related complications. These findings highlight the efficacy of static progressive splints in addressing limited joint mobility in the rehabilitation phase.

In contrast, dynamic splinting has not shown similar therapeutic benefits. According to Jongs et al. (2012), dynamic splints did not significantly improve active wrist extension, flexion, radial deviation, or ulnar deviation in patients with contractures following DRF. Based on these findings, clinical guidelines recommended that static progressive or dynamic splints or orthoses may be employed by clinicians as adjuncts to standard care to enhance passive ROM of the wrist, particularly in DRF patients who

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experience persistent wrist stiffness and have difficulty achieving their functional goals (Mehta et al. 2024).

2.4.6 Strengthening Phase and Therapeutic Exercises

The strengthening phase of rehabilitation following a DRF typically involves a progressive resistance training program. This program includes isotonic and eccentric exercises, power gripping, and perturbation training, all designed to incrementally increase load through the wrist and the entire upper extremity (Mehta et al. 2024). A central objective of this phase is to enhance neuromuscular control, unconscious proprioception, and functional retraining tailored to the individual's specific functional goals and expectations (Karagiannopoulos & Michlovitz 2016). This stage is critical for safely facilitating the return to full daily and occupational activities. However, it is essential to recognize that the timeline for rehabilitation progression may differ across individuals, influenced by factors such as physical demands, the degree of functional impairment, comorbid conditions, and post-fracture complications (Mehta et al. 2024).

Based on the progression of fracture healing and postoperative stability, progressive strengthening exercises targeting the hand, wrist, forearm, and elbow muscles are typically initiated between 6 weeks (Chung et al. 2006) and 8 weeks (Tomruk et al. 2020) following surgery per standard rehabilitation protocols. However, emerging evidence suggests that introducing submaximal strengthening exercises for the wrist and hand as early as two weeks post-surgery or even during cast immobilization may accelerate functional recovery (Bremer & Husband 2014; Nguyen et al. 2020; Kaji et al. 2022).

In the accelerated rehabilitation protocol proposed by Bremer and Husband (2014), strengthening exercises commence at two weeks postoperatively following ORIF with volar plating. This protocol begins with isometric and light putty strengthening exercises, progresses to isotonic and medium putty exercises by four weeks, and introduces heavy putty strengthening exercises by six weeks post-surgery. Their randomized postoperative study concluded that initiating strengthening as early as two weeks facilitates earlier recovery of clinically meaningful function and may support a quicker return to daily, occupational, and recreational activities (Bremer &

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Husband 2014). Similarly, Nguyen et al. (2020) advocated for early initiation of strengthening in older adults with non-operatively managed DRFs under cast immobilization. Their protocol involved isometric finger strengthening beginning in the first week post-injury, with hand strengthening using a rubber ball introduced from weeks two through six. At 12 weeks, the intervention group demonstrated significantly greater grip strength and pain reduction improvements than the control group, which began strengthening only after cast removal at six weeks. Additionally, Kaji et al. (2022) provided evidence that early grip strength training initiated at two weeks postoperatively in surgically treated DRF patients led to improved grip strength and palmar wrist flexion recovery, without contributing to any loss of fracture reduction.

Moderate clinical evidence supports the early initiation of submaximal progressive strengthening exercises such as towel and putty squeezing, as well as light-load gripping, beginning at two weeks postoperatively in individuals with surgically repaired DRFs or during the second week of cast immobilization in non-operative cases. However, this approach is recommended only for uncomplicated cases characterized by stable fractures, satisfactory radioulnar articular alignment, and the absence of ulnar-sided wrist pain. This early strengthening strategy has been associated with improved short-term outcomes (up to six months) in pain reduction, wrist AROM, grip strength, and functional performance, with minimal risk of adversely affecting fracture healing (Mehta et al. 2024).

Functional training, frequently administered by occupational therapists, constitutes an essential component of the rehabilitation program for patients with DRF to enhance upper limb functional capacity (Filipova et al. 2015). This approach targets improvements in mobility, muscular strength, and hand and arm dexterity (Filipova et al. 2015). In their study on conservatively treated DRF patients, Filipova et al. (2015) evaluated the effects of combining OT and PT interventions. The control group received standard PT, which included Galvanic bath therapy, AROM exercises, joint mobilizations, and strengthening exercises. In contrast, the experimental group received the same PT interventions supplemented with 30-minute OT sessions focused on functional strengthening. These sessions involved task-specific hand, wrist, and forearm exerises, utilizing various OT tools and emphasizing ADLs to enhance

dexterity, endurance, and coordination (Filipova et al. 2015). The study concluded that the combined OT and PT intervention led to a statistically significant improvement in grip strength compared to PT alone, particularly within the 12 to 16-week post-fracture period (Filipova et al. 2015).

Moderate evidence from various studies concluded that clinicians should implement appropriately timed therapeutic exercises tailored to the type of fracture management and the stability of the fracture. These exercises may include passive and active ROM, tendon gliding, motor control training, functional tasks, and progressive bilateral resistance exercises targeting the wrist and hand and the scapular and glenohumeral musculature. Such a comprehensive approach is recommended to optimize pain reduction, ROM, strength, and overall upper limb function outcomes in patients recovering from a DRF (Mehta et al. 2024).

2.4.7 Therapeutic Modalities

Therapeutic modalities are recognized as complementary components within a multimodal rehabilitation approach for patients recovering from DRF. These interventions encompass a range of thermal, electrical, and mechanical modalities (Handoll & Elliott 2015; Mehta et al. 2024). Several studies have investigated the efficacy of thermal agents in DRF management (Cheing et al. 2005; Szekeres et al. 2017; Szekeres et al. 2018). Cheing et al. (2005) demonstrated that five days of cryotherapy and exercise effectively reduced post-immobilization swelling. Their findings further indicated that combining pulsed electromagnetic field therapy and ice therapy with exercise yielded superior outcomes in terms of pain reduction and improvements in wrist ROM, specifically ulnar deviation and flexion, when compared to ice plus exercise or pulsed electromagnetic field therapy plus exercise alone (Cheing et al. 2005). Superficial heat modalities, including hot packs and whirlpools, are commonly used to reduce pain and muscle soreness, enhance local blood circulation, and facilitate ROM (Szekeres et al. 2017). According to Szekeres et al. (2018), the primary role of these modalities is to precondition the joint for therapeutic stretching, with only modest gains in ROM expected. Their studies also concluded that both hot packs and whirlpool treatments are clinically acceptable options for preparing patients

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with DRF for further therapy. Notably, whirlpool treatment led to a statistically greater improvement in wrist ROM during therapy sessions than hot pack application, likely due to the added benefit of allowing patients to perform active exercises during the thermal intervention (Szekeres et al. 2018). Besides, other available thermal therapeutic agents, such as fluidotherapy are used in hand therapy but have yet to be researched following DRF (Mehta et al. 2024).

The safety and efficacy of light-emitting therapeutic agents, such as laser therapy, have been explored in the rehabilitation of individuals with DRF. Sæbø et al. (2022) found that photobiomodulation therapy, when used with a home-based rehabilitation exercise program, is safe and associated with long-term reductions in pain and disability. Similarly, Zlatković-Švenda et al. (2019) demonstrated that a combined intervention involving light therapy, cryotherapy, and exercise yielded effective pain management, significant improvements in wrist ROM, and a reduced risk of developing complex regional pain syndrome. Acosta-Olivo et al. (2017) reported that laser therapy led to statistically significant improvements in all aspects of wrist ROM except supination, further supporting its potential therapeutic benefit in DRF rehabilitation).

Electrotherapy modalities, such as transcutaneous electrical nerve stimulation, are widely recognized for their effectiveness in managing pain across various acute and chronic conditions (Minor & Sanford 1999). In the context of DRF rehabilitation, Lee et al. (2015) reported that TENS could provide immediate postoperative pain relief in patients with Colles' fractures; however, the analgesic effect was short-lived and not sustained beyond 24 hours. Their findings suggest that while transcutaneous electrical nerve stimulation may offer temporary pain reduction, its efficacy may not differ significantly from placebo treatment, indicating the need for cautious interpretation and application in clinical practice (Lee et al. 2015). Additionally, although neuromuscular electrical stimulation is commonly utilized in hand therapy settings for muscle strengthening, there is currently a lack of robust evidence supporting its effectiveness specifically in the rehabilitation of DRF patients (Mehta et al. 2024).

2.5 OCCUPATIONAL THERAPY AND WRIST FRACTURES

According to World Federation of Occupational Therapy (2025), OT promotes health

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and wellbeing by supporting participation in meaningful occupations that people want, need, or are expected to do. In OT, occupations refer to the everyday activities that people do as individuals, in families and with communities to occupy time and bring meaning and purpose to life. Occupations include things people need to, want to and are expected to do.

OT practitioners commonly work with individuals experiencing musculoskeletal disorders of the distal upper extremity. Their primary role in upper extremity rehabilitation involves collaboratively identifying client-centered goals and implementing evaluations and interventions aimed to enhance the individual's ability to perform functional tasks independently (Roll & Hardison 2017). The primary objective of hand rehabilitation extends beyond merely improving strength, mobility, and endurance (Guzelkucuk et al. 2007). It also aims to restore the individual's functional capacity to the highest achievable level, enabling a return to active, productive living and successful reintegration into the workforce (Guzelkucuk et al. 2007).

OT interventions encompass a range of approaches, including occupations and activities, interventions that support occupational performance, education and training, advocacy, group interventions, and virtual interventions. These interventions promote engagement in meaningful occupations, helping individuals, groups, and populations in achieving health, well-being, and participation in everyday life (American Occupational Therapy Association (AOTA) 2020).

De-Rosende-Celeiro and Fernández-Barreiro (2023) affirmed that OT services play a significant role in facilitating the return to daily activities and mitigating impairments in body functions following either conservative or surgical treatment of DRF. Additionally, they identified two intervention-related factors that significantly enhance the effectiveness of OT following a DRF: early initiation of treatment and a greater number of therapy sessions (De-Rosende-Celeiro & Fernández-Barreiro 2023).

Amini (2011) systematically reviewed OT interventions targeting work-related injuries and conditions affecting the forearm, wrist, and hand. The review classified OT interventions into several categories: silicone gel sheeting, massage, splinting, early

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mobilization, low-level laser therapy, thermal modalities, exercise, therapeutic gloves, ultrasound, pain management techniques, and workplace-based interventions (Amini 2011). Similarly, Case-Smith (2003) identified comparable OT interventions for hand rehabilitation, including splinting, therapeutic exercises, therapeutic activities, manual therapy, activities of daily living training, and physical agent modalities like ultrasound, hot/cold packs, whirlpool, electrical stimulation, and moist heat.

In line with this, a more recent study by De-Rosende-Celeiro and Fernández-Barreiro (2023) categorized OT interventions for DRF into two main groups, i.e., adjunctive methods and activity-based interventions. Adjunctive methods include splinting, edema control, sensory re-education, therapeutic exercises, scar management, tendon gliding, and the application of physical agent modalities. In contrast, activity-based interventions encompass the therapeutic use of everyday and meaningful activities, assistive devices, environmental modifications, training in daily living skills, and returning to occupations (De-Rosende-Celeiro & Fernández-Barreiro 2023).

According to De-Rosende-Celeiro and Fernández-Barreiro (2023), splinting interventions for DRF primarily focus on providing education and guidance regarding splint application and wearing schedules. OT strategies for managing edema commonly involve elevation and positioning, light compression, Coban wrapping, contrast baths, active movement, and engagement in functional tasks (De-Rosende-Celeiro & Fernández-Barreiro 2023). Sensory re-education approaches include proprioceptive training, graded motor imagery, laterality recognition, explicit motor imagery, mirror therapy, and various sensory stimulation activities (De-Rosende-Celeiro & Fernández-Barreiro 2023). In terms of therapeutic exercises post-DRF, the authors recommend a progressive, pain-free regimen that incorporates active range of motion (ROM) for unaffected joints, dart-throwing movements, gradual active and active-assisted ROM exercises for affected joints, passive ROM, occupationally focused tasks, and progressive functional strengthening (De-Rosende-Celeiro & Fernández-Barreiro 2023).

According to the AOTA (2014), OT practitioners may use physical agent modalities (PAMs) as part of a comprehensive intervention plan to enhance

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occupational engagement. These modalities are intended to prepare clients for occupational performance and should be integrated into a broader therapeutic approach rather than applied in isolation (AOTA 2020). PAMs may reduce pain, facilitate wound healing, manage edema, or prepare muscles for movement, thereby supporting improved functional performance (AOTA 2020).

Given the intricate anatomical structure of the hand, determining the most effective treatment approach for hand injuries can be challenging (Guzelkucuk et al. 2007). However, evidence suggests that ADL simulations may enhance hand function more effectively than conventional exercise-based rehabilitation methods (Guzelkucuk et al. 2007). This is because movements involved in daily tasks are inherently complex and require coordinated, three-dimensional actions across various tissues (Guzelkucuk et al. 2007). The authors note that ADL simulations such as locking and unlocking a door, turning a faucet, screwing, grasping large objects, untying knots, and using scissors promote more effective mobilization of adhesions and elongation of ligaments, capsules, and muscles (Guzelkucuk et al. 2007). These tasks encourage dynamic, multi-directional movements, unlike traditional unidirectional exercises (e.g., simple flexion and extension), which may offer more limited functional gains (Guzelkucuk et al. 2007).

Collis et al. (2022) demonstrated that integrating graded, modified activities during the early stages of rehabilitation promotes wrist mobility, enhances overall well-being, and supports the habituation of wrist movement. Their study emphasized the significant role that daily activities and meaningful occupations play in restoring movement and function following surgical intervention for DRFs. (Collis et al. 2022). According to their findings, Collis et al. (2022) had provided valuable insights on the roles of occupations, including acting as a driving force for rehabilitation, offering ready-to-hand challenges for opportunistic and automatic movements, inviting intentional use of affected wrist, habituating the wrist to movement through repetitions and confidence-building, and by drawing on the psychosocial resources of individuals (Collis et al. 2022).

OT interventions have been proven effective in enhancing functional outcomes

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following a DRF (Yang et al. 2018; Case-Smith 2003; De-Rosende-Celeiro & Fernández-Barreiro 2023). A Cochrane systematic review by Handoll et al. (2006) reported that, although no significant long-term benefits were observed, OT administered during the immobilization period resulted in notable short-term improvements in grip strength, pinch strength, and ROM. Yang et al. (2018) identified significant correlations between wrist flexion, wrist extension, ulnar deviation, and forearm supination with changes in QuickDASH scores over time. Their findings highlighted the critical role of patient education and early intervention during immobilization in maintaining hand-related ROM and enhancing functional recovery following DRF. Furthermore, research by Case-Smith (2003) demonstrated that individuals recovering from upper-extremity injuries or surgical interventions experienced clinically and statistically significant improvements in functional performance after participating in 6 to 8 weeks of client-centered OT. On average, participants received 13 hours of OT, typically involved using PAMs, manual techniques, and therapeutic activities. In addition, De-Rosende-Celeiro and Fernández-Barreiro (2023) provided evidence supporting the effectiveness of an OT program in facilitating recovery following both conservatively and surgically managed DRFs. Specifically, OT contributes to restoring daily functional activities and reducing impairments in body functions. The findings from their study highlighted that early initiation of therapy and a higher frequency of OT sessions appear to enhance recovery trajectories significantly (De-Rosende-Celeiro & Fernández-Barreiro 2023).

2.6 HAND FUNCTION AND OCCUPATIONAL PERFORMANCE RELATED TO WRIST FRACTURES

Several studies have demonstrated that a significant number of individuals continue to experience residual wrist pain and functional disability even one year after sustaining a DRF (MacDermid et al. 2003; Ydreborg et al. 2015; Nazzal et al. 2020; Pradhan et al. 2022; Farzad et al. 2023; De-Rosende-Celeiro & Fernández-Barreiro 2023). Ikpeze et al. (2016) reported that following a DRF, patients tend to prioritize the ability to perform everyday functional activities over clinical or biomechanical outcomes.

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2.6.1 Functional Disability following Wrist Fractures

Farzad et al. (2023) found that even one year following DRF, patients continued to experience occupational performance and participation challenges, despite improvements in PROMs. Occupational performance was positively correlated with participation (r = 0.62) and inversely correlated with disability (r = –0.62) (Farzard et al. 2023). The study identified ongoing occupational difficulties in three core areas measured by the Canadian Occupational Performance Measure (COPM): self-care (15.21%), leisure (12.16%), and productivity (16.22%) (Farzad et al. 2023).

Furthermore, a majority of participants reported challenges aligned with three chapters of the ICF: domestic life (67 participants, 55%), community, social, and civic life (64 participants, 53%), and major life areas (63 participants, 52%) (Farzad et al. 2023). Similarly, De-Rosende-Celeiro and Fernández-Barreiro (2023) observed that individuals with DRF experienced functional limitations in hand-related daily tasks, including ADLs, IADLs, social participation, leisure, and work-related activities. Their findings also highlighted performance deficits related to grip strength, AROM, pain, tingling, and disrupted sleep.

In a related study, Nazzal et al. (2020) reported that individuals recovering from DRF typically exhibited minimal to mild levels of disability, characterized by pain, reduced grip and pinch strength, limited wrist ROM, especially in flexion and extension, and impaired dexterity. These functional limitations were found to persist for six months to two years post-injury, continuing to impact occupational performance (Nazzal et al. 2020). Additionally, Case-Smith (2003) reported that clients with hand injuries initially presented with severe impairments in ADLs upon admission to OT services. However, upon discharge, most exhibited only mild difficulties, and 20 out of 25 clients successfully returned to their former occupations, indicating positive outcomes associated with structured rehabilitation.

MacDermid et al. (2003) found that patients typically experience significant pain and disability immediately following a DRF. At baseline, 81% of participants reported severe or very severe pain and functional limitations. These symptoms

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improved markedly within the first three months post-injury, with continued but slower progress observed thereafter (MacDermid et al. 2003). These results are consistent with the recent findings of Blomstrand et al. (2023), who reported that patients experienced improvements in pain, hand function, and activity performance within the first three months following a DRF. By one-year post-fracture, 79% of patients reported experiencing no or minimal pain and disability (MacDermid et al. 2003). The PRWE revealed that all specific activities were initially rated as severely difficult, mainly due to movement restrictions and contraindications for repetitive use or lifting during the initial healing phase (MacDermid et al. 2003). Elevated levels of pain and disability were most pronounced during the reparative phase, when soft tissue and bone healing are actively taking place. This phase is followed by the rehabilitative phase, characterized by more gradual recovery, during which most functional gains are typically achieved six months after the injury (MacDermid et al. 2003). This process is further supported by Porter (2013), who observed overall improvements in grip function, reductions in pain following physical activity, and enhanced occupational performance within the first six months following conservative treatment of a DRF.

Ydreborg et al. (2015) reported that 12 months post-surgery, patients had regained nearly full ROM in the affected hand, comparable to the uninjured side. Additionally, grip strength approached normative values, and pain levels, at rest and during activity had significantly decreased (Ydreborg et al. 2015). However, increased pain at rest and during activity was noted between 12 and 24 months postoperatively. Although disability, as measured by the DASH questionnaire, improved progressively over time, it remained elevated in comparison to pre-injury levels (Ydreborg et al. 2015). Similarly, Pradhan et al. (2022) found that many individuals continued to experience persistent pain and functional limitations up to 18 months following wrist fractures. Supporting these findings, a prognostic model developed by Cashin et al. (2019) identified that patients presenting with higher baseline pain levels were more likely to develop long-term persistent pain following wrist or hand fractures.

In terms of the perspective of IADL participation, Tan et al. (2024) reported that, following a DRF, patients may be considered for a driving assessment as early as 4 to 6 weeks post-surgery, provided that pain is well controlled and clinical criteria for

forearm pronation and supination are met.

2.6.2 Time Lost from Work following Wrist Fractures

Studies have shown that surgical management of DRFs is more frequently associated with extended work absences than conservative treatment (Palola et al. 2023; Ax et al. 2024). Similar findings were reported by Neutel et al. (2019) in their study involving 243 workers with traumatic hand injuries. In the recent study, Ax et al. (2024) reported that patients who underwent surgical treatment for a DRF had a mean sick leave duration of 75 days, compared to 63 days for those managed conservatively. These findings align with earlier research by MacDermid et al. (2007), who documented an average sick leave of 9.2 weeks among 227 workers with DRF. Similarly, a recent study reported a median time off work of 55 days (7.9 weeks) following a DRF, with treatment-specific medians of 49 days (7 weeks) for conservatively managed patients and 70 days (10 weeks) for those who received surgical intervention. The longer time lost from work among individuals with operatively treated DRFs may partly be attributed to injury severity, including factors such as more complex fracture morphology and more extensive soft tissue damage (Palola et al. 2023). In contrast, Egund et al. (2020) reported a notably shorter duration of sick leave, averaging only four weeks, in their all-male cohort following DRFs, which is considerably shorter compared to findings from other studies.

MacDermid et al. (2007) reported that work loss following a DRF is highly variable and cannot be reliably predicted based solely on clinical variables. Evidence suggests that patients reporting high levels of pain and disability (MacDermid et al. 2007), as well as those with physically demanding occupations (MacDermid et al. 2007; Ax et al. 2024) at baseline, are at greater risk for prolonged absence from work. Neutel et al. (2019) also reported that the type of work strongly influenced the return to work process among workers with traumatic hand injuries. Besides that, in their previous study of 120 patients with DRFs, MacDermid et al. (2002) highlighted the significant influence of injury compensation on self-reported pain and disability, demonstrating that compensation status was a stronger explanatory factor than injury severity. Patients receiving injury compensation reported more than twice the levels of pain and disability

compared to non-compensated individuals within the study population.

Egund et al. (2020) further highlighted the factors influencing the duration of sick leave following DRF. They identified that DASH scores ($rs = 0.4$, $p < 0.001$), pain intensity ($rs = 0.4$, $p < 0.001$), and the Physical Component Scale of the SF-36 ($rs = -0.4$, $p = 0.002$), measured as early as one-week post-fracture, were the strongest predictors of sick leave duration, irrespective of the treatment approach. In their study, the authors concluded that individuals reporting higher levels of perceived disability and pain as early as one-week post-fracture tended to experience longer durations of sick leave (Egund et al. 2020).

Ax et al. (2024) suggested that reducing the number of sick leave days following a DRF involves considering several interrelated factors. These include the physical demands of the patient's occupation, whether the injury affects the dominant or non-dominant hand, the feasibility of workplace modifications or job task adjustments, and the potential for part-time work as a transitional strategy to support an earlier return to employment while accommodating ongoing functional limitations (Ax et al. 2024). However, in the previous study, Cheng and Cheng (2011) emphasized that when OTs make job modification recommendations for workers to resume their previous role, it should not be assumed that all employers can accommodate such adjustments.

A study by Cheng and Cheng (2011) examining the predictive validity of job-specific functional capacity evaluations (FCEs) for return to work among patients with DRFs found that certain factors negatively impacted the predictive utility of FCEs. Specifically, a longer interval between the injury and the administration of the FCE and the presence of a compensable injury significantly reduced the evaluation's predictive ability (Cheng & Cheng 2011). The authors reported that each additional day from injury to FCE led to a 49.8% decrease in predictive validity, while a compensable injury reduced it by 54.9% (Cheng & Cheng 2011).

Additionally, Fore et al. (2015) found that FCE scores were responsive to changes following functional restoration treatment. The physical demand levels recorded at discharge were significant predictors of return to work and work retention

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one-year post-treatment among individuals with musculoskeletal disorders (Fore et al. 2015). The study identified work status at admission and pain intensity at discharge as significant predictors of return to work. Specifically, individuals employed at admission and reported lower pain levels at discharge had higher probabilities of returning to and retaining work (Fore et al. 2015). In contrast, factors such as length of disability, depressive symptoms, and perceived disability at discharge did not significantly predict return to work or work retention outcomes (Fore et al. 2015).

2.7 ROBOTIC REHABILITATION FOR WRIST

Rehabilitation robots are engineered to deliver therapy sessions that are repetitive, task-specific, intensive, precise, and cost-efficient (Molteni et al. 2018; Hussain et al. 2020 Banyai & Brișan 2024). These robotic systems also facilitate the objective evaluation of patient progress by recording kinematic and kinetic parameters, thereby supporting personalized rehabilitation strategies through adjustable levels of assistance (Hussain et al. 2020; Giansanti 2021; Garcia et al. 2024; Banyai & Brișan 2024). Based on their mechanical configuration, rehabilitation robots are generally classified into two categories: exoskeletons and end-effector systems (Lo & Xie 2012; Laut et al. 2016; Molteni et al. 2018; Hussain et al. 2020; Fareh et al. 2023; Garcia et al. 2024; Banyai & Brișan 2024). Technically, these two types of systems differ significantly in their operational principles, movement control mechanisms, assistance levels, degrees of freedom, and the types of movements they facilitate. Both exoskeletons and end-effector devices present distinct advantages and limitations (Laut et al. 2016; Molteni et al. 2018; Hussain et al. 2020).

2.7.1 End-effector Versus Exoskeleton Robotic Devices

End-effector robotic devices are designed to interact with specific distal body parts such as the hands, legs, or head to facilitate targeted rehabilitation exercises through assisted movement and sensory feedback (Banyai & Brișan 2024). These systems typically connect to the patient at a single distal point, such as a handle or footplate, allowing motion to be generated from the extremity without requiring precise joint alignment between the patient and the robot (Laut et al. 2016; Molteni et al. 2018; Giansanti 2021). The end-effector system enables flexibility in application and

simplifies setup compared to an exoskeleton-type system (Banyai & Brișan 2024). A well-known example of such a device is the Bi-Manu-Track, which supports upper limb rehabilitation through bilateral coordinated movement (Banyai & Brișan 2024).

Robotic exoskeletons are wearable mechatronic systems (Giansanti 2021) that typically cover the affected limb or its segment, mirroring the patient's kinematic and dynamic activity, and are classified based on the number of joints controlled, as well as whether they operate unilaterally or bilaterally (Molteni et al. 2018; Giansanti, 2021). They are designed to support and assist individuals with motor impairments by facilitating limb movements through mechanical actuation and, in some cases, electrical stimulation (Banyai & Brișan 2024). These devices are particularly effective in rehabilitating patients with paralysis or muscle weakness, as they provide targeted assistance to either the upper or lower limbs (Banyai & Brișan 2024). A defining feature of exoskeleton systems is their one-to-one correspondence with human joints, where each joint is guided along a preprogrammed trajectory, enabling precise control of motion (Molteni et al. 2018; Giansanti 2021). Besides that, the exoskeleton systems are equipped with advanced software settings that allow clinicians to customize training sessions by adjusting the degree of motor assistance according to each patient's condition and rehabilitation goals (Molteni et al. 2018). This adaptability ensures that exoskeletons can deliver the minimum necessary support, encouraging the patient's active participation and optimizing motor recovery within the controlled movement pattern (Molteni et al. 2018).

2.7.2 Robotic Devices for Rehabilitation

In upper limb motor rehabilitation, specialized robotic devices are employed to assist and enhance the motor functions of the arms and hands. These systems deliver repetitive, controlled exercises that support functional recovery following stroke or other neurological impairments (Banyai & Brișan 2024). Notable examples of upper limb rehabilitation robots include MIT-MANUS, MIME, InMotion, ARM Guide, ARMin, CAREX, CADEN-7, L-EXOS, T-Wrex, REHAROB, BONES, and HandSOME (Laut et al. 2016; Qassim & Hasan 2020; Banyai & Brișan 2024). In lower limb motor rehabilitation, robotic systems facilitate gait training by providing body

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weight support and guiding leg movements to simulate natural walking patterns. Prominent examples include Lokomat, ReWalk exoskeleton (Banyai & Brișan 2024), LOPES and AnkleBot (Laut et al. 2016).

Additionally, some robotic systems are designed to assist individuals with limited mobility in performing ADLs, such as feeding, dressing, and object manipulation (Banyai & Brișan 2024). The PR2 personal assistance robot and the JACO robotic arm are examples of such technologies (Banyai & Brișan 2024). Furthermore, interactive social robots, including NAO, Pepper, and PARO, foster social interaction and communication skills, particularly among individuals with autism spectrum disorders or neurodegenerative conditions (Banyai & Brișan 2024). These robots promote emotional engagement, provide cognitive stimulation, enhance well-being, and reduce social isolation (Banyai & Brișan 2024).

2.7.3 Effectiveness of Robotic Rehabilitation

Human-robot interaction is fundamental to the effectiveness of rehabilitation exercises, and control strategies in rehabilitation robotics must be designed to modulate this interaction to promote active patient engagement during therapy (Molteni et al. 2018; Mayetin & Kucuk 2021; Guatibonza et al. 2024). Force sensors embedded in these systems serve as critical interfaces between the patient and robot, enabling real-time monitoring of the patient's participation and tracking progress throughout the rehabilitation process while ensuring safety and comfort (Mayetin & Kucuk 2021). To develop comprehensive and adaptable rehabilitation systems, it is essential to design robots that accommodate the full anatomical range of motion across all limb joints (Guatibonza et al. 2024). Achieving such generalization enhances the robot’s capacity to support diverse therapeutic needs (Guatibonza et al. 2024).

Furthermore, as Molteni et al. (2018) highlight, the effectiveness of robotic rehabilitation is not solely dependent on the number of repetitions performed but on the patient's perception of movement, intention to move, and the motivational and emotional intensity associated with the activity. This marks a significant shift from repetition-focused models to intention-driven and cognitively engaging rehabilitation

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strategies using the rehabilitation robotic systems (Molteni et al. 2018). Furthermore, Molteni et al. (2018) emphasize that robotic therapy should be regarded not merely as a means of facilitating movement, but as a comprehensive intervention capable of delivering controlled multisensory stimulation that engages both motor and sensory systems. The authors stated that sensory input plays an equally critical role as motor output in enhancing performance, as integrating these components supports the development of complex internal representations of movement (Molteni et al. 2018). These sensory-motor experiences can be encoded in the central nervous system through stimulation, emulation, and motor imagery, thereby fostering neuroplasticity and motor learning (Molteni et al. 2018).

Giansanti (2021) highlighted that rehabilitation robots have been shown to produce a wide range of therapeutic benefits for both upper and lower limbs. For lower limb rehabilitation, robotic systems contribute to improved trunk control, enhanced sleep-wake rhythms, and reduced perceived fatigue during daily activities (Giansanti 2021). Additional benefits include pain relief, improvements in mental health, better regulation of intestinal and bladder functions, and favourable changes in anthropometric characteristics such as reduced fat mass and increased lean mass (Giansanti 2021). Similarly, in upper limb rehabilitation, robots facilitate neuromotor improvements, enhance limb functionality, alleviate pain, and contribute to improved cognitive function and psychological well-being (Giansanti 2021). This argument is further supported by Moulaei et al. (2023), who reported that upper limb rehabilitation robots can enhance musculoskeletal functions such as strength, coordination, flexibility, and ROM while reducing spasticity and pain. Additionally, they offer safe, reliable treatment with minimal side effects, promote patient independence, improve adherence, shorten rehabilitation duration, and contribute to better overall outcomes and quality of life (Moulaei et al. 2023).

In the context of orthopaedics rehabilitation, rehabilitation robotics presents promising new avenues for therapeutic intervention in orthopaedics, particularly for patients recovering from musculoskeletal injuries such as bone fractures (Padilla-Castañeda et al. 2018). Padilla-Castañeda et al. (2018) developed an end-effector robotic system integrated with virtual reality designed to rehabilitate of upper limb

injuries affecting forearm mobility. The system targets restoring strength and ROM in key movements, including pronation/supination and elbow flexion-extension, thereby supporting functional recovery in orthopaedic contexts (Padilla-Castañeda et al. 2018).

2.7.4 Robotic Devices for Wrist Rehabilitation

Similar to other upper limb rehabilitation systems, wrist rehabilitation robots are generally categorized into two main types: end-effector and exoskeleton robots (Hussain et al. 2020). Both categories have been extensively evaluated in clinical settings, particularly with neurologically impaired patients, and have demonstrated promising outcomes in restoring motor function in both the upper and lower limbs (Hussain et al. 2020; Banyai & Brișan 2024). Among the most widely used biomedical devices in rehabilitation, wrist robots support comprehensive ROMs crucial for wrist functionality, including forearm pronation/supination, wrist flexion/extension and radial/ulnar deviation (Mayetin & Kucuk 2021). In this context, Garcia et al. (2024) identify critical factors for developing wrist rehabilitation devices, highlighting the importance of degrees of freedom, wrist movement capabilities, actuator selection, control strategies, safety mechanisms, and the incorporation of artificial intelligence alongside serious gaming or virtual reality technologies.

Several studies have demonstrated the safety and efficacy of wrist robot-assisted rehabilitation in both neurological and orthopaedic populations (Hu et al. 2014; Mazzoleni et al. 2018; Hussain et al. 2020; Albanese et al. 2021; Banyai & Brișan 2024). Mazzoleni et al. (2018) provided evidence of a distal-to-proximal generalization of motor recovery in subacute stroke patients following wrist robot-assisted therapy, highlighting its potential for promoting broader functional improvements. Complementing this, Hu et al. (2014) found that combining neuromuscular electrical stimulation with robotic therapy under voluntary motor intention control monitored via electromyography resulted in significantly greater improvements in upper limb function, particularly in wrist and finger movements, compared to robot-assisted therapy alone. These findings support the safety and effectiveness of integrating wrist robot-assisted rehabilitation to enhance rehabilitation outcomes among neurological patients (Hu et al. 2014; Mazzoleni et al. 2018; Hussain et al. 2020; Banyai & Brișan

2024).

In addition to neurological applications, wrist rehabilitation robots have shown promise in orthopaedic rehabilitation. Albanese et al. (2021) RCT demonstrated that a 3-week robot-aided rehabilitation program was as effective as conventional therapy for workers recovering from wrist injuries. No significant differences were found between groups regarding functional outcomes, pain levels, grip strength, or manual dexterity. This finding suggests that robotic therapy can be a viable alternative to traditional rehabilitation methods in orthopaedic contexts.

2.7.5 Advantages and Challenges of Robotic Rehabilitation

The present literature review highlights an enormous heterogeneity and extreme variability of treatment approaches in robotic systems used for upper and lower limbs rehabilitation among neurological patients (Molteni et al. 2018). In clinical studies, there is no apparent difference between the various robotic systems used (i.e., end-effector, exoskeletons, proximal, distal, unilateral, bilateral) for rehabilitating of the upper or lower limbs (Molteni et al. 2018).

Banyai and Brișan (2024) highlighted several advantages of rehabilitation robotic technologies, particularly their capacity for precise, real-time patient performance and progress monitoring. This continuous data collection enables the dynamic adjustment of therapy parameters, ensuring an individualized balance of assistance and challenge throughout each session (Banyai & Brișan 2024). Furthermore, integrating gaming and virtual reality elements has enhanced the motivational aspect of therapy, making rehabilitation more engaging for patients and potentially improving adherence (Banyai & Brișan 2024). The authors also noted that robotic systems can alleviate therapists' physical and cognitive demands by automating repetitive tasks, thereby allowing clinicians to focus on personalized, high-value interventions. These advantages contribute to improved overall efficiency and effectiveness in rehabilitation care.

Despite the advantages of robotic rehabilitation technologies, several challenges

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such as high equipment costs, the need for specialized staff training, and the requirement for adaptations to existing clinical infrastructure remain (Fareh et al. 2023; Banyai & Brișan 2024). While robotic systems have demonstrated measurable improvements in motor control and muscle strength, further research is needed to fully translate these gains into functional autonomy and improvements in daily activities (Banyai & Brișan 2024). The direct applicability of motor improvements to real-life tasks continues to be limited, highlighting the necessity of tailoring interventions to each patient's needs and capabilities (Banyai & Brișan 2024). To ensure the broader and more effective integration of robotic technologies into clinical practice, it is essential to prioritize therapy personalization while also addressing economic and logistical constraints such as cost, staff development, and infrastructure readiness (Fareh et al. 2023; Banyai & Brișan 2024).

When integrated with conventional therapy, robotic systems can significantly enhance the rehabilitation experience for patients (Fareh et al. 2023). However, no existing robotic system has yet demonstrated the capacity to fully replace traditional therapeutic approaches (Fareh et al. 2023). Furthermore, Laut et al. (2016) and Yakub et al. (2014) also emphasized that the true transformative potential of robotic rehabilitation lies in developing telerehabilitation solutions that leverage low-cost devices, enabling effective and efficient delivery of therapy in home-based settings. In this context, given the rising costs associated with long-term rehabilitation and the challenges in delivering rehabilitation services at the necessary duration and intensity to manage disability effcetively, the cost-effective development of robotic rehabilitation technologies is both necessary and justified (Laut et al. 2016).

2.8 HYBRID ASSISTIVE LIMB (HAL®)

The Hybrid Assistive Limb (HAL®) exoskeleton, developed by Sankai (2010), is a cyborg-type robotic system designed to enhance human physical capabilities through Cybernics, an interdisciplinary field combining research domains of cybernetics, mechatronics, and informatics, and integrates neuroscience, robotics, systems engineering, information technology, "kansei" engineering, ergonomics, physiology, social science, law, ethics, management, economics etc. (Sankai 2010). HAL® systems,

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categorized under Cybernoids, represent advanced human-machine hybrids (Sankai 2010). The technology is available in three main types: the HAL® lower limb (ML-05), single joint (MS-01), and lumbar (BB-04) models (Sankai 2010; Cyberdyne Inc. 2024).

The HAL® exoskeleton features a Cybernic Control System, a hybrid framework composed of Cybernic Voluntary Control (CVC) and Cybernic Autonomous Control (CAC), designed to deliver adaptable physical support based on the user's condition and intention (Sankai 2010).

The CVC utilizes bioelectrical signals such as myoelectric activity to detect the wearer's voluntary movement intentions and provides real-time physical assistance by amplifying joint torque (Sankai 2010). This control mode is particularly effective for supporting healthy or physically challenged individuals in activities like walking or standing (Sankai 2010). Because bioelectrical signals are generated just before visible muscle activation, they serve as a reliable and intuitive interface for voluntary motion support (Sankai 2010).

In contrast, the CAC operates autonomously to generate desired functional motions based on the wearer's body constitution, condition, movement goals, and additional sensor data such as joint angles, postural control, and reaction forces (Sankai 2010). This mode is especially suited for rehabilitation and gait training in patients lacking bioelectrical signals, providing tailored, comfortable assistance independent of voluntary input (Sankai 2010).

2.8.1 Hybrid Assistive Limb Single Joint Type (HAL-SJ)

Several studies have investigated the safety of HAL-SJ training in neurological populations, including individuals with stroke (Ohmae et al. 2025; Taketomi et al. 2023; Saita et al. 2017) and spinal cord injury (Shimizu et al. 2014; Kubota et al. 2018; Yoshikawa et al. 2019, Soma et al. 2021; Lafitte et al. 2022; Koseki et al. 2023). Furthermore, HAL-SJ clinical versatility has been demonstrated through its successful application to multiple limb joints, such as the elbow, knee, shoulder, and ankle (Ohmae et al. 2025; Taketomi et al. 2023; Saita et al. 2017; Shimizu et al. 2014; Kubota et al.

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2018; Yoshikawa et al. 2019, Soma et al. 2021; Lafitte et al. 2022; Koseki et al. 2023; Mrotzek et al. 2022; Maeda et al. 2024; Makihara et al. 2017; Soma et al. 2022).

Ohmae et al. (2025) reported that combining HAL-SJ therapy with conventional OT for individuals with upper limb paralysis after acute stroke led to significant improvements in motor function, as measured by the Fugl-Meyer Assessment Upper Extremity and the Action Research Arm Test. These results underscore the importance of high-frequency training in promoting functional recovery (Ohmae et al. 2025). Similarly, Taketomi et al. (2023) found that shoulder-targeted HAL-SJ intervention resulted in enhanced shoulder ROM, reduced muscle tone, and improved Fugl-Meyer Assessment Upper Extremity and the Action Research Arm Test scores, suggesting its potential as an effective rehabilitation strategy for upper limb dysfunction following stroke.

Makihara et al. (2017) and Lafitte et al. (2022) further confirmed that the HAL-SJ system is safe for shoulder application, specifically in assisting scapular plane shoulder flexion-extension. According to Makihara et al. (2017), the HAL® facilitated smooth flexion-extension movements of the shoulder joint in healthy adults, without inducing adverse effects on vital signs, shoulder fatigue, or pain. Lafitte et al. (2022) also highlighted the feasibility of HAL-SJ therapy for deltoid-related impairments for shoulder elevation following C5 nerve root injuries, indicating its broader clinical applicability beyond stroke rehabilitation.

In terms of elbow function, studies had validated the safety and effectiveness of HAL-SJ for patients recovering from postoperative C4 quadriplegia (Shimizu et al. 2017); C5 paralysis (Kubota et al. 2018) and brachial plexus injuries (Kubota et al. 2018). The device facilitated early repetitive joint movement with real muscle contraction, leveraging biofeedback and proprioceptive engagement to improve elbow flexion and muscle strength (Kubota et al. 2018). According to Shimizu et al. (2017) the volitional activation of C5-level muscles previously paralyzed prior to the HAL-SJ intervention suggested the occurrence of neuroplastic changes within the central nervous system. Additionally, Saita et al. (2017) demonstrated that integrating elbow HAL-SJ robotic therapy with botulinum toxin A treatment in spastic hemiplegia

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resulted in sustained functional improvements, with neuroplastic changes evident in imaging studies up to four months post-intervention.

2.8.2 HAL-SJ for Orthopaedic Rehabilitation

The Hybrid Assistive Limb Single Joint (HAL-SJ) has gained increasing attention in the field of orthopaedic rehabilitation, particularly for patients undergoing conservative or postoperative treatment for knee-related conditions (Yoshioka et al., 2016; Goto et al., 2017; Mrotzek et al., 2022; Soma et al., 2022; Maeda et al., 2024).

Early reports by Yoshioka et al. (2016) and Goto et al. (2017) established the safety and feasibility of HAL-SJ for post-total knee arthroplasty rehabilitation. Yoshioka et al. (2016) demonstrated that HAL-SJ-assisted knee extension training was well-tolerated and free from adverse effects, while Goto et al. (2017), in a study involving 20 postoperative total knee arthroplasty patients, found that HAL-SJ could facilitate early functional recovery and potentially prevent long-term complications, such as quadriceps arthrogenic muscle inhibition.

More recently, Maeda et al. (2024) RCT provided stronger evidence for the efficacy of HAL-SJ in acute-phase post- total knee arthroplasty rehabilitation. The study reported that knee extension training with HAL-SJ significantly improved in pain reduction and ROM compared to conventional physiotherapy. The authors also emphasized the HAL-SJ's ability to enhance patient engagement by providing visual feedback on muscle activation and real-time guidance for correcting knee movement patterns (Meada et al. 2024).

With high patient acceptance, Mrotzek et al. (2022) supported the feasibility and safety of using HAL-SJ in the early postoperative period after total knee arthroplasty. However, their findings did not demonstrate statistically significant superiority in clinical outcomes compared to standard therapy (Mrotzek et al. 2022).

Beyond TKA, Soma et al. (2022) expanded the application of HAL-SJ to patients following anterior cruciate ligament reconstruction. Their findings suggest that

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HAL-SJ training may improve neuromuscular control by reducing co-contraction between the hamstring and quadriceps muscles, thereby optimizing muscle efficiency and joint ROM during rehabilitation (Soma et al. 2022).

While the use of the HAL-SJ in orthopaedics rehabilitation has gained interest, there remains a notable lack of published evidence specifically examining its feasibility and effectiveness in the rehabilitation of wrist fractures. To date, most HAL-related research has concentrated on neurological rehabilitation, particularly in populations with stroke, spinal cord injury, or other central nervous system disorders, where the device has shown promising results in enhancing motor function, promoting neuroplasticity, and facilitating task-specific training.

In contrast, the application of HAL-SJ in upper limb orthopaedic conditions, such as wrist fractures, is significantly underrepresented in the literature. This represents a critical gap, especially considering the prevalence of wrist fractures, particularly among working age adults, and the functional limitations they often impose on daily activities and return to work potential.

2.8.3 Neural Feedback and Personalization in HAL-SJ Assisted Rehabilitation

Lafitte et al. (2022) emphasized the importance of physiologically congruent motion and sensory feedback in facilitating neuroplastic changes during HAL-SJ training. They proposed that movement aligned with the user's internal motor predictions could lead to central nervous system activity modification, thereby promoting adaptive muscle recruitment and functional recovery (Lafitte et al. 2022). Additionally, the repetitive nature of the training was identified as a critical factor in enhancing therapeutic outcomes (Lafitte et al. 2022).

A key advantage of the HAL® system lies in its adaptive control features, including adjustable gain and torque parameters, which allow the level of robotic assistance to be tailored according to the patient's evolving clinical needs (Lafitte et al. 2022).

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In support of this perspective, Molteni et al. (2018) advocated for a shift from standardized to personalized rehabilitation strategies, emphasizing the importance of customizing robotic interventions to the patient's specific neuromuscular profile. They proposed the use of electroencephalography and surface electromyography to optimize patient-robot interaction (Molteni et al. 2018). In particular, surface electromyography offers a non-invasive means to monitor motor control and coordination across multiple joints. It is a valuable tool for assessing real-time neuromuscular responses and guiding robotic assistance (Molteni et al. 2018). Thus, the quality of patient-robot interaction is increasingly recognized as a critical determinant of the success of exoskeleton-assisted therapy (Molteni et al. 2018).

Given the well-established understanding that rehabilitation outcomes are positively influenced by both the amount and intensity of therapeutic exercise as well as the quality of motor learning, it is reasonable to explore technologies that can optimize these factors. The HAL-SJ represents a novel robotic intervention that is designed to support voluntary movement by detecting and responding to bioelectrical signals from the user's muscles. This technology facilitates active-assisted movement, thereby promoting patient engagement and potentially enhancing motor learning.

Although HAL-SJ is a relatively new device, it shares several therapeutic characteristics with existing robotic rehabilitation technologies, such as providing repetitive, controlled, and task-specific movements, which have been shown to contribute to improved neuromuscular function and functional outcomes in various populations. These features are particularly relevant in the context of wrist fractures, where early and guided mobilization is critical to prevent stiffness, improve joint function, and restore hand use in ADLs.

Therefore, applying HAL-SJ to patients with wrist fractures warrants focused investigation. Studying its effects in this context, especially among injured workers whose ability to return to work hinges on effective upper limb rehabilitation, can generate valuable evidence regarding the clinical effectiveness, safety, and practical feasibility of HAL-SJ as an intervention tool in hand therapy and upper extremity rehabilitation.

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This research can potentially bridge existing gaps in the literature regarding HAL-SJ interventions for wrist fractures and contribute to the development of evidence-based rehabilitation protocols that incorporate wearable assistive technologies like HAL-SJ.

2.9 SUMMARY

OT following DRF integrates patient education, therapeutic exercise, physical agent modalities, and occupation-based strategies. Evidence consistently supports the OT's role in improving ROM, grip strength, and functional performance, particularly when interventions are client-centered and embedded within multimodal rehabilitation programs (De-Rosende-Celeiro & Fernández-Barreiro 2023; Case-Smith 2003). Early initiation and higher therapy intensity appear to optimize outcomes, while activity-based, ADL-simulated tasks may enhance functional recovery more effectively than isolated exercises. However, the literature remains heterogeneous, with variable intervention protocols, small sample sizes, and limited comparative trials between occupation-based and impairment-focused approaches. The mechanisms through which occupation-focused interventions translate into functional gains are also insufficiently explored.

Although most individuals experience substantial recovery within the first three to six months post-DRF, persistent pain, functional limitations, and participation restrictions remain common up to one year or longer. MacDermid et al. (2003) demonstrated rapid early reductions in pain and disability, followed by slower improvements, yet some patients continued to experience significant limitations at one year. Similar findings from Ydreborg et al. (2015) and Pradhan et al. (2022) indicate that near-normal ROM and grip strength may not equate to full functional recovery. From an occupational perspective, Farzad et al. identified ongoing challenges in self-care, productivity, leisure, and social participation, highlighting a persistent gap between biomechanical recovery and meaningful occupational performance.

Return-to-work outcomes further underscore the complexity of DRF recovery. Surgical management is often associated with longer sick leave, although confounding

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by injury severity complicates interpretation. Predictors of delayed return to work consistently include baseline pain and disability, physically demanding employment, compensation status, and early patient-reported outcomes (e.g., DASH). Functional capacity evaluations can support planning, but their predictive validity is limited by delayed administration or compensable injury contexts. These findings reveal that conventional rehabilitation models may inadequately address occupational reintegration, despite favorable impairment-level recovery.

Rehabilitation robotics offers potential solutions by delivering high-intensity, task-specific, and precisely controlled therapy while providing objective performance monitoring. Systems are broadly classified into end-effector devices and wearable exoskeletons, with evidence suggesting improvements in motor control, strength, ROM, and pain across neurological and orthopaedic populations. However, superiority over conventional therapy is not consistently demonstrated, and benefits appear to be linked to active patient engagement, multisensory feedback, and adaptive human–robot interaction rather than to repetition alone.

The single-joint variant of the HAL® (HAL-SJ), developed by Yoshiyuki Sankai (2010), has demonstrated safety and efficacy in neurological populations and in orthopaedic knee rehabilitation, improving ROM, pain, and neuromuscular control. Yet its application in wrist fracture rehabilitation remains largely unexplored. Existing studies focus predominantly on neurological conditions or lower-limb interventions, limiting generalizability to post-DRF populations, which present with distinct challenges, including pain, stiffness, and task-specific functional demands.

This gap is clinically significant. Early, guided mobilization and task-specific training are critical for optimal DRF recovery, particularly for working-age adults who require timely return to productive roles. Conventional therapy may be constrained in delivering sufficient intensity, task specificity, and real-time feedback. A wearable, intention-driven exoskeleton such as HAL-SJ could augment active engagement, provide quantifiable performance data, and facilitate occupation-relevant training. However, rigorous investigation is needed to establish feasibility, efficacy, and impact on both impairment-level and participation-level outcomes, including return-to-work

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trajectories.

Addressing this research gap will clarify whether integrating intention-driven robotic assistance can enhance functional recovery and occupational reintegration in DRF rehabilitation, moving beyond technological innovation toward demonstrable clinical and occupational benefits.

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CHAPTER III

METHODOLOGY

3.1 INTRODUCTION

This was a single-center, prospective RCT where the effects of the study treatment (intervention) were compared with those of a control treatment after the patients were being randomly assigned to the two groups, i.e., the control group and the intervention group. The trial was registered with the Australian New Zealand Clinical Trials Registry (registration number: ACTRN12622000413729). In addition, the study has obtained ethical approval from the Research Ethics Committee of Universiti Kebangsaan Malaysia (JEP-2021-201) and the Scientific Committee of PERKESO Rehabilitation Centre (PRPTAR.600-5 (48)). The research team consisted of the researcher, who is the primary author and an occupational therapist with 14 years of experience, along with Therapist A (an occupational therapist), Therapist B (a physiotherapist), and Therapist C (an occupational therapist), each having over five years of clinical experience as well as a case manager who is responsible for the recruitment process.

3.2 TRIAL SITE

The trial was conducted at PERKESO Rehabilitation Centre, a subsidiary body under Social Security Organization (PERKESO) that appears to be one of the largest rehabilitation facilities in Malaysia. It plays a vital role in providing free comprehensive and intensive rehabilitation program to all injured workers covered under the PERKESO scheme.

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3.3 PARTICIPANTS

The target participants were PERKESO insured workers with wrist fractures that matched the inclusion and exclusion criteria and were receiving rehabilitation management at PERKESO Rehabilitation Centre. The recruitment process for this study was conducted between June 2021 and January 2025. All eligible individuals were provided comprehensive information regarding the study, including its objectives and methodology. Those who consented to participate were required to sign an informed consent form before the commencement of their involvement in the study.

3.3.1 Inclusion Criteria

a. PERKESO-insured Malaysian workers on medical leave; have not returned to work; and are receiving rehabilitation program at PERKESO Rehabilitation Centre
b. wrist fracture involving individual or combined distal radius, distal ulna, distal radioulnar, radiocarpal joint
c. extraarticular fracture, partial articular fracture, and/or complete articular fracture

3.3.2 Exclusion Criteria

a. aged below 18 years old or above 60 years old (based on PERKESO scheme)
b. associated peripheral nerve injuries, neuropathy or/and tendon injuries to the affected upper limb
c. associated neurological conditions related to the central nervous system
d. cognitive impairment or psychiatric condition
e. severe and uncontrolled medical conditions e.g. cardiovascular disorders, respiratory disorders, cancer
f. cardiac pacemaker
g. skin disorders e.g. eczema, psoriasis, open would etc. of the affected forearm and hand that prevent electrode placements
h. severe contracture of the affected wrist joint

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i. forearm size that is not fit to wear the HAL-SJrobotic exoskeleton

3.4 SAMPEL SIZE

The sample size for each hypothesis was calculated using G*Power analysis. Since this was a novel study without reference from previous research, the sample size was determined using ANOVA repeated measures, within-between interaction, with a Cohen's f effect size set at 0.25 for a medium effect, an alpha error of 0.05, and 80% power. The results indicated that a total of 34 participants would be required. Factoring in a 10% dropout rate, the necessary sample size increased to 38 participants, with 19 allocated to the interventional group and 19 to the control group.

3.5 OUTCOME MEASURES

This study employed patient-reported and performance-based outcome measures. The selection of these measures was guided by their relevance to the corresponding domains of the ICF model, specifically focusing on body functions and structures, activities, participation, and environmental factors.

3.5.1 Primary Outcome Measure

a. Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure

The DASH Outcome Measure is a widely utilized, region-specific, patient-reported instrument designed to evaluate physical function and symptoms in individuals with upper limb musculoskeletal disorders. It serves both evaluative and discriminative purposes and is extensively applied in clinical and research settings, particularly hand therapy. This instrument was first developed by the American Academy of Orthopedic Surgeons, the Council of the Musculoskeletal Speciality Societies, and the Institute for Work and Health, Toronto, Ontario, and published in 1996 (Hudak et al. 1996; Klerk et al. 2018). The DASH was developed to measure physical function and symptoms for single or multiple musculoskeletal conditions of the upper limb (Kennedy & Beaton 2017). The instrument consists of 30 items rated on a 5-point scale to measure disability and symptoms. The total DASH score is computed using a standardized formula, with higher scores reflecting greater disability (MacDermid 2000). The DASH has been

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translated into multiple languages including the Malay (Al-Husuny et al. 2011) and Simplified Chinese (Chen et al. 2015).

DASH score formula:

Total score = ([(sum of n responses)/n]-1) × 25

There is extensive research evidence of its psychometric properties (Klerk et al. 2018). Extensive evidence supports the DASH outcome measure's validity, reliability, and responsiveness. It has been effective across the entire upper extremity, showing strong performance in proximal and distal disorders (Beaton et al. 2001). In the study by Beaton et al. (2001), the DASH exceeded the recommended standards for test-retest reliability, achieving an intraclass correlation coefficient (ICC) of 0.96, making it suitable for individual and group-level interpretation.

Convergent construct validity was supported by moderate to high correlations with other established measures of disability and symptoms, with Pearson correlation coefficients ranging from 0.68 to 0.92 and Spearman correlations from 0.69 to 0.92. Discriminative validity was also demonstrated through significant differences in DASH scores between patients who were employed versus those who were not (mean scores: 26.8 vs. 50.7; $t = -7.51$, $p < 0.0001$), and between patients who were functioning versus those who were not (23.6 vs. 47.1; $t = -5.81$, $p < 0.0001$).

The DASH has shown sensitivity to changes in patient condition, with standardized response means ranging from 0.74 to 0.80 following treatment, and from 0.92 to 1.40 in patients who experienced functional improvement. Furthermore, the Malay version of the DASH has demonstrated excellent psychometric properties, with a high internal consistency (Cronbach's $\alpha = 0.99$) and strong test-retest reliability (ICC = 0.94) (Al-Husuny et al. 2011).

3.5.2 Secondary Outcome Measure

a. Visual Analogue Scale (VAS)

The VAS is a widely recognized and validated tool for assessing pain intensity, particularly in rehabilitation settings (Crossley et al. 2004). It is a single-item measure

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designed to capture the full spectrum of the pain experience straightforwardly. The VAS consists of a 100 mm horizontal line with endpoints labelled “no pain” and “severe pain.” Patients were asked to indicate their pain level by marking a point along the line with a vertical mark. Due to its simplicity, ease of administration, and sensitivity to changes in pain levels, the VAS is suitable for use in both clinical practice and research contexts (Boonstra et al. 2008).

b. Grip and Pinch Strength

Grip strength was measured using a Jamar hand dynamometer, which has been identified as the most reliable instrument for assessing grip strength (Mathiowetz et al., 1984). The intra-tester reliability of the Jamar dynamometer has been reported to be high, with ICC ranging from 0.90 to 0.97 (Peolsson et al., 2001). Each participant’s grip strength was measured 3 times. Handle position 2 was used as it is recommended for measuring grip strength by the American Society of Hand Therapists (Fess 1992). Meanwhile, lateral pinch strength, tripod pinch strength, and tip-to-tip pinch strength were measured using the B&L Engineering Pinch Gauge (Mathiowetz et al. 2000).

c. Active Range of Motion (AROM)

Range of motion measurement was performed using the goniometer. AROM of the wrist and fingers of the fractured wrist were assessed (Adams et al. 2003; Bland et al. 2008; Goldhahn et al. 2014; Waljee et al. 2016). Assessment began with wrist flexion, extension, radial deviation, ulnar deviation, forearm supination, and forearm pronation using a wrist goniometer. This was followed by assessments on the same wrist and forearm joints to evaluate the end feel. For fingers, AROM of the MCPJ, PIPJ and DIPJ are assessed using a finger goniometer.

d. Purdue Pegboard Test (PPT)

The PPT is a standardized tool for assessing manual dexterity through four subtests. The test apparatus includes a board equipped with pins, collars, and washers. In the first three subtests, participants were instructed to place as many pins as possible into holes on the pegboard within 30 seconds, using the dominant hand, non-dominant hand, and

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both hands simultaneously, respectively. The fourth subtest required participants to assemble components, including the pins, collars, and washers, using alternating hands over 60 seconds. An additional composite score was obtained by summing the results of the first three subtests (Shahar et al. 1998).

The PPT has been recognized as one of the top three assessments of hand dexterity among healthcare professionals, owing to its high reliability and validity. Moreover, it is less influenced by confounding variables such as age, gender, and hand dominance than similar tools (Lindstrom-Hazel & Veenstra 2015).

e. Box and Block Test (BBT)

The BBT is a widely used functional outcome measure to assess gross manual dexterity. It is valued for its simplicity and quick administration, making it suitable for use across various clinical populations (Mathiowetz et al. 1985; Kontson et al. 2017). During the test, the participant was required to move as many 2.5 cm^3 wooden blocks as possible from one side of a partitioned box to the other within 60 seconds, using the testing hand. The blocks were initially arranged in various orientations, and the final score was determined by the total number of blocks successfully transported over a 15.2 cm-high partition within the time limit (Mathiowetz et al., 1985; Kontson et al. 2017).

The BBT has demonstrated high inter-rater and test-retest reliability, with ICC ranging from 0.85 to 0.97 (Desrosiers et al., 1994; Platz et al., 2005; Canny et al., 2009). Additionally, Mathiowetz et al. (1985) established normative data for adults based on a sample of 628 individuals without disabilities, ranging in age from 20 to over 70 years.

f. Lam Assessment on Stages of Employment Readiness (LASER) Questionaire

The LASER questionnaire was developed to measure one's psychological readiness to return to work after an extended period of unemployment due to disability (Lam et al. 2010). LASER contains 14 items corresponding to Prochaska's stages of change model, which describe behaviours in the pre-contemplation (6 statements), contemplation (4 statements), and action stages (4 statements). The participants were asked to rate each item on a five-point Likert Scale with "1" indicating strongly disagree to "5" indicating

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strongly agree. The scores were added and allocated under different sub-scores representing the corresponding stages, forming a continuous measure. The highest sub-score will represent a participant's tendency towards the corresponding stage. Participants at the pre-contemplation stage do not see unemployment as a problem, and are often not interested in working, or believe that they cannot work. Participants at the contemplation stage begin to consider the pros and cons of working but have not yet participated in any related action, such as job searching. Participants at the action stage have decided to work by engaging in job-seeking behaviours and removing many barriers related to returning to work (Chan et al. 2006). The correlations between the factors were −0.50 (between pre-contemplation and conptemplation), −0.56 (between pre-contemplation and action), and 0.74 (between contemplation and action), and the correlations between the three pairs of error terms were 0.34, 0.33, and 0.27. The Cronbach's alphas (a measure of internal consistency) for the pre-contemplation and contemplation scales are 0.77 and the action scale is 0.82 (Lam et al. 2010). The LASER Questionnaire has been translated into both Chinese and Malay languages. Both translated versions of LASER Questionnaires have shown good test-retest reliability. The ICC for the Chinese version ranged from 0.55 to 0.79 (Chan et al. 2006) while the ICC for the Malay version ranged between 0.707 and 0.917 (Chandran & Jamaludin 2009).

3.6 STUDY PROCEDURE AND INTERVENTION PROTOCOL

This study engaged multiple clinicians and administrative personnel from the PERKESO Rehabilitation Centre, including the researcher (TEW), Therapist A (Occupational Therapist), Therapist B (Physiotherapist), Therapist C (Independent Therapist), and a case manager. All patients with wrist fractures referred to the centre were initially identified and categorized via the admission database by the case manager. The primary researcher subsequently screened eligibility based on predefined inclusion and exclusion criteria.

The primary researcher, a certified HAL-SJ operator accredited by Cyberdyne Inc., was responsible for administering the robotic intervention to participants allocated to the intervention group. Therapist A functioned as both the baseline and outcome

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assessor and provided conventional OT services. Before group allocation, which was done through a randomization process managed by Therapist C, baseline assessments were completed by Therapist A for all eligible participants. Concurrently, Therapist B delivered the conventional physiotherapy interventions per the study protocol.

The study flow was elucidated to the selected participants upon confirmation of their eligibility for the study. An information sheet outlining the study's objectives, procedures, potential risks and benefits, and data confidentiality measures was provided and thoroughly reviewed with each participant. Participation in the study commenced only after the informed consent form was signed.

Subsequently, baseline assessments were conducted by Therapist A before the randomization process to preserve blinding of both the therapists and participants. The researcher did not participate in any part of the baseline or outcome assessment procedures throughout the study to avoid assessment bias.

After completing of baseline assessments, participants were assigned to either the control or intervention group through a simple randomization process conducted by Therapist C, with allocation concealment maintained throughout. Each participant received a sealed opaque envelope containing a randomly assigned allocation card marked with either the letter "C" (Control group) or "I" (Intervention group). Group assignment was revealed only after the envelope was opened by Therapist C, ensuring the integrity of the randomization procedure.

Participants in the control and intervention groups underwent two daily sessions of conventional therapy comprising OT and PT, conducted five days per week. Each OT and PT session lasted 90 minutes. Within two hours after the conventional therapy sessions, participants in the intervention group received a 60-minute HAL-SJ robotic therapy session administered by the researcher each day, following the standard therapy regimen. This treatment schedule was maintained for a total duration of four weeks.

During the first week, therapeutic interventions focused on restoring joint mobility and managing pain. OT included active and passive ROM exercises for the

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fingers, elbow, and shoulder, active ROM exercises for the wrist and forearm rotation, tendon gliding exercises, and dexterity training. Concurrently, PT comprised joint and soft tissue mobilization, retrograde massage, thermotherapy (heat/cold), ultrasound therapy, and electrical stimulation.

The conventional therapy program from Week 1 was continued into Week 2, with the addition of functional activity training in OT. Furthermore, isometric and isotonic strengthening exercises were introduced in the PT sessions to enhance muscle engagement and functional recovery.

In the third week, the focus transitioned to a graded strengthening program. This included continued isometric and isotonic exercises, progressive resistance training, and open and closed kinetic chain exercises. Interventions from Weeks 1 and 2 were sustained and adjusted according to the patient's progression.

The program's final week emphasized work simulation, work conditioning, and work hardening activities to prepare participants for return-to-work functionality. Interventions from the previous weeks were continued and modified based on each participant's clinical condition and functional capacity.

The HAL-SJ robotic therapy protocol employed the gentle mode of the HAL-SJ exoskeleton and was structured into four progressive phases over the 4-week intervention period. The protocol was individualized based on adjustments to four key parameters: assist gain, assist level, flexion/extension signal balance, and active/relax phase duration. Each therapy session targeted four types of wrist movements: extension, flexion, supination, and pronation. The protocol entailed three sets of exercises, with 50 repetitions for each specific movement. Movements were executed using a 10-second active phase followed by a 10-second relaxation phase. The assist level was held constant at x1 throughout the intervention period. However, assist gain and flexion/extension signal balance were progressively adjusted to match each participant's recovery stage.

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The intervention began with maximum assist gain (75–100%), and the flexion/extension signal balance was set equally at 100% for both flexion and extension, supporting all movements at their fullest assistance. At Week 2, the assist gain was reduced to 50–75%, while the flexion/extension signal balance remained unchanged at 100% flexion / 100% extension, continuing to provide symmetrical assistance. Further progression to Week 3 involved lowering the assist gain to 25–50%, and the signal balance was adapted based on the direction of movement. During wrist extension or supination, the flexion/extension signal balance level was set at 50% extension (supination)/100% flexion (pronation), and vice versa. In the final phase at Week 4, the assist gain was minimized to 0–25%, promoting increased voluntary control. The flexion/extension signal balance was fine-tuned such that 25% of the signal supported the intended movement, while 100% was assigned to the antagonistic direction, encouraging active muscle engagement. The details of the study protocol are outlined in Table 3.1 as follows:

Table 3.1 Study Protocol for Conventional Therapy and HAL-SJ Robotic Intervention for Wrist Fracture

Week	**Control Group & Intervention Group (Conventional Therapy)**	**Intervention Group (HAL-SJ Robotic Intervention)**
1	Interventions to improve joint mobility and to reduce pain: Occupational Therapy: Active and passive range of motion exercise of digits, elbow, and shoulder Active range of motion exercise of wrist and forearm rotation Tendon gliding exercise Dexterity exercise Physiotherapy: Joint mobilization Soft tissue mobilization Retrograde massage Heat/Cold modalities Ultrasound	HAL-SJ – Gentle Mode i) Extension: 50 repetitions; 3 sets ii) Flexion: 50 repetitions; 3 set iii) Supination: 50 repetitions; 3 sets iv) Pronation: 50 repetitions; 3 sets Parameters: Assist Gain: 75-100 Assist Level: x1 Flexion/Extension Signal Balance: 100%/100% Active/Relax Phase: 10 seconds/10 seconds

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	Electrical stimulation	
2	Interventions to improve joint mobility and pain PLUS Occupational Therapy: Functional activities training Physiotherapy Isometric strengthening exercises Isotonic strengthening exercises	HAL-SJ – Gentle Mode i) Extension: 50 repetitions; 3 sets ii) Flexion: 50 repetitions; 3 sets iii) Supination: 50 repetitions; 3 sets iv) Pronation: 50 repetitions; 3 sets Parameters: Assist Gain: 50-75 Assist Level: x1 Flexion/Extension Signal Balance: 100% : 100% Active/Relax Phase: 10 seconds/10 seconds
3	Interventions to improve joint mobility and pain PLUS Occupational Therapy: Functional activities training Physiotherapy: Isometric strengthening exercises Isotonic strengthening exercises Progressive resisted exercises Open kinetic chain activities Closed kinetic chain activities	HAL-SJ – Gentle Mode i) Extension: 50 repetitions; 3 sets ii) Flexion: 50 repetitions; 3 sets iii) Supination: 50 repetitions; 3 sets iv) Pronation: 50 repetitions; 3 sets Parameters: Assist Gain: 25-50 Assist Level: x1 Flexion/Extension Signal Balance: i) 50% : 100% ii) 100% : 50% Active/Relax Phase: 10 seconds/10 seconds
4	Interventions to improve joint mobility and pain PLUS Occupational Therapy: Work activity simulation Work conditioning Work hardening Physiotherapy:	HAL-SJ – Gentle Mode i) Extension: 50 repetitions; 3 sets ii) Flexion: 50 repetitions; 3 sets iii) Supination: 50 repetitions; 3 sets iv) Pronation: 50 repetitions; 3 sets Parameters: Assist Gain: 0-25 Assist Level: x1 Flexion/Ext Signal Balance:

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Isometric strengthening exercises	i) 25% : 100%
Isotonic strengthening exercises	ii) 100% : 25%
Progressive resisted exercises	Active/Relax Phase:
Open kinetic chain activities	10 seconds/10 seconds
Closed kinetic chain activities	

3.7 SINGLE JOINT HYBRID ASSISTIVE LIMB (HAL-SJ) ROBOTIC EXOSKELETON

Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton is certified by ISO 13485:2016 (certificate number: 1757.181211) and EC (registration number: DD 601417310001) for rehabilitation and physical therapy usage. The upper limb HAL-SJ is a wearable movement support robot that detects bioelectrical signals on the skin surface and assists joint movements by controlling and operating an actuator placed outside the respective joint. The power units of HAL generate power assist torque by amplifying the wearer's joint torque estimated from their bioelectrical signals, and the support motions are consequently controlled. The device is recognized as safe for rehabilitation interventions, having received approval from regulatory bodies including the FDA, EC, and MDA. However, some minor side effects may occur, such as (a) skin allergy or reddening of area where electrode is affixed, however, the reddening should disappear shortly after the electrode was taken off; (b) abrasion of areas that contact the device e.g. cuffs and straps; and (c) muscle and joint soreness (due to post exercise effect). Throughout all HAL-SJ robotic therapy sessions, the researcher, certified as a HAL-SJ operator accredited by Cyberdyne Inc. had implemented necessary precautions and maintained close supervision to minimize these adverse effects. The HAL-SJ robotic exoskeleton is shown in Photos 3.1(a) and (b).

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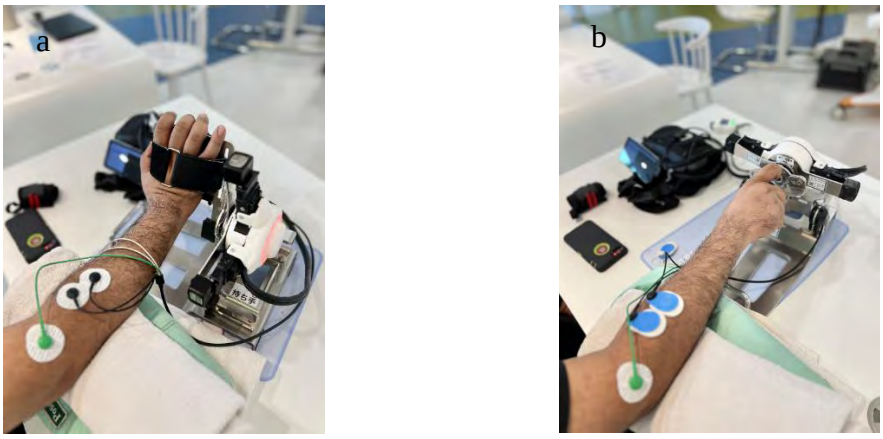

Photo 3.1a) HAL-SJ (wrist extension) and b) HAL-SJ (foream pronation)

3.8 STATISTICAL ANALYSIS

Data was analyzed using the IBM® SPSS® Statistics version 29 in this study. Descriptive statistics for categorical data, including gender, marital status, hand dominance, type of medical management and intervention, type of wrist fractures, educational level, employment status, and type of PERKESO compensation scheme, were expressed in frequency and percentage. The Shapiro-Wilks test was used to test the normality of the continuous data. All statistical tests were performed using two-sided tests at the 0.05 significance level. Descriptive statistics for continuous data, including age, the scores of a primary outcome measure of DASH, and the secondary outcome measures, including ROM, grip and pinch strength, pain, hand dexterity, and work readiness were expressed in mean, standard deviation, maximum, and minimum.

Repeated Measures ANOVA was used to analyze the mean differences in treatment outcomes within and between the groups at baseline and after 4 weeks of intervention. Repeated Measures ANOVA was used to measure the dependent variable (functional outcome) over two time points (baseline and after 4 weeks of interventions), i.e., where "time" is the "within-subjects" factor, but also when the participants had been assigned into two separate groups when they underwent difference interventions (i.e. the control and intervention group). The independent factors in this study were the combination of robotic intervention with conventional therapy and the conventional therapy alone, with DASH scores (primary outcome), and all six secondary outcomes acted as a dependent variable, respectively. This study assessed the main effects of time

and group and their interaction effect. The change in the pre- and post-functional level (DASH scores) (main effect 1) among workers with wrist fractures between the intervention and control groups (main effect 2) was compared and analyzed. The study also explored the difference in functional level between pre- and post-interventions in both control and intervention groups (interaction effect). The results were expressed as mean differences between groups, along with their corresponding two-sided 95% confidence intervals. Statistical significance was determined by p-values, which were reported to three decimal places. For p-values less than 0.001, the notation "<0.001" was used.

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CHAPTER IV

RESULTS

4.1 INTRODUCTION

The study involved workers insured by PERKESO who were undergoing rehabilitation management at the PERKESO Rehabilitation Centre in Melaka, Malaysia, between June 2021 and January 2025. The research team consisted of the researcher, who is the primary author and an occupational therapist with 14 years of experience, along with Therapist A (an occupational therapist), Therapist B (a physiotherapist), and Therapist C (an occupational therapist), each having over five years of clinical experience as well as a case manager who is responsible for the recruitement process.

4.2 RECRUITMENT AND FOLLOW UP

The CONSORT flow chart (Figure 4.1) presents the recruitment of participants and the progression through the 4-week intervention period. A total of 38 participants who met the inclusion criteria were enrolled in the study. These participants were randomly allocated to either the control group or the intervention group, with 19 participants assigned to each. By the conclusion of the study, all 38 participants had successfully completed the 4-week intervention.

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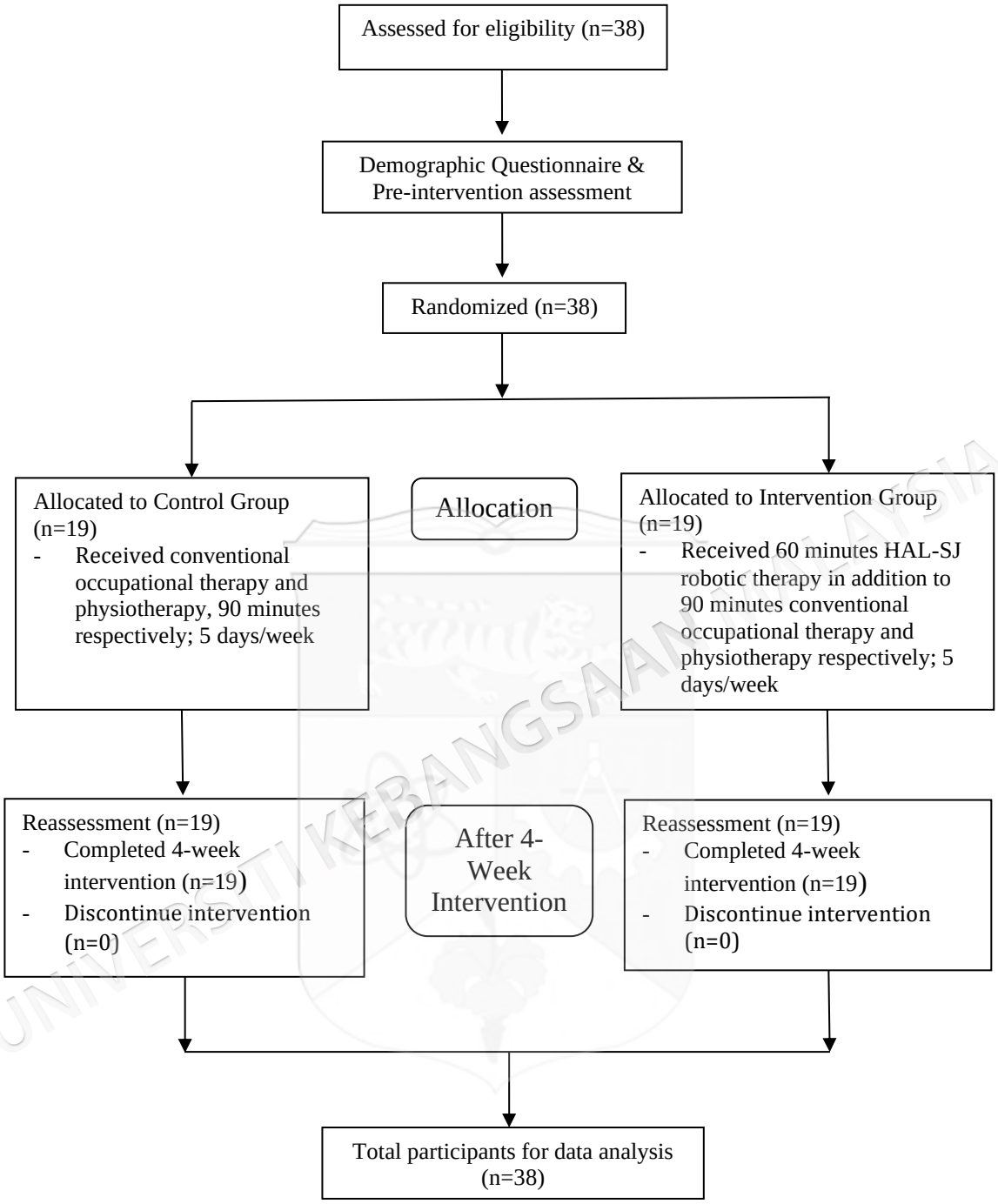

Figure 4.1 CONSORT flow chart

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4.3 DEMOGRAPHICS OF PARTICIPANTS

The demographic characteristics of the participants including age, gender, marital status, occupation, educational level, hand dominance, affected side of the hand, type of wrist fracture, mechanism of injury, type of medical intervention, employment status, and PERKESO schemeare presented in Table 4.1.

A total of 38 participants, aged between 22 to 65 with a mean age of 39.26 had completed the 4-week intervention program. The majority of the study participants were male, accounting for 28 (73.7%) of the 38 participants. More than half of the participants were married (n = 21, 55.3%), while the rest were either single (n = 14, 36.8%) or divorced (n = 3, 7.9%). Regarding the participants' educational levels, the highest level attained was a bachelor's degree (n = 8, 21.1%), while the majority had completed secondary school with an SPM certificate (n = 14, 36.8%). A total of 34 (89.5%) participants remain employed by their respective companies, while 4 (10.5%) lost their employment due to injuries. Majority of participants can be grouped as technicians (n = 12, 31.6%) and the operators and assemblers (n = 11, 28.9%). Other groups include services and sales (n = 4, 10.5%), managers (n = 3, 7.9%), professionals (n = 3, 7.9%), clerical (n = 2, 5.3%), elementary (n = 2, 5.3%) and skilled workers (n = 1, 2.6%). With respect to PERKESO scheme, 35 (92.1%) of the participants are covered under the employment injury scheme, while 3 (7.9%) of the participants are covered by the invalidity scheme.

A total of 35 participants (92.1%) were right-hand dominant, and 23 wrist fractures were reported to affect the dominant hand of the participants (unilateral n = 21, 55.3%; bilateral n = 2, 5.3%). The types of wrist fractures involved include the DRF (n = 23, 60.5%), distal radius and ulna fractures (n = 13, 34.2%), distal ulna fractures (n = 1, 2.6%), and scaphoid fracture (n =1, 2.6%). A total of 34 (89.5%) fractures were caused by motor vehicle accidents, while 4 (10.5%) were resulted from falls. Surgical interventions were the primary treatment for 36 (94.7%) wrist fractures with the remaining two fractures (5.3 %) were treated conservatively.

The Shapiro-Wilk test revealed that age distribution of the participants is not normal (p = 0.041). Meanwhile, the Mann-Whitney U test results (p = 0.325) indicated

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no significant difference in age between the groups. Additionally, results from the chi-Square test indicated that there were no significant differences observed for the other demographic data between the groups ($p > 0.05$), with the exception of employment status ($p = 0.034$), as shown in Table 4.1.

Table 4.1 Demographics of participants by study groups

Demographics	**Control group (n = 19)**	**Intervention group (n =19)**	***p value***
Age			0.325 [a]
Minimum – Maximum	23-65	22-59	
M (SD)	41.32 (12.481)	37.21 (12.537)	
Gender			0.141 [b]
Male	16	12	
Female	3	7	
Marital status			0.827 [b]
Married	11	10	
Single	7	7	
Divorced	1	2	
Educational level			0.403 [b]
UPSR	0	1	
PMR	2	1	
SPM	8	6	
STPM	2	3	
Diploma	5	2	
Bachelor's degree	2	6	
Employment status			0.034 [b]
Employed	15	19	
Unemployed	4	0	
Occupation groups			0.568 [b]
Managers	1	2	
Professionals	2	1	
Technicians	6	6	
Clerical	0	2	
Services and sales	2	2	
Skilled workers	1	0	
Operators and assemblers	5	6	
Elementary	2	0	
Hand dominance			0.547 [b]
Right	17	18	
Left	2	1	
Affected hand			0.150 [b]
Dominance	10	13	
Non-dominance	9	6	
PERKESO Scheme			0.547 [b]
Employment injury	18	17	
Invalidity	1	2	

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…continuation

Types of wrist fracture			0.171 [b]
Distal radius	9	14	
Distal radius and ulna	9	4	
Distal ulna	1	0	
Scaphoid	0	1	
Mechanism of injury			0.290 [b]
Motor vehicle accident	18	16	
Fall	1	3	
Types of medical management			1.000 [b]
Surgery	18	18	
Conservative	1	1	

UPSR=Ujian Pencapaian Sekolah Rendah
PMR=Penilaian Menengah Rendah
SPM=Sijil Pelajaran Malaysia
STPM=Sijil Tinggi Persekolahan Malaysia
n: Total number of participants
M (SD): Mean (standard deviation)
[a] Mann-Whitney U test, [b] Chi-Square test
p value is significant at $p<0.05$

4.4 PRIMARY OUTSOME COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

A repeated measures ANOVA was used to investigate the effectiveness of HAL-SJ robotic therapy in improving functional level among workers with wrist fractures after 4 weeks of intervention.

The Shapiro-Wilk, F_{max} and Levene's test statistics were used to test the assumptions of normality and homogeneity of variance. The assumptions for a repeated measures ANOVA were not violated. The Shapiro-Wilk test showed normal distributions for both pre-DASH score ($p = 0.961$) and post-DASH score ($p = 0.225$). In addition, the histograms represent bell curves and the data points are close to the diagonal line one the Q-Q plots for both pre and post DASH scores. Based on the calculation, the F_{max} is 1.44 and neither Levene's Test for Equality Error Variances for both pre and post DASH scores was significant at $\alpha = 0.05$, $F(1,36) = 0.147$, $p = 0.704$; $F(1, 36) = 0.045$, $p = 0.832$.

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Table 4.2 Repeated Measures ANOVA analysis for time, group and interaction main effects in term of functional level between control and intervention groups

Main Effects	Baseline Assessment M(SD)	Reassessment M(SD)	F(1, 36)	p	Eta
Time	34.547(16.1853)	24.271(14.0905)	17.711	<0.001	0.330
Group			0.945	0.338	0.026
Interaction			0.005	0.943	<0.001
CG	32.547(16.5557)	22.095(13.7957)			
IG	36.547(15.9983)	26.447(14.4151)			

CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$

Table 4.2 shows a significant main effect for time was obtained $F(1, 36) = 17.711$, $p < 0.001$, partial $\eta^2 = 0.33$ in functional levels measured with DASH, in which after the 4-week interventions, functional levels ($M = 24.271$, $SD = 14.09$) were significantly improved as compared to the baseline ($M = 34.547$, $SD = 16.19$). A significant main effect for group was not found in term of DASH functional level, $F(1, 36) = 0.945$, $p = 0.338$, partial $\eta^2 = 0.26$. An insignificant interaction between time and intervention groups was also reported for functional level after 4-week intervention, $F(1, 36) = 0.005$, $p = 0.943$, partial $\eta^2 = <0.001$, which is consistent with parallel lines plotted in Figure 4.2. The results indicated that there was no statistically significant difference in term of functional level improvement between the two groups after the 4-week interventions. Thus, hypothesis 1 is not supported.

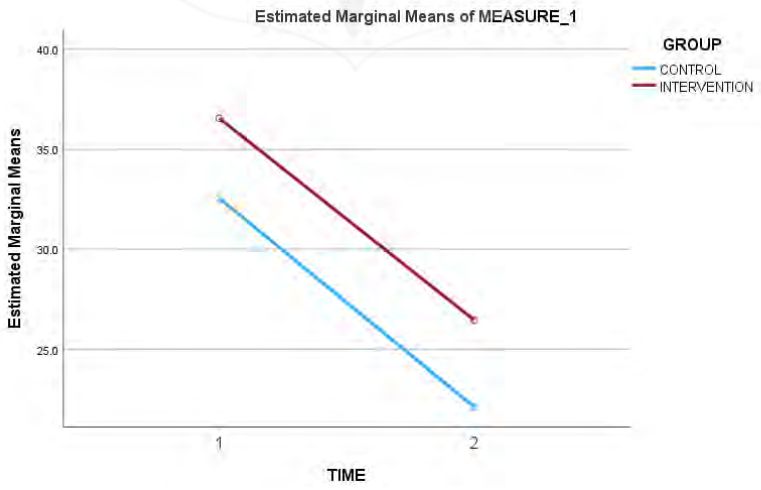

Figure 4.2 Interaction effect between time and group in Disabilities of the Shoulder, Arm and Hand (DASH) score

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4.5 SECONDARY OUTSOMES COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

A repeated measures ANOVA was conducted to assess the effectiveness of Single Joint Hybrid Assistive Limb (HAL-SJ) robotic therapy in enhancing physical performance, as measured by the secondary outcome measures: (1) pain intensity; (2) grip strength; (3) pinch strength; (4) wrist AROM; (5) fingers AROM; (6) PPT; and (7) BBT.

4.5.1 PAIN SCALE COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

The Shapiro–Wilk test indicated that the pain scale scores were not normally distributed at both baseline ($p = 0.04$) and reassessment ($p < 0.01$). However, given that the data points in the Q–Q plots closely aligned with the diagonal line for both pre- and post-intervention scores, and all Cook's distance values were below 1, the data were considered to approximate a normal distribution, satisfying the assumption of multivariate normality. Based on the calculation, the F_{max} was 6.90. The Levene's Test for Equality Error Variances for pain score during baseline assessment was insignificant at $\alpha = 0.05$, $F(1,36) = 0.897$, $p = 0.350$, but significant during reassessment at $\alpha = 0.05$, $F(1, 36) = 10.398$, $p = 0.003$.

Table 4.3 indicates that a significant main effect for time was found in pain intensity for both groups, $F(1, 36) = 43.049$, $p < 0.001$, partial $\eta^2 = 0.545$. Pain intensity had significantly reduced after the 4-week interventions in both groups from baseline assessment ($M = 3.32$, $SD = 2.810$) to reassessment ($M = 1.00$, $SD = 1.489$). No significant main effect was found between the two groups, $F(1, 36) = 0.061$, $p = 0.806$, partial $\eta^2 = 0.002$. Additionally, there was no significant interaction between time and group, $F(1, 36) = 3.758$, $p = 0.060$, partial $\eta^2 = 0.095$, in relation to pain intensity among the study population. Although the interaction effect did not reach statistical significance at the conventional 0.05 level, the p-value of 0.060 suggests a marginal trend that may indicate a potential effect. This warrants further investigation, particularly in studies with larger sample sizes. The interaction effect between time and group in pain intensity is shown as Figure 4.3.

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Table 4.3 Repeated Measures ANOVA analysis for time, group and interaction main effects in term of pain intensity between control and intervention groups

Main Effects	Baseline Assessment M(SD)	Reassessment M(SD)	F(1, 36)	p	Eta
Time	3.32(2.810)	1.00(1.489)	43.049	<0.001	0.545
Group			0.061	0.806	0.002
Interaction			3.758	0.060	0.095
CG	2.89(2.885)	1.26(1.790)			
IG	3.74(2.746)	0.74(1.098)			

CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$

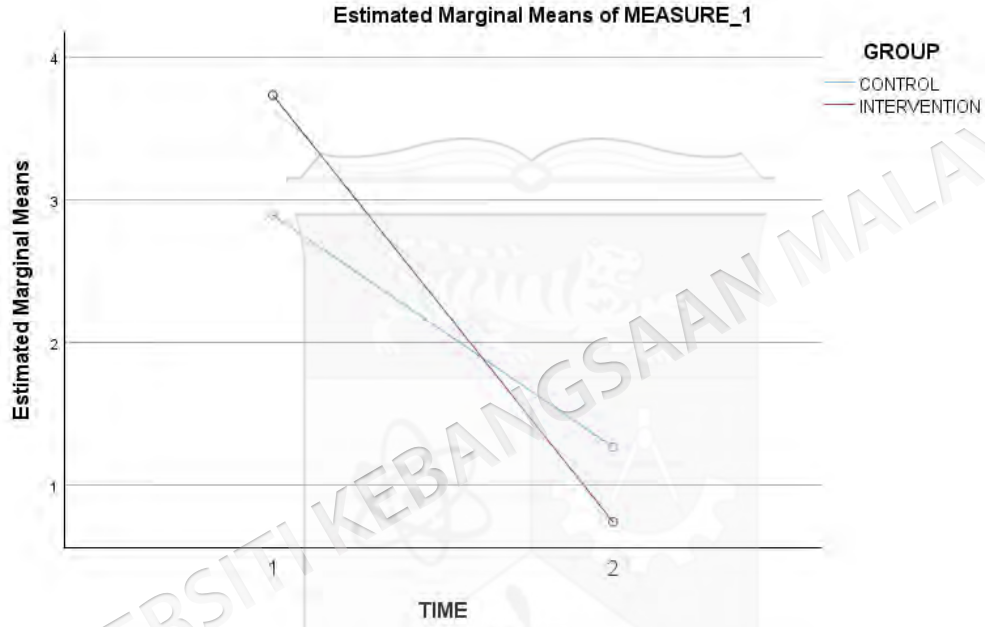

Figure 4.3 Interaction effect between time and group in pain intensity

4.5.2 HAND STRENGTH COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

With respect to the secondary outcomes of hand strength, the Shapiro-Wilk test showed normal distribution for the baseline assessments of grip strength ($p = 0.14$); lateral pinch ($p = 0.418$); tripod pinch ($p = 0.132$); and tip pinch ($p = 0.341$). Besides, the Shapiro-Wilk test also indicated normal distribution for the reassessments of grip strength ($p = 0.47$); lateral pinch ($p = 0.635$); tripod pinch ($p = 0.163$); and tip pinch ($p = 0.587$). In addition, the data points for the grip and pinch strength are close to the diagonal line of the Q-Q plots for both baseline assessments and reassessments and the values for the

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Cook's distance are less than 1, thus, the data was considered to have a normal distribution.

The F_{max} was used to assess the homogeneity of variance assumption. Based on the calculation, the F_{max} values for the hand strength were (1) grip strength: 1.977; (2) lateral pinch: 2.052; (3) tripod pinch: 1.435; and (4) tip pinch: 2.288. The Levene's Test for Equality Error Variances during baseline assessment was insignificant at $\alpha = 0.05$ for hand strength, (1) grip strength: $F(1,36) = 0.846$, $p = 0.364$; (2) lateral pinch: $F(1,36) = 2.232$, $p = 0.144$; (3) tripod pinch: $F(1,36) = 0.918$, $p = 0.344$; and (4) tip pinch: $F(1,36) = 2.354$, $p = 0.134$. Similarly, the Levene's Test for Equality Error Variances during reassessment was insignificant at $\alpha = 0.05$ for hand strength (1) grip strength: $F(1,36) = 3.406$, $p = 0.073$; (2) lateral pinch: $F(1,36) = 0.725$, $p = 0.400$; (3) tripod pinch: $F(1,36) = 0.557$, $p = 0.460$; and (4) tip pinch: $F(1,36) = 1.804$, $p = 0.188$. This result suggests that the variances were not significantly different and the assumption of homogeneity of variance was likely met.

Table 4.4 reveals a significant main effect for time, $F(1, 36) = 17.711$, $p < 0.001$, partial $\eta^2 = 0.33$, indicating a notable improvement grip strength performance following the 4-week interventions ($M = 24.271$, $SD = 14.09$) compared to the baseline ($M = 34.547$, $SD = 16.19$). However, a significant main effect for group was not found in term of grip strength performance, $F(1, 36) = 2.246$, $p = 0.143$, partial $\eta^2 = 0.059$. Similarly, neither a significant interaction between time and intervention groups was reported for grip strength performance, $F(1, 36) = 0.784$, $p = 0.382$, partial $\eta^2 = 0.021$.

Table 4.4 also shows a significant main effect for time was found in all pinch strength performance for both groups; (1) lateral pinch: $F(1, 36) = 58.159$, $p < 0.001$, partial $\eta^2 = 0.618$; (2) tripod pinch: $F(1, 36) = 65.335$, $p < 0.001$, partial $\eta^2 = 0.645$; and (3) tip pinch: $F(1, 36) = 60.719$, $p < 0.001$, partial $\eta^2 = 0.628$. Pinch strength had significantly improved after the 4-week of interventions in both groups. The mean scores for all pinch strength had improved significantly from baseline assessment: (1) lateral pinch ($M = 4.455$, $SD = 2.0327$); (2) tripod pinch ($M = 4.005$, $SD = 2.0762$); and (3) tip pinch ($M = 3.018$, $SD = 1.4781$) to reassessment: (1) lateral pinch ($M = 5.653$, $SD = 2.1697$); (2) tripod pinch ($M = 5.066$, $SD = 2.1291$); and (3) tip pinch ($M = 3.979$,

SD = 1.6772). However, neither a significant main effect between both groups nor a significant interaction between time and intervention groups was reported for pinch strength performance. Figure 4.4 illustrates the interaction effect between time and the study groups across all measured outcomes of hand strength, including the grip strength lateral pinch strength, tripod pinch strength and tip pinch strength. For each outcome, the lines representing the respective study group are displayed in parallel, indicating their comparative progression over time.

Table 4.4 Repeated Measures ANOVA analysis for time, group and interaction main effects in term of hand strength between control and intervention groups

Main Effects	**Baseline Assessment M(SD)**	**Reassessment M(SD)**	**F(1, 36)**	**p**	**Eta**
Grip					
Time	12.424(9.2609)	17.600(9.9918)	83.928	<0.001	0.700
Group			2.246	0.143	0.059
Interaction			0.784	0.382	0.021
CG	14.942(9.8661)	19.616(11.3876)			
IG	9.911(8.0988)	15.584(8.1830)			
Lateral Pinch					
Time	4.455(2.0327)	5.653(2.1697)	58.159	<0.001	0.618
Group			1.914	0.175	0.050
Interaction			0.007	0.934	<0.001
CG	4.916(2.3229)	6.100(2.3319)			
IG	3.995(1.6277)	5.205(1.9535)			
Tripod Pinch					
Time	4.005(2.0762)	5.066(2.1291)	65.335	<0.001	0.645
Group			2.506	0.122	0.065
Interaction			0.033	0.858	0.001
CG	4.537(2.2071)	5.574(2.2035)			
IG	3.474(1.8421)	4.558(1.9794)			
Tip Pinch					
Time	3.018(1.4781)	3.979(1.6772)	60.719	<0.001	0.628
Group			2.049	0.161	0.054
Interaction			1.185	0.283	0.032
CG	3.437(1.6239)	4.263(1.8431)			
IG	2.600(1.2184)	3.695(1.4883)			

CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$

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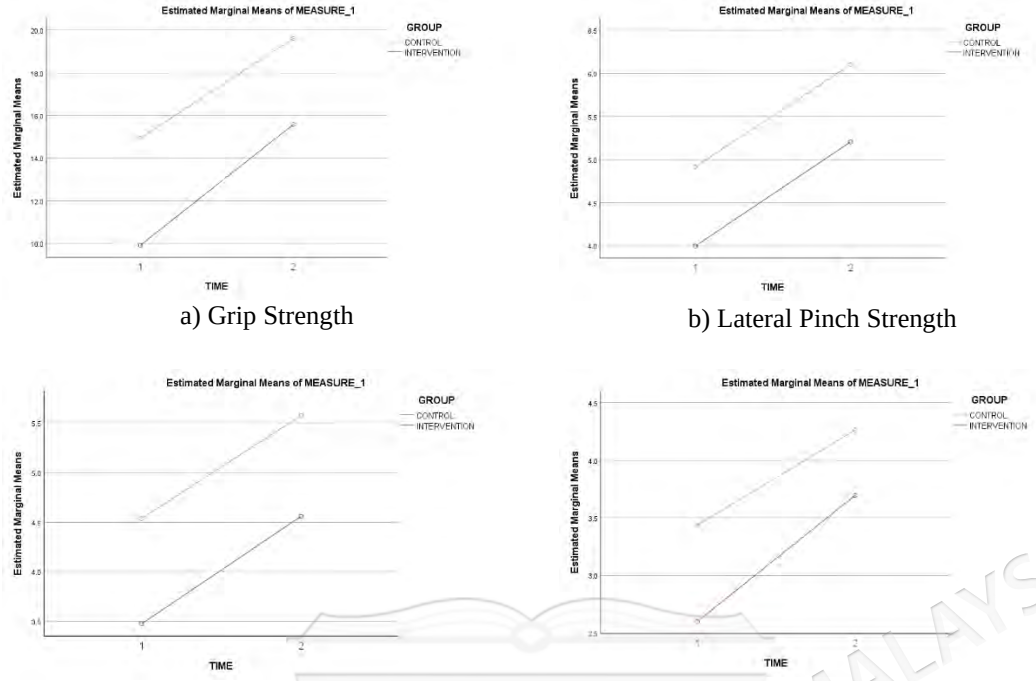

Figure 4.4 Interaction effect between time and group in a) grip strength b) lateral pinch strength c) tripod pinch strength d) tip pinch strength

4.5.3 WRIST ACTIVE RANGE OF MOTION COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

The Shapiro-Wilk test did not show normal distributions for the all the baseline assessments of wrist AROM; (1) supination ($p < 0.01$); (2) pronation ($p < 0.01$); (3) extension ($p = 0.004$); (4) flexion ($p = 0.016$); (5) radial deviation ($p = 0.014$); and (6) ulnar deviation ($p = 0.021$). The normality test for reassessments indicated normal distributions for the following measures: (1) flexion ($p = 0.204$); (2) radial deviation ($p = 0.133$); and (3) ulnar deviation ($p = 0.212$). However, normality was not observed for (1) supination ($p < 0.01$); (2) pronation ($p < 0.01$); and (3) extension ($p = 0.001$). Nevertheless, given the data points for wrist AROM closely aligned with the diagonal line on the Q-Q plots for both baseline assessments and reassessments, and the Cook's distance of all values stayed less than 1, the data, therefore, could be considered as normally distributed and met the criteria for multivariate normality.

The F_{max} values calculated for the wrist AROM were (1) supination: 5.077; (2) pronation: 2.391; (3) extension: 1.647; (4) flexion: 1.688; (5) radial deviation: 1.296;

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and (6) ulnar deviation: 1.456. The Levene's Test for Equality Error Variances during baseline assessment was insignificant at α = 0.05 for wrist AROM, (1) supination: $F(1,36) = 3.148$, $p = 0.084$; (2) pronation: $F(1,36) = 0.321$, $p = 0.574$; (3) extension: $F(1,36) = 0.005$, $p = 0.944$; (4) flexion: $F(1,36) = 1.525$, $p = 0.225$; (5) radial deviation: $F(1,36) = 0.167$, $p = 0.685$; and (6) ulnar deviation: $F(1,36) = 0.108$, $p = 0.745$. Similarly, the Levene's Test for Equality Error Variances during reassessment was also insignificant at α = 0.05 for wrist AROM (1) supination: $F(1,36) = 2.835$, $p = 0.101$; (2) pronation: $F(1,36) = 0.113$, $p = 0.738$; (3) extension: $F(1,36) = 0.367$, $p = 0.548$; (4) flexion: $F(1,36) = 0.726$, $p = 0.400$; (5) radial deviation: $F(1,36) = 0.186$, $p = 0.669$; and (6) ulnar deviation: $F(1,36) = 0.073$, $p = 0.788$. The results suggested that the variances were not significantly different, and the assumption of homogeneity of variance was likely met.

Table 4.5 presents a significant main effect for time across all measures of wrist AROM. The results include: (1) supination: $F(1, 36) = 19.744$, $p < 0.001$, partial $\eta^2 = 0.354$; (2) pronation: $F(1, 36) = 20.004$, $p < 0.001$, partial $\eta^2 = 0.357$; (3) extension $F(1, 36) = 25.985$, $p < 0.001$, partial $\eta^2 = 0.419$; (4) flexion: $F(1, 36) = 39.228$, $p < 0.001$, partial $\eta^2 = 0.521$; (5) radial deviation: $F(1, 36) = 25.763$, $p < 0.001$, partial $\eta^2 = 0.417$; and (6) ulnar deviation: $F(1, 36) = 33.988$, $p < 0.001$, partial $\eta^2 = 0.486$. All wrist movements showed significant improvement after the 4-week interventions compared to the baseline. Besides, the results consistently demonstrated that the intervention group gained a greater mean improvement in all wrist AROM as compared to both the control group and the baseline, highlighting the effectiveness of the HAL-SJ robotic therapy in improving the wrist AROM.

Table 4.5 also presents that there were no significant main effects for the control and intervention groups, no significant difference was observed in the results for all wrist AROM. Similarly, no significant interaction effect between time and intervention was found for any of the wrist AROM after the 4-week intervention. Figure 4.5 illustrates the interaction effect between time and the different study groups across all wrist AROM outcomes, including forearm supination and pronation. For each AROM outcome, the lines representing the respective study groups are displayed in parallel,

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suggesting that changes in AROM over time followed a similar trend across groups, with no substantial divergence in their trajectories.

Table 4.5 Repeated Measures ANOVA analysis for time, group and interaction main effects in term of wrist active range of motion between control and intervention groups

Main Effects	Baseline Assessment M(SD)	Reassessment M(SD)	F(1, 36)	p	Eta
Supination					
Time	69.47(21.460)	76.97(17.612)	19.744	<0.001	0.354
Group			0.199	0.658	0.005
Interaction			2.680	0.110	0.069
CG	69.47(25.325)	74.21(22.253)			
IG	69.47(17.472)	79.74(11.239)			
Pronation					
Time	75.00(20.697)	81.29(16.089)	20.004	<0.001	0.357
Group			0.094	0.761	0.003
Interaction			1.765	0.192	0.047
CG	76.84(20.562)	81.26(18.538)			
IG	73.16(21.227)	81.32(13.728)			
Extension					
Time	41.24(19.598)	49.87(17.224)	25.985	<0.001	0.419
Group			2.229	0.144	0.058
Interaction			2.134	0.153	0.056
CG	46.68(19.250)	52.84(18.919)			
IG	35.79(18.876)	46.89(15.271)			
Flexion					
Time	37.45(17.912)	48.68(15.452)	39.228	<0.001	0.521
Group			0.948	0.337	0.026
Interaction			9.219	0.004	0.204
CG	42.63(16.276)	48.42(14.147)			
IG	32.26(18.381)	48.95(17.044)			
Radial deviation					
Time	16.34(9.843)	21.18(9.687)	25.763	<0.001	0.417
Group			3.582	0.066	0.090
Interaction			1.218	0.277	0.033
CG	19.63(9.209)	23.42(10.145)			
IG	13.05(9.565)	18.95(8.910)			
Ulnar deviation					
Time	28.55(12.076)	34.34(13.314)	33.988	<0.001	0.486
Group			0.433	0.515	0.012
Interaction			0.486	0.490	0.013
CG	30.26(11.723)	35.26(14.147)			
IG	26.84(12.496)	34.34(13.314)			

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CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$

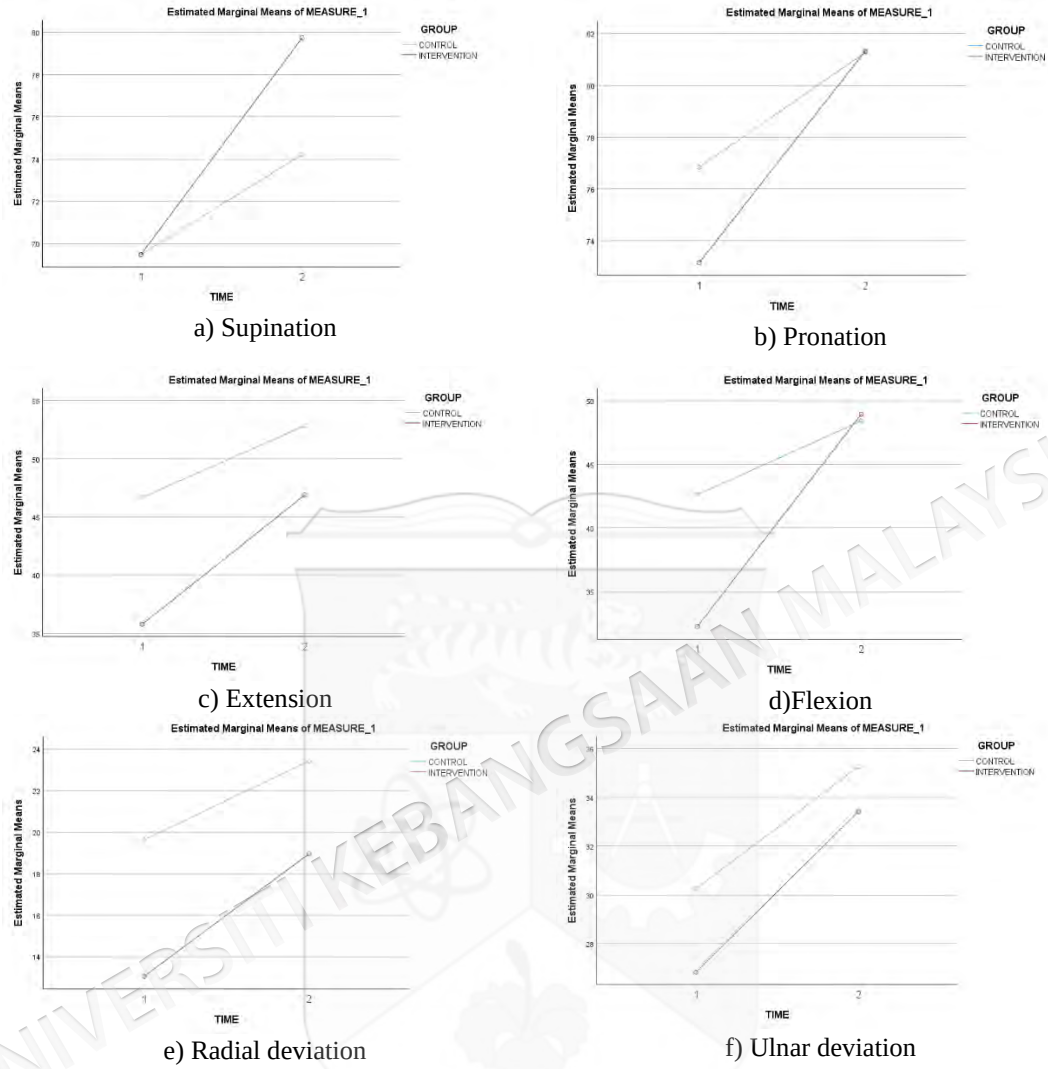

Figure 4.5 Interaction effect between time and group in a) wrist supination b) wrist pronation c) wrist extension d) wrist flexion e) wrist radial deviation f) wrist ulnar deviation

4.5.4 FINGERS ACTIVE RANGE OF MOTION COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

Normality test for the fingers active fingers ROM was analyzed by the Shapiro-Wilk test which did not show normal distributions for the all the baseline assessments; (1) thumb MCPJ ($p = 0.013$); (2) thumb IPJ ($p < 0.01$); (3) index finger MCPJ ($p < 0.01$); (4) index finger PIPJ ($p < 0.01$); (5) index finger DIPJ ($p = 0.007$); (6) middle finger MCPJ ($p < 0.01$); (7) middle finger PIPJ ($p < 0.01$); (8) middle finger DIPJ ($p = 0.002$); (9) ring finger MCPJ ($p < 0.01$); (10) ring finger PIPJ ($p < 0.01$); (11) ring finger DIPJ ($p < 0.01$); (12) little finger MCPJ ($p < 0.01$); (13) little finger PIPJ ($p < 0.01$); and (14)

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little finger DIPJ ($p < 0.01$). Similarly, the Shapiro-Wilk test for reassessments did not show normal distributions for the all the reassessments either; (1) thumb MCPJ ($p = 0.003$); (2) thumb IPJ ($p < 0.01$); (3) index finger MCPJ ($p < 0.01$); (4) index finger PIPJ ($p < 0.01$); (5) index finger DIPJ ($p = 0.001$); (6) middle finger MCPJ ($p < 0.01$); (7) middle finger PIPJ ($p < 0.01$); (8) middle finger DIPJ ($p < 0.01$); (9) ring finger MCPJ ($p < 0.01$); (10) ring finger PIPJ ($p < 0.01$); (11) ring finger DIPJ ($p < 0.01$); (12) little finger MCPJ ($p < 0.01$); (13) little finger PIPJ ($p < 0.01$); and (14) little finger DIPJ ($p < 0.01$). Nevertheless, given the data points for the fingers active ROM were close to the diagonal line one the Q-Q plots for both baseline assessments and reassessments and the respective values for the Cook's distance were less than 1, therefore, the data could be considered as normally distributed and met the criteria for multivariate normality.

The F_{max} values calculated for the fingers active ROM were (1) thumb MCPJ: 1.549; (2) thumb IPJ: 1.847; (3) index finger MCPJ: 2.722; (4) index finger PIPJ: 2.400; (5) index finger DIPJ: 1.460; (6) middle finger MCPJ: 3.386; (7) middle finger PIPJ: 9.317; (8) middle finger DIPJ: 1.539; (9) ring finger MCPJ: 2.682; (10) ring finger PIPJ: 3.041; (11) ring finger DIPJ: 2.450 (12) little finger MCPJ: 3.603; (13) little finger PIPJ: 5.329; and (14) little finger DIPJ: 1.765.

The Levene's Test for Equality Error Variances during baseline assessment were insignificant at $\alpha = 0.05$ for fingers AROM except for PIPJ of the middle, ring and little fingers, (1) thumb MCPJ: $F(1,36) = 0.788$, $p = 0.381$; (2) thumb IPJ: $F(1,36) = 0.914$, $p = 0.345$; (3) index finger MCPJ: $F(1,36) = 3.415$, $p = 0.073$; (4) index finger PIPJ: $F(1,36) = 2.868$, $p = 0.099$; (5) index finger DIPJ: $F(1,36) = 0.917$, $p = 0.345$; (6) middle finger MCPJ: $F(1,36) = 1.326$, $p = 0.257$; (7) middle finger PIPJ: $F(1,36) = 11.989$, $p = 0.001$; (8) middle finger DIPJ: $F(1,36) = 0.013$, $p = 0.908$; (9) ring finger MCPJ: $F(1,36) = 0.874$, $p = 0.356$; (10) ring finger PIPJ: $F(1,36) = 5.145$, $p = 0.029$; (11) ring finger DIPJ: $F(1,36) = 0.000$, $p = 1.000$; (12) little finger MCPJ: $F(1,36) = 1.730$, $p = 0.197$; (13) little finger PIPJ: $F(1,36) = 7.341$, $p = 0.010$; (14) little finger DIPJ: $F(1,36) = 0.280$, $p = 0.600$.

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Similarly, the Levene's Test for Equality Error Variances during reassessment is insignificant at α = 0.05 for fingers active range of motion except for little finger PIPJ, (1) thumb MCPJ: $F(1,36) = 0.703$, $p = 0.407$; (2) thumb IPJ: $F(1,36) = 1.544$, $p = 0.222$; (3) index finger MCPJ: $F(1,36) = 1.805$, $p = 0.187$; (4) index finger PIPJ: $F(1,36) = 0.908$, $p = 0.347$; (5) index finger DIPJ: $F(1,36) = 0.166$, $p = 0.686$; (6) middle finger MCPJ: $F(1,36) = 3.011$, $p = 0.091$; (7) middle finger PIPJ: $F(1,36) = 4.704$, $p = 0.037$; (8) middle finger DIPJ: $F(1,36) = 0.251$, $p = 0.619$; (9) ring finger MCPJ: $F(1,36) = 0.524$, $p = 0.474$; (10) ring finger PIPJ: $F(1,36) = 1.992$, $p = 0.167$; (11) ring finger DIPJ: $F(1,36) = 2.417$, $p = 0.129$; (12) little finger MCPJ: $F(1,36) = 1.077$, $p = 0.306$; (13) little finger PIPJ: $F(1,36) = 6.177$, $p = 0.018$; and (14) little finger DIPJ: $F(1,36) = 0.427$, $p = 0.518$.

According to Tabachnick and Fidell (2007), homogeneity of variance can be assumed when F_{max} is less than 10. Based on the calculations, the F_{max} values for all fingers ROM were less than 10, indicating that the homogeneity of variance assumption had not been violated. Results from the Levene's Test for Equality Error Variances for both baseline and reassessment of the active fingers ROM suggested that the variances were not significantly different, and the assumption of homogeneity of variance was likely met. However, the Levene's test was significant for the baseline assessment of PIPJ AROM for the middle, ring and little fingers as well as the reassessment of little finger PIPJ AROM. The result indicated that the assumption of homogeneity of variance was violated for the respective data.

Table 4.6 presents a significant main effect for time across all measures of fingers AROM. Active movements of all fingers showed significant improvement after the 4-week interventions as compared to baseline.

In addition, Table 4.6 also presents insignificant main effect for group of all fingers AROM. Similarly, no significant interaction between time and intervention groups was found for all fingers AROM after the 4-week intervention. These results indicated that there was no significant difference in the improvement of fingers AROM between the two groups following the 4-week intervention. Figure 4.6 presents the interaction effect between time and the study groups across all finger AROM outcomes.

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The trajectories of each finger joint-specific outcome are represented by parallel lines for the respective study groups, indicating that the progression of AROM over time was comparable across groups, with no notable deviations in their patterns.

Table 4.6 Repeated Measures ANOVA analysis for time, group and interaction main effects in term of fingers active range of motion between control and intervention groups

Main Effects	Baseline Assessment M(SD)	Reassessment M(SD)	F(1, 36)	p	Eta
Thumb MCPJ					
Time	62.11(20.945)	68.68(17.502)	33.988	<0.001	0.486
Group			0.655	0.424	0.018
Interaction			4.405	0.043	0.109
CG	65.79(21.491)	70.00(18.105)			
IG	58.42(20.279)	67.37(17.270)			
Thumb IPJ					
Time	65.79(26.826)	72.24(24.815)	23.286	<0.001	0.393
Group			0.002	0.963	<0.001
Interaction			0.786	0.381	0.021
CG	65.00(29.814)	72.63(28.006)			
IG	66.58(24.270)	71.84(21.935)			
Index finger MCPJ					
Time	68.68(14.781)	76.05(12.311)	32.036	<0.001	0.471
Group			2.770	0.105	0.071
Interaction			2.615	0.115	0.068
CG	73.16(12.825)	78.42(9.436)			
IG	64.21(15.569)	73.68(14.515)			
Index finger PIPJ					
Time	68.95(24.746)	82.37(28.230)	54.219	<0.001	0.601
Group			0.556	0.461	0.015
Interaction			0.083	0.774	0.002
CG	66.05(28.943)	78.95(31.117)			
IG	71.84(20.084)	85.79(25.400)			
Index finger DIPJ					
Time	45.00(25.362)	55.68(22.904)	30.989	<0.001	0.463
Group			0.896	0.350	0.024
Interaction			0.007	0.935	<0.001
CG	48.68(27.276)	59.21(23.289)			
IG	41.32(23.443)	52.16(22.576)			
Middle finger MCPJ					
Time	70.92(14.278)	76.97(11.540)	25.631	<0.001	0.416
Group			1.387	0.247	0.037
Interaction			0.048	0.827	0.001

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CG	73.16(11.692)	79.47(8.959)			
IG	68.68(16.486)	74.47(13.426)			
Middle finger PIPJ					
Time	69.08(20.463)	84.47(23.675)	71.587	<0.001	0.665
Group			2.083	0.158	0.055
Interaction			2.306	0.138	0.060
CG	65.53(27.177)	78.16(29.824)			
IG	72.63(9.771)	90.79(13.361)			
Middle finger DIPJ					
Time			30.150	<0.001	0.456
Group			0.535	0.460	0.015
Interaction			0.121	0.730	0.003
CG	55.26(24.064)	65.00(20.480)			
IG	49.47(24.715)	60.53(19.923)			
Ring finger MCPJ					
Time	69.87(16.664)	77.37(13.692)	19.987	<0.001	0.357
Group			0.284	0.597	0.008
Interaction			2.221	0.145	0.058
CG	72.37(14.565)	77.37(11.349)			
IG	67.37(18.587)	77.37(16.018)			
Ring finger PIPJ					
Time	71.71(20.477)	83.29(23.170)	37.033	<0.001	0.507
Group			1.000	0.324	0.027
Interaction			0.019	0.891	0.001
CG	68.42(24.611)	79.74(26.639)			
IG	75.00(15.275)	86.84(19.164)			
Ring finger DIPJ					
Time	49.74(26.887)	62.63(21.141)	29.271	<0.001	0.448
Group			0.060	0.809	0.002
Interaction			3.523	0.069	0.089
CG	52.89(27.554)	61.32(24.599)			
IG	46.58(26.565)	63.95(17.605)			
Little finger MCPJ					
Time	66.32(22.412)	74.87(14.355)	13.929	<0.001	0.279
Group			0.064	0.802	0.002
Interaction			2.060	0.160	0.054
CG	68.68(19.425)	73.95(15.597)			
IG	63.95(25.363)	75.79(13.361)			
Little finger PIPJ					
Time	69.08(23.620)	83.63(24.634)	42.542	<0.001	0.542
Group			1.594	0.215	0.042
Interaction			1.593	0.215	0.042
CG	65.79(29.310)	77.53(31.369)			
IG	72.37(16.276)	89.74(13.589)			

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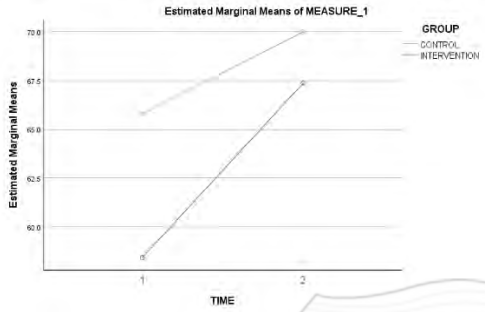
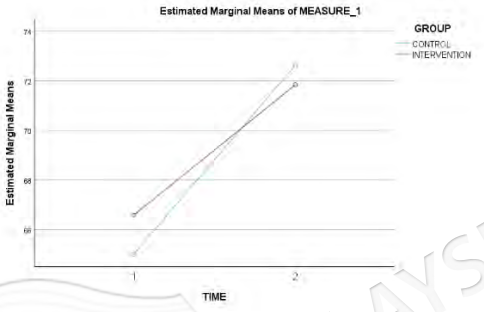
Little finger DIPJ					
Time	54.11(26.348)	65.53(21.365)	19.393	<0.001	0.350
Group			0.072	0.790	0.002
Interaction			0.422	0.520	0.012
CG	53.95(27.868)	63.68(22.164)			
IG	54.26(25.501)	67.37(20.974)			

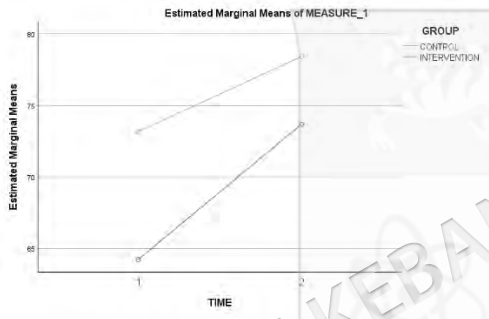
CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$



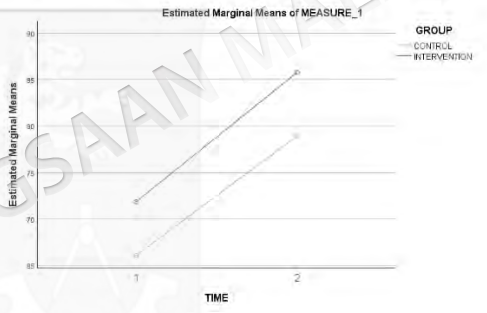
a) Thumb MCPJ



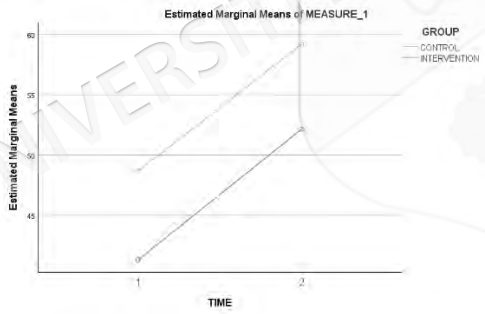
b) Thumb IPJ



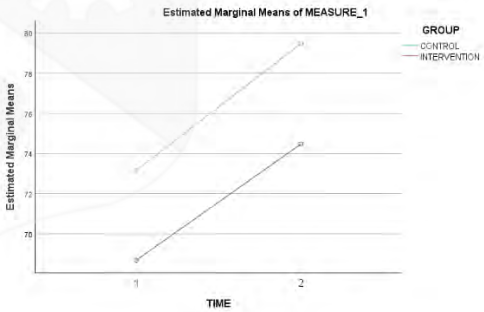
c) Index finger MCPJ



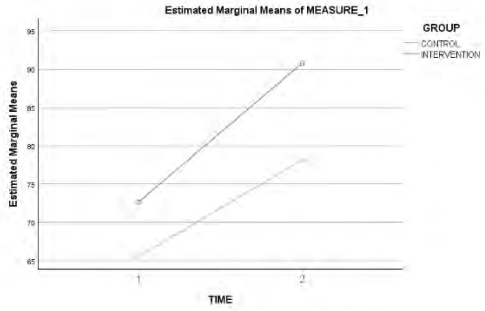
d) Index finger PIPJ



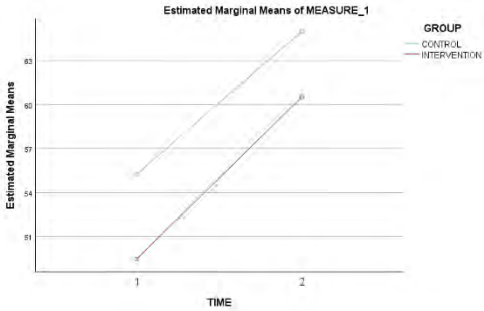
e) Index finger DIPJ



f) Middle finger MCPJ



g) Middle finger PIPJ



h) Middle finger DIPJ

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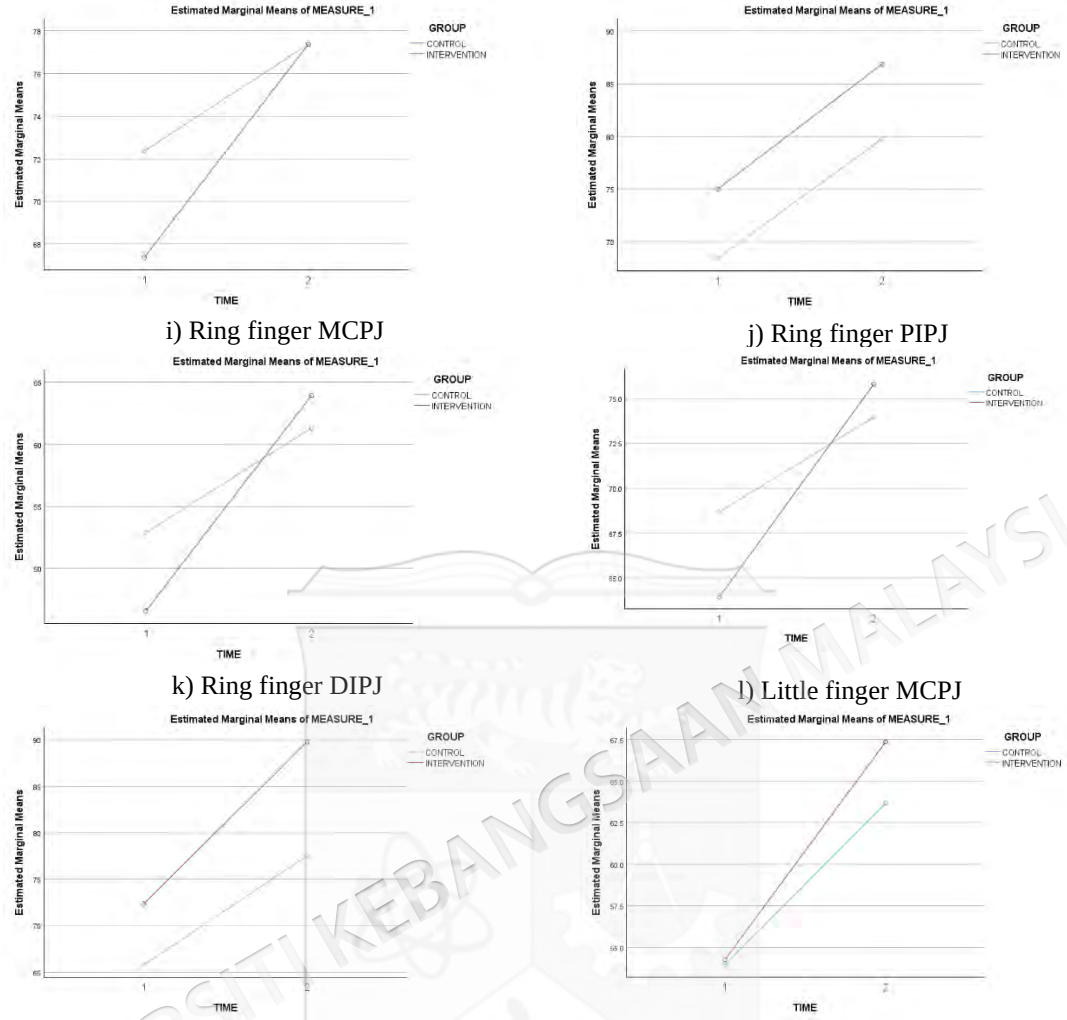

i) Ring finger MCPJ

j) Ring finger PIPJ

k) Ring finger DIPJ

l) Little finger MCPJ

m) Little finger PIPJ

n) Little finger DIPJ

Figure 4.6 Interaction effect between time and group in AROM of a) thumb MCPJ b) thumb IPJ c) index finger MCPJ d) index finger PIPJ e) index finger DIPJ f) middle finger MCPJ g) middle finger PIPJ h) middle finger DIPJ i) ring finger MCPJ j) ring finger PIPJ k) ring finger DIPJ l) little finger MCPJ m) little finger PIPJ n) little finger DIPJ

4.5.5 HAND DEXTERITY AND COORDINATION COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

The Shapiro-Wilk test was used to analyze the normality of hand dexterity scores of PPT. The test did not show normal distributions for the baseline assessments of (1) PPT right hand ($p = 0.006$); (2) PPT left hand ($p < 0.001$); (3) PPT both hands ($p < 0.001$); (4) PPT assembly ($p = 0.018$); and (5) PPT right, left hand and both hands ($p = 0.002$). Besides, the Shapiro-Wilk test also indicates that the reassessments of PPT was not normally distributed, (1) PPT right hand ($p = 0.003$); (2) PPT left hand ($p < 0.001$); (3) PPT both hands ($p < 0.001$); (4) PPT assembly ($p = 0.013$); and (5) PPT right, left hand

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and both hands (p = 0.001). However, given the data points for the PPT subtests were close to the diagonal line of the Q-Q plots for both baseline assessments and reassessments, and the respective values for the Cook's distance were less than 1, thus, the data could be considered to be normally distributed and achieved multivariate normality.

The normality test for the hand coordination function score of BBT showed normal distribution for both baseline assessment (p = 0.299) and reassessment (p = 0.388).

The F_{max} was used to assess the homogeneity of variance assumption. Based on the calculation, the F_{max} values for the hand dexterity and coordination scores were (1) PPT right hand: 2.220; (2) PPT left hand: 4.569; (3) PPT both hands: 3.705; (4) PPT assembly: 4.367; (5) PPT right, left and both hands: 2.842; and (6) BBT: 2.654.

The Levene's Test for Equality Error Variances for baseline assessment of the hand dexterity and coordination was not significant at α = 0.05, except for PPT both hands, PPT assembly and PPT right, left and both hands; (1) PPT right hand: $F(1,36) = 0.927$, $p = 0.342$; (2) PPT left hand: $F(1,36) = 4.130$, $p = 0.050$; (3) PPT both hands: $F(1,36) = 10.243$, $p = 0.003$; (4) PPT assembly: $F(1,36) = 15.080$, $p < 0.001$; (5) PPT right, left and both hands: $F(1,36) = 9.552$, $p = 0.004$; and (6) BBT: $F(1,36) = 0.996$, $p = 0.325$. For the reassessment data, the Levene's Test for Equality Error Variances were insignificant at α = 0.05, except for PPT left hand and PPT assembly; (1) PPT right hand: $F(1,36) = 0.161$, $p = 0.691$; (2) PPT left hand: $F(1,36) = 5.189$, $p = 0.029$; (3) PPT both hands: $F(1,36) = 1.747$, $p = 0.195$; (4) PPT assembly: $F(1,36) = 5.125$, $p = 0.030$; (5) PPT right, left and both hands: $F(1,36) = 3.324$, $p = 0.077$; and (6) BBT: $F(1,36) = 0.633$, $p = 0.431$.

The calculated F_{max} values for all PPT subtests and BBT were less than 10, indicating that the homogeneity of variance assumption had not been violated. Additionally, results from the Levene's Test for Equality Error Variances for both baseline and reassessment of the PPT and BBT suggested that the variances were not significantly different, supporting the assumption of homogeneity of variance.

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However, the Levene's test was significant for the baseline assessments of PPT both hands, PPT assembly and PPT right, left and both hands as well as the reassessment of PPT left hand and PPT assembly. The results indicated that the assumption of homogeneity of variance was violated for the respective data.

Table 4.7 Repeated Measures ANOVA analysis for time, group and interaction main effects in term of hand dexterity and coordination between control and intervention groups

Main Effects	Baseline Assessment M(SD)	Reassessment M(SD)	F(1, 36)	p	Eta
PPT right hand					
Time	13.455(3.6629)	15.263(2.9833)	50.275	<0.001	0.583
Group			0.011	0.916	<0.001
Interaction			0.450	0.507	0.012
CG	13.426(4.0875)	15.405(2.7430)			
IG	13.484(3.2968)	15.121(3.2754)			
PPT left hand					
Time	12.597(3.2405)	14.089(3.2382)	66.437	<0.001	0.649
Group			0.027	0.871	0.001
Interaction			0.035	0.853	0.001
CG	12.700(4.1102)	14.158(4.2043)			
IG	12.495(2.1609)	14.021(1.9668)			
PPT both hands					
Time	10.045(3.0267)	11.550(2.8197)	55.339	<0.001	0.606
Group			0.250	0.620	0.007
Interaction			1.432	0.239	0.038
CG	9.689(3.8235)	11.437(3.3380)			
IG	10.400(1.9863)	11.663(2.2745)			
PPT assembly					
Time	29.463(9.4894)	34.026(9.0627)	62.494	<0.001	0.634
Group			0.418	0.522	0.011
Interaction			<0.001	0.986	<0.001
CG	28.495(12.2066)	30.432(5.8410)			
IG	33.068(10.8435)	34.984(7.0220)			
PPT right, left & both hands					
Time	36.384(7.9537)	40.616(7.7267)	54.503	<0.001	0.602
Group			0.006	0.940	<0.001
Interaction			0.076	0.785	0.002
CG	36.211(9.8054)	40.600(9.3531)			
IG	36.558(5.8163)	40.632(5.9362)			

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BBT					
Time	53.84(11.924)	59.18(10.206)	19.152	<0.001	0.347
Group			0.191	0.665	0.005
Interaction			0.038	0.847	0.001
CG	53.21(14.105)	58.32(11.729)			
IG	54.47(9.617)	60.05(8.657)			

PPT: Purdue Pegboard Test
BBT: Box and Block Test
CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$

A significant main effect for time was found in the physical performance of hand dexterity. Table 4.7 shows that all the subtests scores of the PPT had improved significantly after the 4-week intervention. The results include: (1) PPT right hand, $F(1, 36) = 50.275$, $p < 0.001$, partial $\eta^2 = 0.583$; (2) PPT left hand, $F(1, 36) = 66.437$, $p < 0.001$, partial $\eta^2 = 0.649$; (3) PPT both hands, $F(1, 36) = 55.339$, $p < 0.001$, partial $\eta^2 = 0.606$; (4) PPT assembly $F(1, 36) = 62.494$, $p < 0.001$, partial $\eta^2 = 0.634$; and (5) PPT right, left and both hands, $F(1, 36) = 54.503$, $p < 0.001$, partial $\eta^2 = 0.602$. A significant main effect between both groups were not found in all the PPT subtests as reported in Table 4.7. Besides, Table 4.7 also shows an insignificant interaction between time and intervention groups in term of physical performance of hand dexterity.

Additionally, Table 4.7 shows a significant main effect for time, with $F(1, 36) = 19.152$, $p < 0.001$, partial $\eta^2 = 0.347$, indicating that hand coordination, as measured by BBT score, significantly improved after the 4-week intervention ($M = 59.18$, $SD = 10.206$) compared to baseline levels ($M = 53.84$, $SD = 11.924$). However, no significant main effect for group was found in terms of BBT score, $F(1, 36) = 0.191$, $p = 0.665$, partial $\eta^2 = 0.005$. Additionally, there was no significant interaction between time and intervention groups for functional levels after the 4-week intervention, as indicated by the BBT score, $F(1, 36) = 0.038$, $p = 0.847$, partial $\eta^2 = 0.001$. These results suggested that there was no significant difference in hand coordination improvement between the two groups after the 4-week intervention. Figure 4.7 presents the interaction effect between time and the study groups on hand dexterity and coordination outcomes. The outcome trajectories for each study group are depicted as parallel lines, indicating that the progression of hand dexterity and coordination over time was consistent across groups, with no significant divergence in their patterns.

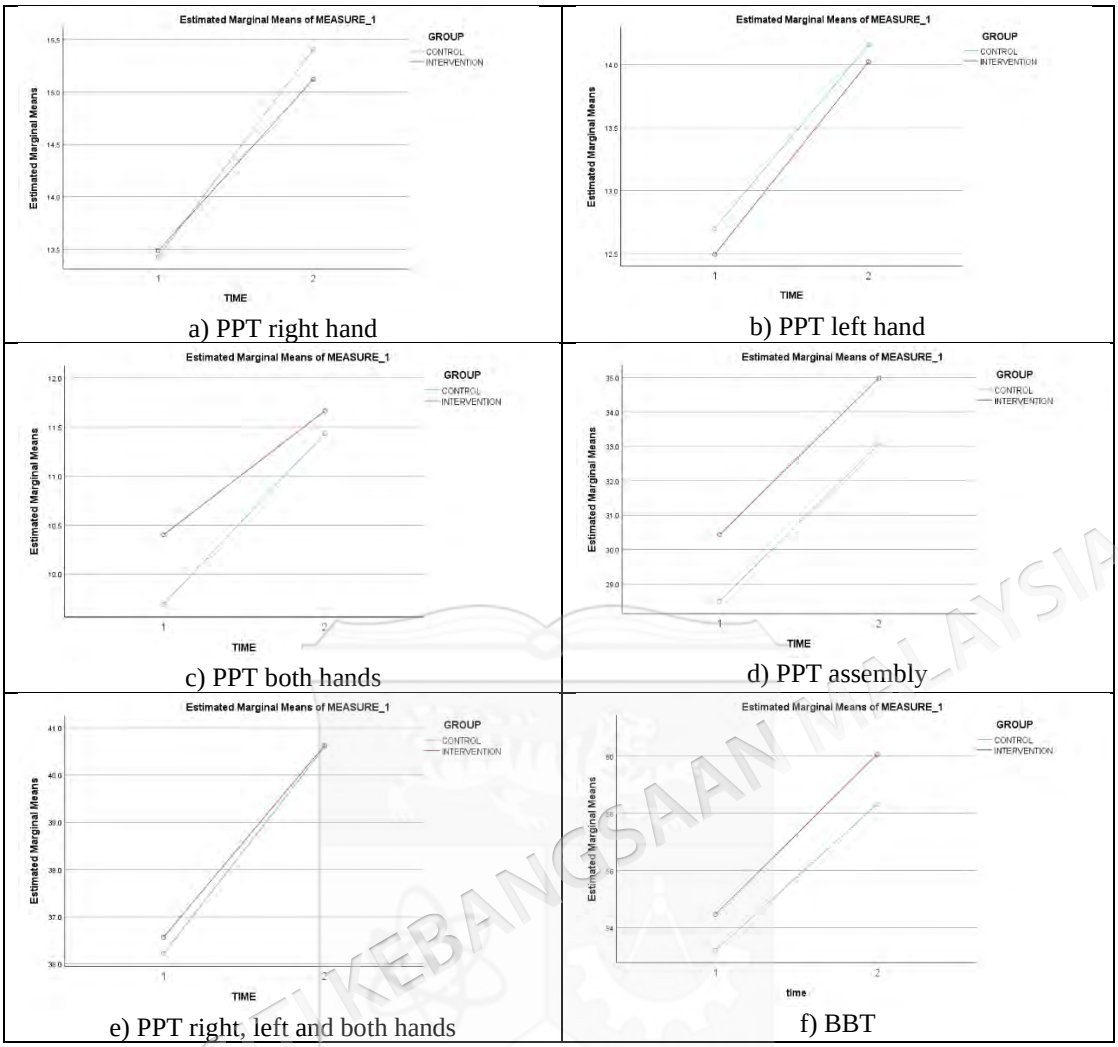

Figure 4.7 Interaction effect between time and group in a) PPT right hand b) PPT left hand c) PPT both hands d) PPT assembly e) PPT right, left and both hands f) BBT

4.5.6 WORK READINESS COMPARISON BETWEEN CONTROL AND INTERVENTION GROUPS

A Chi-Square test was conducted to compare the different work readiness stages between the groups. At baseline, 12 participants (31.6%) were at the pre-contemplation stage, 6 (15.8%) were at the contemplation stage, and 20 (52.6%) were at the action stage. The findings revealed that 13 participants (34.2%) from the control group were in the action stage, out of a total of 20 in that stage. Additionally, the control group had 5 participants (13.2%) in the pre-contemplation stage and 1 participant (2.6%) in the contemplation stage.

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During reassessment, the total number of participants in the action stage increased to 26 (68.4%). Among these, the number of participants in the intervention group rose from 7 (18.4%) to 13 (34.2%), while the number of participants in the control group remained at 13 (34.2%). The total number of participants in the pre-contemplation stage decreased from 12 (31.6%) to 6 (15.8%). Meanwhile, the number of participants in the contemplation stage remained unchanged at 6 (15.8%).

The results from the Chi-Square test showed that there was no significant association between types of interventions and work readiness, X^2 (2, n = 38) < 0.001, p = 1.000, as reported in Table 4.8.

Table 4.8 Chi-Square test for stages of employment readiness between control and intervention groups

Stages of employment readiness	**Baseline assessment**		***p* value**	**Reassessment**		***p* value**
	CG (n = 19)	**IG (n = 19)**		**CG (n = 19)**	**IG (n = 19)**	
Pre-Contemplation	5	7	0.091	3	3	1.000
Contemplation	1	5		3	3	
Action	13	7		13	13	

CG: Control Group, IG: Intervention Group
p value is significant at $p<0.05$

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CHAPTER V

DISCUSSION

5.1 INTRODUCTION

There are limited studies of the application of robotic intervention in orthopaedic rehabilitation. This RCT aimed to compare the effectiveness of HAL-SJ robotic therapy in improving functional level, physical performance, and work readiness among workers with wrist fractures after 4 weeks of intervention.

5.2 DEMOGRAPHICS AND WRIST FRACTURE CHARACTERISTICS

The mean age of participants for this study was 39.26 years (SD 12.513 years) which is relatively younger as compared to the mean age of other studies, i.e., 67.5 years (SD 10 years) (Tsang et al. 2017); 59.30 years (SD 13.61) (Kleinlugtenbelt et al. 2018); 52 years (range, 23 to 81 years) (Bot et al. 2012); and 62 years (SD 13 years) (Ingall et al. 2021). Norton et al.'s (2022) systematic review of the functional outcome measures used for gauging intervention for people aged 19–64 years with a DRF between 2010 and 2020 identified 118 articles with 3 of them reporting a mean age of between 19 and 34 years, 28 articles between 35 and 49 years, and 87 articles between 50 and 64 years.

The incidence of fractures of the distal radius has increased recently in all age groups. The exact cause for this rise is unclear. Some theories include lifestyle influences (urban versus rural living) (Omsland et al. 2011), types of activities (Nellans et al, 2012; Koo et al. 2013), and osteoporosis (Amorosa et al. 2011; Nellans et al. 2012; Koo et al. 2013; Porrino et al. 2014). Particularly, postmenopausal osteoporosis is a risk factor for DRF among elderly women (Amorosa et al. 2011; Koo et al. 2012). Although men have a reduced incidence of severe fractures owing to the lower prevalence of

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osteoporosis (Harper et al. 2014); they are more vulnerable to sustaining fractures between 19 and 49 years old (Porrino et al. 2014) due to sporting activities and motor vehicle accidents (Nellans et al. 2012).

Statistics of the studies related to the DRF done on Western populations showed that the majority of the participants were women (Bot et al. 2012; Tsang et al. 2017; Kleinlugtenbelt et al. 2018; Ingall et al. 2021; Norton et al. 2022; Soerensen et al. 2024). However, in our study, the highest incidence is represented by men (n=28, 73.7%), coinciding with the epidemiology study of DRF conducted by our neighbouring country – Singapore with male participants (n=238, 56.8%) outnumbered the females (n=181, 43.2%) (Koo et al. 2013). The reason is attributed to the higher rate of industrial work injuries and motor vehicle accidents, especially motorcycle accidents among male workers that commonly happen in Malaysia and Singapore (Koo et al. 2013).

Of the total participants in this study, 35 (92.1%) were right-hand dominant. Wrist fractures involving the dominant hand were reported in 23 cases, including 21 unilateral (55.3%) and 2 bilateral (5.3%) fractures. In this context, a systematic review conducted by Norton et al. (2022) found that 45% of the included studies reported the dominance of the injured hand, with 48% of participants sustaining injuries to their dominant hand. Additionally, one participant was identified as ambidextrous. Conversely, Koo et al. (2013) reported that most patients fell onto their non-dominant hands; however, the study reported no significant correlation between hand dominance and the fracture site.

DRF predominant wrist fractures studied in this study (n=23, 60.5%). This is followed by combined distal radius and ulna fractures (34.2%, n = 13), isolated distal ulna fractures (2.6%, n = 1), and scaphoid fractures (2.6%, n = 1). These findings are consistent with the previous epidemiological data reported (Nogueira et al. 2019; Soerensen et al. 2024). Both Nogueira et al. (2019) and Soerensen et al. (2024) identified DRF as the most prevalent, representing 98% of 5,426 distal forearm fractures, whereas distal ulna fractures constituted less than 2%. In our study, motor vehicle accidents were the leading cause, accounting for 89.5% (n =34) of cases, while falls contribute to 10.5% (n = 4). Our findings contrast with those of Soerensen et al.

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(2024), who identified falls as the most common mechanism of injury, accounting for 81.9% of cases, whereas motor vehicle accidents represented only 2.4% of the total injuries. Besides that, our study also revealed that surgical management was employed in 94.7% (n = 36) of cases, with only two patients receiving conservative treatment.

5.3 FUNCTIONAL LEVEL OF WORKERS WITH WRIST FRACTURES FOLLOWING 4-WEEK INTERVENTIONS

5.3.1 Primary Outcome

a. Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure

In this RCT, both the control and intervention groups showed statistically significant improvements in functional outcomes after four weeks of treatment, as reflected by a reduction in mean DASH scores. Specifically, the control group's mean DASH score decreased from 32.547 to 22.095 (i.e., a reduction of 10.452); whilst the intervention group's score declined from 36.547 to 26.447 (i.e., a reduction of 10.1). Despite these improvements within groups, the difference in functional recovery between-groups was not statistically significant. Our results were comparable and similar to the clinical outcomes of Albanese et al. (2021) which demonstrated that the robot-assisted rehabilitation approach was effective, yielding results comparable to those of conventional therapy. Both the robot-assisted and traditional rehabilitation methods contributed to the recovery of wrist function, specifically in the function subscale of the PRWE. Furthermore, no significant differences were observed between the experimental and control groups before or after the rehabilitation period (Albanese et al. 2021).

DASH is the most used outcome measure within the Activity/Participation domain of the ICF for individuals with distal radius fractures. Its use was nearly three times higher than that of the Patient-Rated Wrist Evaluation (PRWE). Usage of the DASH increased substantially from 55% in 2012 to 85% in 2018, followed by a slight decline to 73% in 2019 (Norton et al. 2022). Based on the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN), Kleinlugtenbelt et al. (2018) present strong evidence that the DASH questionnaire demonstrates good content

validity, reliability, and internal consistency for evaluating patients DRF, justifying our decision of using DASH as our primary outcome measure.

In our study, the minimal clinically important difference (MCID) for the DASH scores was 10.452 for the control group and 10.1 for the intervention group. A 10-point change is commonly accepted as a meaningful threshold for the DASH score, as supported by Beaton et al. (2011) (10.7 points), Sorensen et al. (2013) (10 points), and Franchignoni et al. (2014) (10.83 points). Our findings indicate a clinically relevant improvement in functional status for both groups, justifying a potential need for adjustments in patients' wrist fracture rehabilitation management. Additionally, Kleinlugtenbelt et al. (2018) reported that the DASH had a smaller smallest detectable change (SDC) of 14.1 points compared to the PRWE's 20.5 points, suggesting that the DASH may be potentially more useful in clinical settings.

The functional impact of DRF is influenced by a combination of physical and psychological factors. Bot et al. (2012) reported that general upper limb disability, measured by the DASH was significantly predicted by a triad of motion, pain, and psychological distress. They found that specific task-related disabilities, such as opening a tight jar, were closely associated with wrist flexion and pain catastrophizing. Tasks not directly dependent on wrist mobility, such as writing or making a bed, were variably influenced by factors such as pain, depressive symptoms, limb dominance, and age, indicating a multifactorial basis for perceived disability. Notably, forearm rotation had no measurable effect on task performance of the DASH activities. Complementing these findings, Ydreborg et al. (2015) provided longitudinal evidence that although DASH scores improve over time after surgical intervention for DRF, they often remain higher compared to pre-injury levels. In line with these findings, this study included supplementary analysis examining the correlation between DASH scores and physical performance measures, including pain intensity, grip strength, and ROM.

5.3.2 Secondary Outcomes

a. Visual Analogue Scale (VAS) for Pain

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During the 4-week intervention, the average pain intensity measured by the VAS decreased from 3.32 to 1.00, i.e., a reduction of 2.32 points. In comparison, the control group experienced a smaller decrease of 1.63 points (from 2.89 to 1.26), while the intervention group saw a greater reduction of 3.00 points (from 3.74 to 0.74). According to Randall et al. (2022), a MCID for VAS pain scores in non-shoulder upper limb postoperative patients ranges between 1.6 and 1.9, with substantial clinical benefit (SCB) values between 2.2 and 2.6. Olaiya et al. (2024) also suggested that a 0.7 to 0.9 cm change on the VAS is considered clinically significant for patients with long-term thumb osteoarthritis. Tashjian et al. (2009) identified a MCID of 1.4 for VAS in patients with rotator cuff tears. The values observed in our study align closely with those reported in previous research, suggesting that the interventions implemented were clinically important and meaningful in reducing pain intensity among patients with wrist fractures, especially the robotic-assisted therapy.

Although these studies do not specifically examine VAS scores in wrist fracture populations, they offer valuable insights into the SDC and MCID for the VAS in various traumatic and non-traumatic hand and upper extremity conditions (Tashjian et al. 2009; Randall et al. 2022; Olaiya et al. 2024). The VAS is commonly used alongside other patient-reported outcome measures (PROMs) to evaluate pain intensity, with changes in VAS scores often reflecting similar trends in related PROMs. As specific SDC values for VAS in wrist fractures are limited, MCID estimates from comparable conditions can serve as a useful reference for interpreting clinically meaningful changes in pain levels.

In the study by Swart et al. (2012), pain was reported as one of the important determinants of patient rated outcomes after DRF for which pain continued to improve up to 2 years postoperatively. Therefore, should our current study be follow-up for a longer period, for example, a year or two, a greater reduction in pain will likely be observed, though pain may not be completely resolved within that timeframe. This postulation is based on a longitudinal data by MacDermid et al. (2003), that most patients continued to experience minimal pain by six months, precisely, 3% with moderate pain, 4% with severe pain, and 1% with very severe pain 1 year following distal radius fracture. However, supplementary analysis in this study found no

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significant correlation between pain intensity and DASH scores, suggesting that pain may not directly reflect functional disability in this sample.

While Goldhahn et al. (2013) recommended that measurement of pain should include measures of both intensity and frequency as core attributes in clinical practice and research for DRF, the inclusion of only pain intensity without pain frequency in our current study may have precluded the understanding of patients' overall pain experience. The use of VAS, as a unidimensional pain scale, further complicated this understanding. Stern et al. (2021) underscored the multidimensional nature of pain, framing it as a biopsychosocial construct from the perspective of hand therapists. The integration of biological, psychological, and social components enables practitioners to acknowledge and validate patients' pain experiences, thereby facilitating the provision of holistic care. Regrettably, our current study approached pain exclusively from a biological standpoint, missing out the invaluable pain-related psychological and social impacts.

b. Grip Strength and Pinch Strength

The findings of this study demonstrated significant improvements in both grip and pinch strength following a 4-week intervention period. Participants showed an increase in mean grip strength from 12.42 kg (SD = 9.26) at baseline to 17.60 kg (SD = 9.99) post-intervention. When comparing groups, the intervention group exhibited a more notable improvement, with an average gain of 5.67 kg (from 9.91 kg to 15.58 kg), whereas the control group recorded a smaller increase of 4.67 kg (from 14.94 kg to 19.62 kg). Similarly, greater enhancements in pinch strength were observed in the intervention group, with mean improvements of 1.21 kg in lateral pinch, 1.084 kg in tripod pinch, and 1.095 kg in tip pinch. In contrast, the control group showed gains of 1.184 kg, 1.037 kg, and 0.826 kg in the respective pinch types. These results suggest that the addition of robotic-assisted therapy may have contributed to a more substantial improvement in grip and pinch strength compared to conventional therapy alone.

Numerous studies had shown that grip strength measurement had been widely used as an index of recovery following distal fracture surgeries (Kong et al. 2025; Johnston et al. 2024; Monareng et al. 2024; Lee & Gong 2022; Kaji et al. 2022; Bobos

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et al. 2020; Hong et al. 2020; Bobos et al. 2017; Goehre et al. 2014; Karantana et al. 2013; Brogren et al. 2011; Arora et al. 2011; Rozental et al. 2009; Egol et al. 2008; Wilcke et al. 2007; Beharrie et al. 2004). A recent study by Szekeres et al. (2024) reported strong to very strong correlations between pinch strength and grip strength, highlighting the value of incorporating both performance-based measures in functional assessments. This finding by Szekeres et al. (2024) supports the inclusion of both grip and pinch strength assessments in our study in capturing a more comprehensive picture of hand function recovery.

Grip strength assessment is a reliable and valid procedure for patients with DRF (Bobos et al. 2020) and appeared to be one of the important determinants of patient rated outcomes after DRF (Swart et al. 2012). Additionally, grip strength is a sensitive indicator of wrist function recovery, i.e., grip strength significantly predicted the PRWE score (regression coefficient -1.09, 95% confidence interval -1.76 to -0.42, $p < 0.01$) in Karnezis and Fragkiadakis's (2002) study.

Kim et al. (2014) established MCID for hand grip strength following DRF as 6.5 kg, aligning with Nitschke et al.'s (1999) report that a change exceeding 6 kg is required to reflect a true improvement with 95% confidence. Our study's average grip strength improvement of 5.18 kg (intervention group: 5.67 kg > control group: 4.67 kg) approximated results of these aforementioned studies, signifying our patients have nearly gaining a true and clinically important improvement in grip strength, especially those receiving robotic-assisted therapy. Kong et al. (2025) reported that patients with a history of DRF demonstrated a 4.1% increased likelihood of sustaining a secondary fracture for every 1 kg decrease in grip strength ($p < 0.008$), independent of age and sex. Therefore, although we were unable to achieve the MCID as reported by Kim et al. (2014) and Nitschke et al. (1999), the inclusion of grip strength in our study was highly invaluable. Essentially, grip strength carries clinical significance as a predictive marker for fracture risk to prevent recurrent fractures, and an indicator of functional improvement following intervention.

Beumer and Lindau (2014) introduced the grip strength ratio (GSR) as a quick method to assess function and symptoms in patients with wrist disorders. The GSR

compares the grip strength of the affected hand to that of the unaffected (or dominant) hand, calculated by dividing the grip strength of the injured or non-dominant hand by that of the non-injured or dominant hand. Their study found that GSR had a stronger correlation with the DASH score ($r = 0.763$) than grip strength alone, justifying the contradicting findings reported by Swart et al. (2012) and Souer et al. (2008), earlier on. Typically, Swart et al. (2012) reported that grip strength was significantly correlated with DASH scores (regression coefficient -0.46, 95% confidence interval -0.63 to -0.29, $p < 0.01$) among patients with distal radius fracture; whilst Souer et al. (2008) reported that grip strength was correlated poorly with DASH score ($r = -0.14$), signifying grip strength served as a dominant predictor of Mayo Wrist score but not DASH score. Beumer and Lindau (2014) also noted that GSR can be particularly helpful for evaluating patients with intellectual or language impairments. In their findings, patients with DRF had an average GSR of 0.52. Recent study by Monareng et al. (2024) had also indicated that GSR is a significant predictor of patient reported outcomes following volar plating of DRF.

In order to compare our findings with the studies, a supplementary analysis was conducted to examine the correlation between GSR and DASH scores. In our sample, the mean GSR was 0.58, which closely aligns with the values reported by Beumer and Lindau (2014). Furthermore, our results demonstrated a significant negative correlation between GSR and DASH scores ($r = -0.39$, $p < 0.01$), indicating that higher GSR values were associated with lower levels of disability.

Conversely, a review of the current literature indicates that pinch strength has received considerably less attention than dynamometry. As a result, there is limited existing research available for direct comparison with our findings.

Rice et al. (1998) contended that grip and pinch dynamometry alone do not adequately capture the complexity of hand function. They advocated for the assessment of specific grasp patterns and stressed the importance of analyzing hand-object interactions in therapeutic settings. Building on this perspective, Wachter et al. (2018) provided empirical support for using assessments of grip, tip pinch, tripod grip, and key

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pinch strength as effective tools for monitoring and quantifying hand strength recovery during rehabilitation.

c. Wrist Range of Motion

In our study, all wrist movements showed significant improvement after the 4-week interventions with a mean AROM of 49.87° extension, 48.68° flexion, 21.18° radial deviation and 34.34° ulnar deviation as well as forearm movements of 76.97° supination and 81.29° pronation respectively.

The improvements in wrist AROM post-intervention observed in our study approached the reported functional benchmarks (Palmer et al. 1985; Ryu et al. 1991; Nelson et al. 1994; Gates et al. 2016) suggesting that participants likely regained the capacity to perform most daily and personal care activities. However, the fact that full ROM was not restored in all planes implies that some complex tasks such as perineal care, opening a jar lid and rising from a chair using armrests may remain challenging, particularly for individuals with residual limitations in extension, flexion and/or ulnar deviation.

Ryu et al. (1991) reported that most tasks could still be performed with 40° of extension and flexion (approximately 70% of the full ROM). The earlier study by Palmer et al. (1985) reported an even smaller arc of the functional wrist motions, i.e., between 5° flexion, 30° extension, 10° radial deviation, and 15° ulnar deviation. A more recent study by Gates et al. (2016) further quantified the wrist ROM necessary to perform ADL, reporting that 38° of flexion, 40° of extension, 38° of ulnar deviation, and 28° of radial deviation were sufficient to complete all tasks assessed.

These studies had provided quantitative characterizations of the wrist motions required to complete different activities of daily living (Palmer et al. 1985; Nelson et al. 1994; Gates et al. 2016). Understanding the wrist functional ROM is essential in making clinical decision and setting treatment goals in OT practice.

Wrist kinematics are complex, with strong coupling observed between flexion-extension and radial-ulnar deviation. A growing body of evidence indicated that most

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ADLs were performed using the dart-throwing motion (DTM), an oblique movement pattern that traverses from radial extension to ulnar flexion (Kaufman-Cohen et al. 2018; Garg et al. 2014; Moritomo et al. 2007; Li et al. 2005). While the orientation of the DTM plane may differ between individuals and tasks, it has been identified as a fundamental axis of functional wrist movement. Moritomo et al. (2007) characterized the DTM plane as a key contributor to wrist functionality and highlighted its relevance for clinical applications. They also reported that the DTM is likely to be guided by the extensor carpi ulnaris and the flexor carpi radialis. Supporting this perspective, Moser et al. (2020) reported that radial-ulnar deviation may be less functionally significant than either flexion-extension or DTM during task-oriented motion.

Building on the biomechanical importance of the DTM, Moritomo et al. (2007) also proposed that wrist rehabilitation should prioritize the preservation of midcarpal function, which plays a central role in facilitating DTM. They suggested that early reintroduction of midcarpal motion may be appropriate following complex surgeries involving the RCJ or proximal carpal row, such as scapholunate ligament repairs or intra-articular distal radius fractures, provided that rehabilitation protocols are carefully designed to restrict movement within the DTM plane. Clinically, facilitating wrist motion along a plane angled approximately 30° to 45° from the sagittal plane can support functional movement while limiting radiocarpal joint involvement, which may be beneficial during the early stages of recovery.

Li et al. (2005) further emphasized the relevance of radial extension and ulnar flexion movement patterns, recommending their consideration in both ergonomic workstation design and wrist rehabilitation programs. Their findings also indicated that wrist ROM in both flexion-extension and radial-ulnar deviation is maximal near the anatomical neutral position. Deviation from this neutral alignment in one direction was shown to constrain available motion in the other, reinforcing the importance of optimizing wrist positioning for both therapeutic and functional outcomes.

Additionally, Anderton and Charles (2012) observed that wrist movements are frequently accompanied by motions in adjacent planes: wrist flexion tends to occur alongside ulnar deviation and forearm supination, while wrist extension is commonly

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associated with radial deviation and forearm pronation. These coordinated patterns further highlight the interdependent nature of wrist and forearm kinematics, underscoring the need for integrated approaches to both ergonomic design and clinical rehabilitation.

Given the evidence presented in previous studies, the DTM represents an inherent and functionally significant movement pattern, consistently utilized in the performance of ADLs. As such, various DTM plane angles should be firmly established as a foundational component of wrist rehabilitation protocols following injury, ensuring the restoration of natural, task-relevant motion (Kaufman-Cohen et al. 2018). An understanding of preferred wrist and forearm kinematics is critical for informing effective rehabilitation strategies. By identifying the movement patterns most frequently utilized in daily tasks such as those associated with the DTM, clinicians can tailor therapy to focus on restoring and reinforcing functional motion paths. This approach allows valuable therapy time to be directed toward the rehabilitation of the most relevant joints and planes of motion, rather than expending effort on less frequently used or biomechanically constrained areas. Ultimately, targeting preferred and functional kinematic pathways may enhance recovery efficiency and improve patient outcomes.

Considering the clinical relevance of wrist kinematics in the effective rehabilitation of wrist fractures, the HAL-SJ facilitates targeted and specific wrist movements by providing neuromuscular control through calibrated parameters, namely assist-gain, assist level, and the balance between flexion and extension. These adjustments enable the execution of specific and high-repetition exercises essential for rehabilitation. Moreover, the HAL-SJ intervention necessitates conscious engagement, requiring the individual to intentionally initiate and actively perform wrist movements following the desired motor patterns. HAL-SJ enables the patients to relearn precise and functional movements earlier by supporting active-assisted exercises. In addition, HAL-SJ offers real-time monitoring and adjustment of movement patterns, providing therapists with quantitative data on joint angles, movement quality, and muscular activation. This allows for fine-tuning of the neuromuscular control of the movements and the treatment plans according to the individual's progress.

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In this study, wrist ROM was assessed using reliable and valid manual goniometric measurements of flexion-extension, radial-ulnar deviation, and supination-pronation with measurements taken in static positions. Incorporating the study of dynamic wrist motions in future research would be valuable for gaining a more comprehensive understanding of wrist kinematics during functional activities. One potential reason the DTM has not yet been widely incorporated into standard hand therapy protocols is the absence of precise, accessible measurement tools for assessing multiplane wrist motion. Currently, dynamic wrist kinematics are evaluated through time-consuming and expensive methods, such as electrogoniometers or three-dimensional motion capture systems.

Several studies have explored the relationship between wrist ROM and PROMs. Wilcke et al. (2007) found that diminished wrist extension and ulnar deviation were significantly associated with poorer scores on the DASH questionnaire. This finding aligns with broader evidence suggesting that extension and ulnar deviation are among the most critical movements for performing functional wrist activities. Specifically, Wilcke et al. reported that patients with wrist extension below 85% and ulnar deviation below 80% of the range observed in the uninjured contralateral wrist experienced significantly worse DASH outcomes. In contrast, Karnezis & Fragkiadakis (2002) reported no significant correlation between wrist ROM, measured as the pronation-supination and extension-flexion arcs, and the PRWE score, suggesting that the impact of ROM on perceived wrist function may vary depending on the specific movements assessed and the PROM used. A supplementary analysis in our study yielded results consistent with those of Karnezis and Fragkiadakis (2002), but in contrast to the findings of Wilcke et al. (2007), in which our results reported no significant correlation between DASH scores and wrist ROM, including extension, flexion, ulnar and radial deviation, as well as supination and pronation.

d. Fingers Range of Motion

The findings in our study indicated substantial functional improvement in all finger movements following the 4-week intervention. Notably, MCPJ flexion improved to a range between 74.87° and 77.37°, PIPJ flexion to between 82.37° and 84.47°, and DIPJ

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flexion to between 55.68° and 65.53°. These results suggest enhanced joint flexibility and ROM across all fingers. Additionally, thumb movements showed marked improvement, with the mean AROM reaching 68.68° for MCPJ flexion and 72.24° for IPJ flexion, further supporting the overall effectiveness of the intervention protocol. Our reported active fingers ROM were lower than the documented normal ROM by Hume et al. (1990). However, the thumb active ROM in our study was greater as compared to the same study. Further comparison indicated that our findings were aligned with the functional range of motion required for daily activities as stated in previous studies (Hume et al. 1990; Bain et al. 2015).

Hume et al. (1990) and Bain et al. (2015) provide complementary insights into both the normal and functional ROM of the thumb and fingers, offering valuable benchmarks for clinical assessment and rehabilitation. Hume et al. (1990) reported that the total arc of normal thumb motion ranged from 0° to 124°, with the thumb IPJ demonstrating a ROM of -5° to 73°, and the MCPJ exhibiting two distinct ranges: 0° to 56° in 85% of the population, and a more limited 0° to 27° in the remaining 15%. Functionally, the thumb MCPJ and IPJ showed average ROMs of 21° (± 5°) and 18° (± 5°), respectively, with a combined functional arc of 21° to 65° (mean 40° ± 5°).

For the fingers, Hume et al. (1990) identified a normal total flexion arc of 0° to 290°, with movement distributed across the MCPJ (33%), PIPJ (39%), and DIPJ (28%). Normal ROM values were 0° to 100° (MCPJ), 0° to 105° (PIPJ), and 0° to 85° (DIPJ). Functionally, the MCPJ, PIPJ, and DIPJ demonstrated arcs of 33°–73° (mean 61° ± 12°), 36°–86° (mean 60° ± 12°), and 20°–61° (mean 39° ± 14°), respectively. When analyzing task-specific positioning in activities such as key pinch, tip pinch, precision grip, and power grip, Hume et al. observed only minor variations between digits, none of which were statistically significant, suggesting a consistent functional pattern across the hand during grasping tasks.

Bain et al. (2015) further refined the concept of functional ROM by defining it as the range required to perform 90% of ADLs based on pre-grasp and grasp measurements. They identified functional ranges of 19°–71° at the MCPJ, 23°–87° at the PIPJ, and 10°–64° at the DIPJ, representing 48%, 59%, and 60% of the total active

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motion, respectively. Their findings also highlighted that ulnar digits exhibited significantly greater functional and active ROM at MCPJ and DIPJ, with MCPJ hyperextension being especially important for grasping larger objects. This was supported by Hayashi and Shimizu (2013) who observed a progressive increase in maximum MCPJ flexion angles from the radial to the ulnar fingers. Specifically, the required mean ROM of finger MCPJ of the index, middle, ring, and little fingers required to perform all 19 DASH activities in their study ranged from -10 to 60°, -10 to 75°, -10 to 80°, and -10 to 85°, respectively. A subsequent study by Hayashi et al. (2014) further specified that maintaining hand function requires MCPJ flexion greater than 70°, with extension lag not exceeding 30°. While similar trends were observed in our study for DIP joints across the fingers, the MCPJ ROM of the little finger was slightly lower than that of the radial digits. Bain et al. (2015) further emphasized the pivotal role of the PIPJ in hand function due to its larger active and functional ROM compared with other joints. They observed that the functional ROM of the PIPJ is positioned relatively flexed within the arc of the ROM. This finding was supported by Li et al. (2023), who demonstrated that PIPJ exhibit the largest dynamic ROM and peak velocity, contributing most significantly to finger grasp capability. Consequently, limitations in PIPJ flexion can significantly impair overall hand functionality.

Bain et al. (2015) further categorized functional hand activities into radial, ulnar, and global tasks. Global activities involve the coordinated use of both radial and ulnar aspects of the hand, such as grasping large objects. Radial activities are typically associated with precision tasks, including pinch movements between the thumb and the index or middle finger, whereas ulnar activities involve more gross motor functions, such as power gripping. The differential contribution of finger joints to these activities was examined by Nakamura et al. (1998), who found that joint involvement varied depending on the type of grasp. Specifically, in tip pinch movements, the PIPJ contributed the most (41%), followed by the MCPJ and DIPJ at 36% and 23%, respectively. Conversely, in palmar pinch activities, the MCPJ dominated the motion (59%), with the PIPJ and DIPJ contributing 32% and 9%, respectively. These findings underscore the functional importance of the MCPJ and PIPJ in executing fine and gross motor tasks.

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In addition, Nimbarte et al. (2008) provided valuable insights into finger joint motion as generated by the extrinsic muscles of the hand. Their findings indicated that the flexor digitorum profundus produced average flexion of 19.7°, 41.8°, and 29.4° at the MCPJ, PIPJ, and DIPJ, respectively. The flexor digitorum superficialis contributed an average flexion of 24.8° at the MCPJ and 47.9° at the PIPJ, with no activity at the DIPJ. Meanwhile, the extensor digitorum communis and extensor indicis proprius generated average extension of 18.3°, 15.2°, and 4.0°, and 15.4°, 13.2°, and 3.7° at the MCPJ, PIPJ, and DIPJ, respectively. Although we did not investigate the muscle functions in this study, these findings offer important guidance for developing targeted muscle strengthening and re-education strategies in hand therapy programs.

OT plays a vital role in improving patients' ability to engage in meaningful functional activities. As such, a thorough understanding of both functional and AROM in the fingers is essential for promoting optimal hand performance. Collectively, the reviewed studies emphasize the clinical relevance of distinguishing between the maximum anatomical ROM and the functional ROM necessary for daily living (Hume et al. 1990; Bain et al. 2015). This distinction is crucial for establishing realistic rehabilitation goals, designing effective intervention strategies, and evaluating therapeutic outcomes in both clinical practice and research. Moreover, these insights are instrumental in guiding the development of assistive technologies, such as hand rehabilitation robots, to better support patient recovery and functional independence.

e. Hand Manual and Fine Dexterity

Our study demonstrated significant improvements across all PPT subtests following a 4-week intervention. The average scores observed were: right hand (M = 15.26, SD = 2.98), left hand (M = 14.09, SD = 3.24), both hands (M = 11.55, SD = 2.82), assembly (M = 34.03, SD = 9.06), and a combined score for right, left and both hands (M = 40.62, SD = 7.73). As referred to the mean age for this study which was 39.26 years (SD 12.513 years), comparison to normative data from the recent study by Stijic et al. (2023) for adults aged 40–49 showed that our results were generally consistent, with the exception of a higher assembly subtest score in our sample. Their reported averages were: right hand (males = 14.18, females = 14.61), left hand (males = 13.83, females =

14.00), both hands (males = 11.71, females = 12.16), and assembly (males = 29.91, females = 29.23). Additionally, our findings were in line with an earlier normative study by Hamm and Curtis (1980), which involved adults participating in vocational rehabilitation. Their reported mean scores for individuals aged 35 years and above were: right hand (males = 12.96, females = 14.08), left hand (males = 11.9, females = 15.14), both hands (males = 10.23, females = 11.33), combined hand score (males = 35.1, females = 40.13), and assembly (males = 28.31, females = 31.76).

Further comparison with findings from Lindstrom-Hazel & VanderVlies Veenstra (2015) also indicated our assembly scores were slightly higher. Their study found average assembly scores of 33 (males) and 31 (females) among working adults aged 18–49, and 31 (males) and 27 (females) for those aged 50–62.

We found that the improvement in hand dexterity among the intervention group could be attributed to enhanced neuromuscular control and repetitive training achieved through the HAL-SJ intervention. Although HAL-SJ targets the wrist, the wrist position and stability significantly influence hand function. A stable and well-aligned wrist allows for efficient finger flexion and extension, supporting dexterity in tasks like pinching or manipulating objects. HAL-SJ is capable to reduce muscle co-contraction by promoting voluntary, smooth and isolated wrist actions in the early recovery phase. In addition, HAL-SJ enables high-repetition and low-fatigue training that provide reinforcing motor patterns required for hand use. Through biofeedback and robotic assistance, HAL-SJ helps retrain timing, coordination, and sequencing of wrist-hand movements that are essential for fine motor tasks.

Cederlund (1995) concluded that the PPT was useful for hand dexterity evaluation. This conclusion was further supported by Yancosek & Howell (2009) who recommended its use for evaluating fine finger dexterity. However, some limitations have been noted. Gonzalez et al. (2017) argued that the PPT does not fully capture the range of finger movements involved in daily tasks requiring precision grip, suggesting that time-based assessments may overlook important functional aspects of hand use. Bobos et al. (2018) investigated factors influencing hand dexterity and identified grip strength and wrist ROM as significant predictors, accounting for approximately one-

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third of the variance in PPT performance. Additionally, a normative study by Stijic et al. (2023) revealed that older individuals, males, and patients with diabetes tend to score lower on all PPT subtests, indicating that demographic and health-related factors may also impact test outcomes.

The BBT results in our study showed significant improvement following the 4-week intervention period, with the overall mean score increasing from 53.84 (SD = 11.92) at baseline to 59.18 (SD = 10.21) post-intervention. Both the control and intervention groups exhibited gains. The control group improved from a mean score of 53.21 (SD = 14.11) to 58.32 (SD = 11.73), while the intervention group increased from 54.47 (SD = 9.62) to 60.05 (SD = 8.66). Despite these improvements, the average BBT scores in our study remained lower than those reported in normative studies of healthy populations. Mathiowetz et al. (1985) established normative BBT scores for healthy individuals aged 20 to 94, reporting averages of 76.9 (right hand) and 75.4 (left hand) for males, and 78.4 (right hand) and 75.8 (left hand) for females. Similarly, Li et al. (2019) found higher BBT scores among a healthy Taiwanese population aged 15 to 74. In their study, male participants had right-hand scores ranging from 63.27 to 77.40 and left-hand scores from 60.69 to 73.65, while female participants scored between 69.00 and 78.00 (right hand) and 65.40 to 75.43 (left hand). These comparisons suggested that while our intervention was effective in improving manual dexterity, our participants' performance still lagged behind that of the general healthy population.

Bobos et al. (2018) reported that hand dexterity following DRF showed improvement between 3- and 6-months post-injury; however, full recovery to the level of the uninjured hand was not achieved even by 12 months. Additionally, their study highlighted the influence of age and gender on hand dexterity. Specifically, males demonstrated superior dexterity with medium and large objects, whereas females performed better when manipulating small objects (Bobos et al. 2017; Bobos et al. 2018). Furthermore, grip strength and wrist ROM were identified as key determinants of hand dexterity (Bobos et al. 2018). However, they also suggested that other contributing factors that might have influenced dexterity include pain, motor control, edema, and psychological factors.

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5.4 FUNCTIONAL OUTCOME MEASURES FOR WRIST FRACTURES

In this study, the DASH was employed as the primary outcome measure, while secondary measures included the VAS for pain, grip and pinch strength, wrist and finger AROM, PPT, BBT, and the LASER, structured within the ICF framework. The selection of these functional outcomes was aligned with the most commonly utilized measures in DRF research, as identified by Norton et al. (2022). Their review indicated that 9% of studies incorporated six to eight outcome measures, with the combination of DASH, ROM, grip strength, and pain measures appearing in 20% of studies. Moreover, 42% of studies simultaneously used DASH, ROM, and grip strength. The increasing emphasis on combining PROMs with performance-based tests underscores the absence of a single comprehensive tool that adequately captures all relevant ICF domains. Norton et al. (2022) suggested that the combination of ROM, grip strength, and DASH offers optimal coverage across these domains. However, they also noted a gap in evaluating successful return to meaningful occupation. To address this, the inclusion of the LASER in our study provides an important dimension by assessing employment readiness, thereby enriching the assessment of functional recovery.

5.5 WORK READINESS OF WORKERS WITH WRIST FRACTURES FOLLOWING 4-WEEK INTERVENTIONS

Our findings revealed that 26 participants (68.4%) progressed to the Action stage, while 6 participants (15.8%) remained in both the Precontemplation and Contemplation stages, respectively. According to Lam et al. (2010), individuals in the Action stage tend to have the most favorable employment outcomes, whereas those in the Precontemplation stage experience the poorest outcomes, with the Contemplation stage falling in between. This supports the value of stage-matched interventions, which can enhance service efficiency and employment outcomes. The LASER tool may aid in tailoring interventions by identifying employment readiness stages.

In parallel, Roesler et al. (2013) identified several key prognostic factors contributing to delayed recovery and return-to-work among individuals with acute occupational hand injuries. This included injury severity, locus of control, household size, and negative affect. Significantly, individuals with an external locus of control

were over five times more likely to experience delayed recovery. These findings highlight the critical role of both biological and psychosocial variables in rehabilitation, reinforcing the need for a biopsychosocial approach to managing recovery from traumatic hand injuries

5.6 IMPLICATION OF HAL-SJ FOR OCCUPATIONAL THERAPY PRACTICE

The integration of robotic technologies such as the HAL-SJ represents a significant advancement in the rehabilitation landscape, particularly for individuals recovering from wrist fractures. This study explored the utility, therapeutic outcomes, and clinical implications of HAL-SJ in OT practice, aiming to bridge the gap between traditional rehabilitative techniques and robotic-assisted modalities.

One of the key findings from this investigation is that HAL-SJ promotes active-assisted movement through bioelectrical signal feedback, facilitating voluntary motion and improving neuromuscular coordination. In patients with wrist fractures, especially those with limited AROM or early-stage post-immobilization stiffness, HAL-SJ offers a unique opportunity to engage in goal-oriented, repetitive movements that can accelerate recovery while reducing compensatory motor patterns.

The interactive nature of HAL-SJ, which responds to the patient's own intention to move, contributes to increased motivation and participation which is essential for recovery in OT contexts where client-centeredness and active engagement are core principles.

The combination of voluntary effort and robotic assistance may stimulate cortical reorganization and sensorimotor learning, essential in the post-fracture rehabilitation phase. HAL-SJ thus aligns with current neurorehabilitation theories that emphasize active use-dependent plasticity.

Traditional wrist rehabilitation involves hands-on facilitation by the therapist, which can be labour-intensive and time-consuming. HAL-SJ reduces the physical demand on therapists while still delivering high-intensity, repetitive movement training. This shift can lead to increased efficiency and scalability in clinical settings.

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In summary, the use of the HAL-SJ in OT for wrist fracture rehabilitation offers promising enhancements in patient outcomes, therapist efficiency, and technological integration into clinical care. However, its practical adoption requires systematic training, institutional support, and continued evaluation of cost-benefit ratios. With ongoing innovation and empirical validation, robotic assistive technologies like HAL-SJ are likely to become a complementary standard in the therapeutic arsenal of occupational therapists, particularly in complex or prolonged recovery cases.

5.7 LIMITATIONS

Although all the outcome measures utilized in this study were in accordance with the recommendations set forth by the International Consortium for Health Outcomes Measurement (ICHOM) Standard Set for Hand and Wrist Conditions, a key limitation lies in the deviation from the recommended follow-up time points. Specifically, the ICHOM standard advised outcome measurement at baseline, 3 months, and 6 months, to adequately capture both short-term recovery and long-term functional outcomes (Wouters at al. 2021). However, in this study, the reassessment was conducted at an earlier interval of 4 weeks post-baseline, due to the guarantee letter referral period and each participant's medical leave duration. This shortened follow-up period may limit the ability to observe sustained changes or longer-term functional improvements. As a result, the findings may primarily reflect early outcomes rather than providing a complete picture of recovery or return-to-function over time. Future studies should consider aligning more closely with the ICHOM-recommended time points to enhance comparability, longitudinal understanding, and clinical relevance.

Another limitation of this RCT is the imbalance in treatment design between the control and intervention groups. The control group received only conventional therapy, whereas the intervention group received a combination of conventional therapy and the HAL-SJ robotic therapy. This difference in treatment intensity may confound the outcomes, making it difficult to attribute improvements solely to the HAL-SJ robotic therapy.

This study did not assess psychological factors such as anxiety, depression, or illness behavior, all of which are known to impact functional outcomes following wrist

fractures. Previous studies have highlighted the significant influence of psychological variables on subjective measures like pain intensity and grip strength, which could contribute to variability in DASH or QuickDASH scores (Ross et al., 2015; Goudie et al. 2022; Schmidt et al. 2024; Souer et al. 2007). The exclusion of these factors may limit the understanding of patient-reported disability and recovery.

Hand dominance was not considered in this study, despite evidence suggesting that injuries to the dominant hand are typically linked to greater functional impairment and higher disability scores. The absence of hand dominance control or stratification may have introduced bias in the interpretation of functional outcomes, especially in tasks requiring fine motor skills and strength.

Although gender has been consistently shown to influence recovery outcomes, with female patients often reporting higher disability scores. This study did not stratify or adjust for gender in its analysis. Consequently, potential differences in pain perception, recovery trajectories, and functional performance between male and female participants were not examined, which may limit the generalizability of the results.

Furthermore, one of the primary limitations of this study lies in the exclusive use of the LASER as the sole instrument to evaluate employment readiness. While LASER provides a structured framework for understanding the psychological stages of readiness to return to work, it does not encompass the full spectrum of domains that are critical to a comprehensive assessment of return to work outcomes. Specifically, the study did not incorporate other well-established instruments such as the DASH Work Module, the Work Role Functioning Questionnaire (WRFQ), and the Work Rehabilitation Questionnaire (WORQ) (Wouters et al. 2021). These tools capture additional dimensions that LASER does not assess, including physical function and its impact on job performance (DASH), the worker's ability to meet job demands in the context of their health condition (WRFQ), and environmental and contextual factors affecting work participation (WORQ). By omitting this broader return to work measures, the study potentially overlooks important aspects such as physical limitations, cognitive functioning, work environment challenges, and social support systems that could significantly influence employment outcomes.

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5.8 FUTURE WORKS

Future research should aim to investigate the isolated effectiveness of HAL-SJ robotic therapy by incorporating a more balanced treatment intensity between control and intervention groups. Additionally, assessing intermediate and long-term outcomes in alignment with ICHOM-recommended time points. specifically at baseline, 3 months, and 6 months would enhance the longitudinal validity of findings. Moreover, a more comprehensive approach that incorporates biopsychosocial factors, including demographic, physical, and psychological variables, is also recommended to provide a deeper understanding of recovery trajectories and treatment effects of the wrist fracture population.

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CHAPTER VI

CONCLUSION

This RCT aimed to evaluate the effectiveness of HAL-SJ robotic therapy in enhancing functional outcomes, physical performance, and work readiness among workers recovering from wrist fractures over a four-week intervention period. The findings indicated that both the control and intervention groups demonstrated significant improvements in functional measures following the intervention. However, no statistically significant differences were observed between the groups in terms of functional level, physical performance, or work readiness. This study represents an initial step in integrating HAL-SJ robotic therapy into rehabilitation protocols for wrist fractures, demonstrating the device's safety and utility as a complementary therapeutic modality. Further research is warranted to explore the efficacy of robotic therapy in hand and upper extremity trauma, with the aim of advancing evidence-based practices in hand therapy and OT.

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APPENDIX A

UKM RESEARCH ETHICS COMMITTEE ETHICAL APPROVAL

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The National University of Malaysia

SEKRETARIAT ETIKA PENYELIDIKAN UKM • *UKM RESEARCH ETHICS COMMITTEE*

Ref: UKM PPI/111/8/JEP-2021-201
Date: 02 July 2024

Dr. Chai Siaw Chui
Occupational Therapy Program
Centre for Rehabilitation and Special Needs Studies (iCaReHab)
Faculty of Health Sciences
The National University of Malaysia

ETHICAL APPROVAL OF RENEWAL RESEARCH PERIOD

Research Title : The Effectiveness Of Single Joint Hybrid Assistive Limb (HAL-SJ) Robotic Exoskeleton In Improving Functional Outcomes Among Workers With Wrist Fractures: A Randomized Controlled Trial

Ethics Ref. No. : JEP-2021-201

With reference to the above.

2. The Research Ethics Committee, The National University of Malaysia has approved your application for the renewal of the research period as titled above in the Research Ethics Committee Meeting No. 13/2024 dated 27 June 2024 as below:

Ethics Ref. No.	Approval Period	Renewal Period
JEP-2021-201	21 June 2021- 20 June 2024	21 June 2024- 20 June 2025

3. Please submit any Adverse Events Report, Progress Report every 6 months and Final Report upon completion of the research to the Research Ethics Committee. The minute of meeting no. 13/2024 dated 27 June 2024 is attached for your reference.

Thank you.

Yours sincerely,

PROFESSOR DR MOHD SHAHRIR MOHAMED SAID
Chairman
Research Ethics Committee
The National University of Malaysia

c.c. - **Deputy Dean (Research & Inovation)**
Faculty of Health Sciences
The National University of Malaysia

Sekretariat Etika Penyelidikan Universiti Kebangsaan Malaysia
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ILMU, MUTU DAN BUDI www.ukm.my

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to be continued…

Continuation…

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SEKRETARIAT ETIKA PENYELIDIKAN UKM • *UKM RESEARCH ETHICS COMMITTEE*

- **Head of Occupational Therapy Program**
  Faculty of Health Sciences
  The National University of Malaysia

- **Professor Dr. Yoshiyuki Sankai**
  Centre of Cybernics Research,
  Faculty of Engineering, Information and Systems,
  University of Tsukuba,
  Japan.

- **Dr. Masahiro Shingu**
  CYBERDYNE Inc. Ibaraki,
  Japan.

- **Dr. Hafez Bin Hussain**
  SOCSO Tun Razak Rehabilitation Centre

- **Dr. Nor Afifi Binti Razaob @Razab**
  Centre for Rehabilitation and Special Needs Studies (iCaReHab)
  Faculty of Health Sciences
  The National University of Malaysia

- **Tan Eng Wah (P101608)**
  Occupational Therapy Program
  Faculty of Health Sciences
  The National University of Malaysia

- Approval letter File 2021

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Sekretariat Etika Penyelidikan Universiti Kebangsaan Malaysia
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The National University of Malaysia

MINUTES OF MEETING
RESEARCH ETHICS COMMITTEE
THE NATIONAL UNIVERSITY OF MALAYSIA
NO. 13/2024

Date	:	27 June 2024 (Thursday)
Time	:	2.15 p.m
Application	:	Zoom Cloud Meeting

8. **Presentation list changes / Amendment after approval**

8.2 Endorsement for renewal of the approval from 13 June – 26 June 2024.

8.2.1 The renewal lists were approved.

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APPENDIX B

PERKESO REHABILITATION CENTRE SCIENTIFIC COMMITTEE APPROVAL

PUSAT REHABILITASI PERKESO SDN BHD. (1223453-X)
PERTUBUHAN KESELAMATAN SOSIAL
(Social Security Organization)
Lot PT7263 [JLS (D) 1892/3]
Hang Tuah Jaya, Bandar Hijau,
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Rujukan Tuan :
Rujukan Kami : PRPTAR.600-5/(48)
Tarikh : 18th November 2020

Mr. Tan Eng Wah
Faculty of Health Sciences,
Universiti Kebangsaan Malaysia (UKM),
43600 Bangi, Selangor.

Dear Sir,

STATUS OF APPROVAL OF RESEARCH PROPOSAL: THE EFFECTIVENESS OF SINGLE JOINT HYBRID ASSISTIVE LIMB (HAL-SJ) ROBOTIC EXOSKELETON IN IMPROVING FUNCTIONAL OUTCOMES AMONG WORKERS WITH WRIST FRACTURES: A RANDOMIZED CONTROLLED TRIAL IN SOCSO TUN RAZAK REHABILITATION CENTRE.

I would like to refer to the above mentioned matter.

Research Title : The Effectiveness Of Single Joint Hybrid Assistive Limb (HAL-SJ) Robotic Exoskeleton In Improving Functional Outcomes Among Workers With Wrist Fractures: A Randomized Controlled Trial

Researcher : Mr. Tan Eng Wah

2. I am pleased to inform you that the Research Committee, Research and Development Department, SOCSO Rehabilitation Centre had approved in principle, the study research of the above project.

3. With respect to the research proposal, the researcher is allowed to conduct the data collection and intervention procedures on the targeted subjects, who are the SOCSO insured persons, without any financial obligation.

4. The timeline of the study is as per the Gantt-Chart attached with the proposal.

Thank you

"Look at the Ability, Not the Disability"

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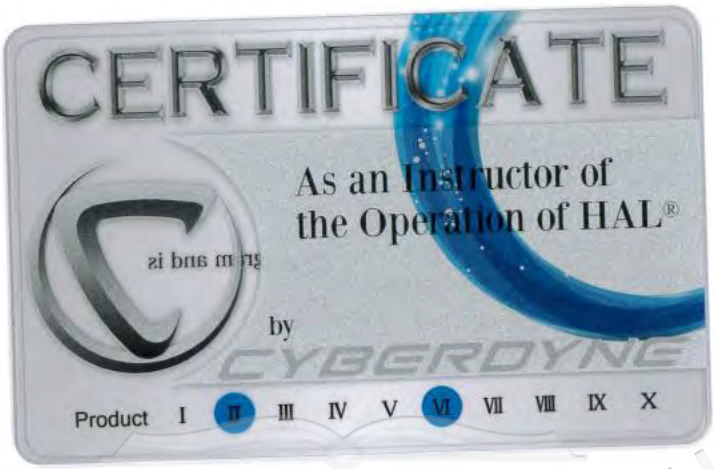
APPENDIX C

CYBERDYNE HYBRID ASSISTIVE LIMB (HAL®) OPERATOR AND INSTRUCTOR CERTIFICATION



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APPENDIX D1

PATIENT INFORMATION SHEET

Research title:
The Effectiveness of Single Joint Hybrid Assistive Limb (HAL-SJ) Robotic Exoskeleton in Improving Functional Outcomes among Workers with Wrist Fractures: A Randomized Controlled Trial

Introduction
You are invited to participate in this research study because you have sustained a wrist fracture that had limited your performance in daily and work activities. Wrist fracture cases can take up to few months and one or two years to achieve maximal functional improvement. The residual disability or pain, along with the long functional recovery period following wrist fracture may impact the socioeconomics of a person, family, and society significantly. Thus, a new intervention with the robotic exoskeleton will be implemented along with the standard hand therapy program to optimize the functional recovery process.

The details of the study will be described in this document. It is important for you to fully understand the purpose of this study and what it will involve. Kindly read through this information thoroughly for your consideration and decision to participate in this study. Ask the researcher if there is anything that is unclear or if you would like more information or clarification. Take time to decide whether or not you wish to take part.

Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the consent form and this Information Sheet. If you do not agree to participate, you do not need to give any reason and nothing will be affected. If you decided to participate, you can still withdraw from the study at any time without any penalty. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled. The researcher may also remove you from the study for a variety of reason.

Purpose of study
The purpose of this study is to evaluate the effectiveness of single joint hybrid assistive limb (HAL-SJ) robotic exoskeleton in improving the functional outcomes among workers with wrist fractures. The application of robotic technology in facilitating upper limb movement and functional recovery training is extensive in the field of neurorehabilitation but limited in the field of orthopaedic rehabilitation particularly in hand therapy practice.
Robotic interventions had been proved to provide motor control/learning, practice-

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induced neuroplasticity, intensity, and task specific training for greater functional recovery. The upper limb HAL-SJ is a wearable movement support robot that detects bioelectrical signals on the skin surface and assists joint movements by controlling and operating an actuator placed outside the respective joint based on the frontier science "Cybernics". Currently, there are vast of studies on the clinical applications of robotic interventions for the neurological population. However, the use of robotic interventions in orthopaedic rehabilitation especially for the wrist and hand remains inadequately explored. Therefore, this study aims to determine the effectiveness of robotic interventions in improving the functions as well as the recovery period following wrist fracture.

A total of 38 participants who sustained wrist fractures as similar to you will be recruited to participate in this study. Your participation in this study will only last for 4 weeks while the whole study will be implemented for 30 months.

What will the study involve?

If you agree to participate in the study, you will be asked to complete a series of questionnaires and complete a few measurements. You will then be randomly assigned to one of the treatment groups below by drawing from concealed envelopes. You have equal chance of being assigned to each of the groups.

Group 1:

a) Participants will undergo receive two conventional therapy sessions daily that include an occupational therapy session and a physiotherapy session on a 5-day/week routine basis.

Group 2:

a) Participants will undergo two conventional therapy sessions daily that include an occupational therapy session and a physiotherapy session on a 5-day/week routine basis.
b) Within two hours after the conventional therapy sessions, participants will be receiving the HAL-SJ robotic therapy session conducted by the researcher at a separate treatment room on a 5-day/week routine basis.

Regardless of your group allocation, you will need to complete the following questionnaires and measurements administered by the therapist at the beginning of the hand therapy treatment (pre-intervention/initial assessment) and after 4 weeks of hand therapy treatment (post-intervention):

a) Functional performance by using Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure
b) Work readiness by using LAM Assessment on Stages of Employment Readiness (LASER) Questionnaire
c) Pain level by using Visual Analogue Scale (VAS)

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d) Physical performance of Active Range of Motion (AROM) of the hand and wrist by using goniometer
e) Physical performance of grip and pinch strength by using Jamar Dynamometer and B&L Engineering Pinch Gauge respectively
f) Physical performance of fine dexterity by using Purdue Pegboard test (PPT)
g) Physical performance of gross dexterity by using Box and Block Test (BBT)

Post-intervention outcome measurements will be performed after the 20th therapy session, i.e., upon the completion of the 4-weeks program.

It is important that you answer all of the questions asked by the therapist honestly and completely. You must inform the therapist if your condition or circumstances change during the study or if you make any changes to any of your current treatments.

After the trial, you will continue receiving the necessary therapy sessions as usual. Whether you complete the study or withdraw early, the best alternatives for your future treatment will be discussed with the treating team.

Risks and benefits:
Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton is certified by ISO 13485:2016 (certificate number: 1757.181211) and EC (registration number: DD 601417310001) for rehabilitation and physical therapy usage.

The potential risks of participating in the Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton session may include:
a) Skin allergy or reddening of area where electrode is affixed. The reddening will disappear shortly after the electrode was taken off.
b) Abrasion of areas that contact the device e.g. cuffs and straps
c) Muscle and joint soreness (due to post exercise effect)

The researcher of this study will take necessary precaution and careful supervision thoughout the entire Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton session to minimise these potential risks. You are advised to communicate and inform the researcher immediately if you have any concern of the above risks.

By participating in this study, you will understand the performance of your physical and psychological functions before and after the therapy program. If you are being allocated to the intervention group that receives an extra Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton session, your performance of physical and psychological functions will facilitate our understanding regarding the therapeutic

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effects of Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton in wrist fracture rehabilitation.

Do you have to take part?

Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the consent form and this Information Sheet. Throughout your participation, you may also refuse to answer any questions that you do not want to answer. If you are not agree to participate, you do not need to give any reason and nothing will be affected. If you decided to participate, you can still withdraw from the study at any time without any penalty. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

Data and confidentiality

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. The data from this study will be made into a report which may be published. Once the data have been gathered and the research completed, the raw materials will be kept in the locked file cabinet in the office of the researcher. Electronic data will be securely kept using password. Access to the data is only by the researcher. After 5 years, the material will be shredded and discarded. The data will be reported in a collective manner with no reference to an individual.

Payment and compensation

This study is self-funded by the researcher himself. No external funding or grant is received. Therefore, no payment will be given to you for participating in this study. If you are allocated into Group 2 (intervention group), you will not be charged for the additional Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton sessions received.

Can this study or my participation be terminated early?

The researcher may stop the study or your participation at any time due to the concerns of your safety. If the study is stopped early for any reason, you will be informed and arrangements will be made for your future care. You will have the opportunity to see your own measurement results upon completion of this study.

Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the researcher, Mr. Tan Eng Wah at telephone number 012-6358531.

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APPENDIX D2

RISALAH MAKLUMAT PESAKIT (BAHASA MELAYU)

Tajuk Kajian:
Keberkesanan Eksoskeletal Robotik *Single Joint Hybrid Assistive Limb (HAL-SJ)* dalam Meningkatkan Kefungsian di Kalangan Pekerja yang Mengalami Kepatahan Tulang Pergelangan Tangan: Percubaan Kawalan Rawak

Pengenalan
Anda telah dijemput untuk menyertai dalam kajian penyelidikan ini kerana anda telah mengalami kepatahan tulang pergelangan tangan yang mengehadkan tahap prestasi anda dalam aktitivi-aktiviti harian dan kerja. Kes-kes kepatahan tulang pergelangan tangan mengambil tempoh masa dalam beberapa bulan sehingga satu atau dua tahun untuk mencapai perkembangan kefungsian yang maksima. Kekurangan keupayaan dan kesakitan di samping tempoh masa penyembuhan yang panjang akibat daripada kepatahan tulang pergelangan tangan boleh memberikan impak yang ketara terhadap tahap sosioekonomi individu, keluarga dan masyarakat. Maka, suatu intervensi baru dengan eksoskeletal robotik akan digunakan dalam program terapi tangan untuk mengoptimumkan proses pemulihan tahap kefungsian.

Maklumat tentang kajian ini akan dinyatakan dalam dokumen kini. Adalah penting untuk anda memahami secara sepenuhnya tentang tujuan dan perkara yang terlibat dalam kajian ini. Sila membaca secara menyeluruh dan mempertimbangkan dengan teliti penerangan yang diberi sebelum anda bersetuju untuk menyertai penyelidikan ini. Jika terdapat sebarang kemusykilan ataupun maklumat lanjut yang anda ingin tahu, anda boleh bertanya kepada terapis yang terlibat dalam penyelidikan ini. Sila mengambil masa yang secukupnya untuk membuat keputusan sama ada anda ingin menyertai dalam kajian penyelidikan ini.

Penyertaan dalam penyelidikan ini adalah secara sukarala. Sekiranya anda bersetuju untuk menyertai dalam penyelidikan ini, anda akan dikehendaki untuk menandatangani Borang Persetujuan atau Keizinan Peserta pada muka surat akhir risalah ini. Sekiranya anda tidak bersetuju untuk menyertai dalam penyelidikan ini, anda tidak perlu memberikan sebarang sebab dan perkara ini tidak akan memberikan sebarang kesan pada anda. Jikalau anda berkeputusan untuk menyertai dalam penyelidikan ini, anda berhak untuk menarik diri pada bila-bila masa tanpa dikenakan sebarang hukuman. Penolakan atau penarikan diri daripada penyelidikan ini tidak akan menjejaskan sebarang faedah perubatan atau kesihatan yang tertakluk kepada hak anda. Penyelidik kajian juga berhak untuk mengecualikan anda daripada penyelidikan ini atas pelbagai sebab.

Tujuan Kajian

Tujuan penyelidikan ini adalah untuk menilai keberkesanan eksoskeletal robotik of *Single Joint Hybrid Assistive Limb (HAL-SJ)* dalam meningkatan kefungsian di kalangan pekerja yang mengalami kepatahan pergalangan tangan. Terdapat banyak aplikasi teknologi robotik digunakan untuk membantu pergerakan anggota atas dan latihan pemulihan kefungsian adalah dalam bidang rehabilitasi neurologi. Namun, aplikasi tersebut adalah amat terhad dalam bidang rehabilitasi ortopedik terutamanya terapi tangan. Intervensi robotik adalah terbukti untuk meningkatkan pemulihan kefungsian melalui pengawalan/pembelajaran motor, neuroplastisiti, intensity dan latihan aktiviti khusus. HAL-SJ anggota atas merupakan sejenis robot yang dapat dipakai untuk menyokong pergerakan. HAL-SJ anggota atas dapat mengesan isyarat bioelektrik pada permukaan kulit dan membantu pergerakan sendi melalui kawalan dan operasi unit penggerak berdasarkan bidang sains yang dikenali sebagai "*Cybernics*". Kini, terdapat banyak kajian terhadap aplikasi klinikal intervensi robotik bagi populasi neurologi. Namun, kajian berkaitan penggunaan intervensi robotik dalam bidang rehabilitasi ortopedik terutamanya bagi bahagian tangan dan pergelangan tangan adalah masih berkurangan. Justeru itu, penyelidikan ini bertujuan untuk menentukan keberkesanan intervensi robotik dalam meningkatkan tahap kefungsian dan tempoh pemulihan berikutan kepatahan pergelangan tangan.

Sebanyak 38 orang peserta yang mengalami kepatahan tulang pergelangan seperti anda akan dijemput untuk mengambil bahagian dalam penyelidikan ini. Penyertaan anda dalam penyelidikan ini hanya akan berlangsung selama 4 minggu sementara keseluruhan kajian penyelidikan ini akan dijalankan selama 30 bulan.

Apakah yang akan terlibat dalam kajian ini?

Sekiranya anda bersetuju untuk menyertai penyelidikan ini, anda akan diminta untuk melengkapkan suatu siri borang kaji selidik dan menyempurnakan beberapa penilaian klinikal. Selepas itu, anda akan diperuntukkan ke dalam salah satu daripada dua kumpulan rawatan secara rawak dengan kaedah cabutan daripada sampul yang tertutup. Anda mempunyai peluang yang sama rata untuk diperuntukkan ke dalam salah satu kumpulan tersebut.

Kumpulan 1:

a) Peserta akan menjalani dua sesi terapi konvensional setiap hari, iaitu satu sesi terapi carakerja dan satu sesi fisioterapi mengikut jadual lima hari dalam semingu.

Kumpulan 2:

a) Peserta akan menjalani dua sesi terapi konvensional setiap hari, iaitu satu sesi terapi carakerja dan satu sesi fisioterapi mengikut jadual lima hari dalam semingu.

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b) Dalam masa dua jam selepas sesi terapi konvensional, peserta akan menerima sesi terapi robotik HAL-SJ yang akan dikendalikan oleh penyelidik di bilik rawatan yang berasingan mengikut jadual lima hari seminggu.

Tanpa mengira kumpulan anda, anda akan dikehendaki untuk menyempurnakan borang kaji selidik dan penilaian klinikal berikut yang akan dikendalikan oleh terapis anda pada sesi permulaan untuk rawatan terapi tangan (pra-intervensi/ penilaian awal) dan selepas 4 minggu rawatan terapi tangan (pasca-intervensi):

1) Prestasi tahap kefungsian dengan menggunakan borang kaji selidik *Disabilities of the Arm, Shoulder and Hand (DASH)*
2) Tahap kesediaan bekerja dengan menggunakan borang kaji selidik *LAM Assessment on Stages of Employment Readiness (LASER)*
3) Tahap kesakitan dengan menggunakan *Visual Analogue Scale (VAS)*
4) Prestasi fizikal julat pergerakan aktif sendi tangan dan pergelangan tangan dengan menggunakan *goniometer*
5) Prestasi fizikal kekuatan genggaman dan picitan tangan dengan menggunakan *Jamar Dynamometer* dan *B&L Engineering Pinch Gauge*
6) Prestasi fizikal ketangkasan halus tangan dengan menggunakan *Purdue Pegboard Test (PPT)*
7) Prestasi fizikal ketangkasan kasar tangan dengan menggunakan *Box and Block Tes*t (BBT)

Penilaian hasil pasca-intervensi akan dilakukan selepas sesi terapi yang kedua puluh, iaitu selepas penyempurnaan program selama 4 minggu.

Adalah penting bahawa anda menjawab semua soalan yang ditanya oleh terapis secara jujur dan menyeluruh. Anda dikehendaki untuk memaklum kepada terapis anda sekiranya kondisi atau keadaan anda berubah dalam tempoh masa penyelidikan atau anda membuat sebarang perubahan kepada rawatan yang sedia ada.

Selepas tempoh penyelidikan, anda akan meneruskan sesi terapi yang diperlukan seperti biasa. Perancangan rawatan akan dibincangkan bersama pasukan rawatan anda selepas anda menyempurnakan penyelidikan berkenaan mahupun menarik diri daripadanya.

Risiko dan Faedah

Eksoskeletal robotik *Single Joint Hybrid Assistive Limb (HAL-SJ)* telah disahkan oleh ISO 13485:2016 (nombor persijilan: 1757.181211) dan EC (nombor pendaftaran: DD 601417310001) untuk digunakan bagi tujuan rehabilitasi dan terapi fizikal.

Risiko yang berpotensi berlaku semasa penyertaan sesi terapi eksoskeletal *robotik Single Joint Hybrid Assistive Limb (HAL-SJ)* berkemungkinan melibatkan:

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a) Alahan kulit atau kemerahan pada bahagian yang dilekatkan dengan elektrod. Kemerahan berkenaan akan menghilang dalam masa yang singkat selepas elektrod ditanggalkan.

b) Lelasan pada bahagian yang mempunyai kontak dengan peralatan berkenaan iaitu *cuff* dan tali pemasangan

c) Rasa sengal pada otot atau sendi (kesan akibat senaman)

Penyelidik dalam kajian penyelidikan ini akan mengambil langkah-langkah pencegahan dan pengawasan yang berpatutan sepanjang sesi terapi eksoskeletal robotik *Single Joint Hybrid Assistive Limb (HAL-SJ)* untuk mengurangkan sebarang risiko yang berpotensi berlaku. Anda adalah dinasihati untuk berkomunikasi dan memberitahu penyelidik secara serta merta sekiranya anda mempunyai sebarang kebimbangan tentang risiko berkenaan.

Dengan menyertai penyelidikan ini, anda akan memahami prestasi kefungsian fizikal dan psikologi anda sebelum dan selepas program terapi. Sekiranya anda diperuntukkan kepada kumpulan intervensi yang menerima sesi terapi eksoskeletal robotik *Single Joint Hybrid Assistive Limb (HAL-SJ)* tambahan, prestasi kefungsian fizikal dan psikologi anda akan memudahkan pemahaman kami mengenai kesan terapeutik eksoskeletal robotik *Single Joint Hybrid Assistive Limb (HAL-SJ)* atas pemulihan pergelangan tangan.

Adakah anda perlu menyertai?

Penyertaan dalam kajian ini adalah secara sukarela. Sekiranya anda telah bersetuju untuk mengambil bahagian dalam kajian ini, anda akan dikehendaki untuk menandatangani Borang Persetujuan atau Keizinan Peserta. Anda akan diberi satu salinan Borang Persetujuan atau Keizinan Peserta dan Helaian Maklumat ini. Sepanjang tempoh penyertaan penyelidikan, anda boleh menolak sebarang persoalan yang anda tidak ingin untuk menjawab. Setelah anda bersetuju untuk menyertai penyelidikan ini, anda masih boleh menarik diri pada bila-bila masa sahaja. Sekiranya anda menarik diri, sebarang data yang dikumpul daripada anda masih akan digunakan dalam penyelidikan ini. Penolakan atau penarikan diri daripada penyertaan penyelidikan ini tidak akan menjejaskan sebarang faedah perubatan atau kesihatan yang tertakluk kepada hak anda.

Data dan kerahsiaan

Segala maklumat anda yang diperolehi dalam penyelidikan ini akan disimpan dan dikendalikan secara sulit berdasarkan peraturan-peraturan dan/ atau undang-undang yang berkenaan. Data kajian ini akan digunakan untuk penghasilan laporan yang mungkin akan diterbitkan. Setelah semua data telah dikumpulkan dan penyelidikan diselesaikan, dokumen tersebut akan disimpan di dalam kabinet fail yang berkunci di pejabat penyelidik. Data akan disimpan di dalam komputer yang dikawal dengan menggunakan kata laluan. Akses kepada data hanya boleh dilakukan oleh penyelidik.

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Selepas 5 tahun, dokumen tersebut akan dirincih dan dibuang. Data yang berkenaan akan dilaporkan secara kolektif tanpa merujuk kepada individu.

Pembayaran dan pampasan

Pembiayaan penyelidikan ini adalah ditanggung sendiri oleh penyelidik. Tiada pembiayaan luar atau geran yang diterima. Oleh itu, tiada bayaran yang akan diberi kepada anda untuk penyertaan anda dalam penyelidikan ini. Jika anda diperuntukkan ke dalam kumpulan 2 (kumpulan intevensi), anda juga tidak akan dikenakan caj bayaran bagi sesi terapi eksoskeletal robotik *Single Joint Hybrid Assistive Limb (HAL-SJ)* yang diterima.

Bolehkah penyelidikan ataupun penyertaan saya ditamatkan lebih awal daripada yang dirancang?

Penyelidik boleh menamatkan penyelidikan ini ataupun menamatkan penyertaan anda dalam penyelidikan ini pada bila-bila masa, jika perkara ini diperlukan demi keselamatan anda. Sekiranya penyelidikan ini dihentikan lebih awal atas sebab-sebab tertentu, anda akan dimaklumkan dan rawatan yang bakal anda terima selepas itu akan diuruskan. Anda juga akan diberi peluang untuk melihat keputusan penilaian anda pada rawatan susulan yang terakhir setelah tamat penyelidikan ini.

Siapakah yang perlu saya hubungi sekiranya saya mempunyai sebarang pertanyaan?

Anda boleh menghubungi penyelidik, En. Tan Eng Wah pada sambungan telefon 012-6358531 sekiranya anda mempunyai sebarang pertanyaan mengenai penyelidikan ini.

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APPENDIX D3

PATIENT INFORMED CONSENT FORM (ENGLISH)

Title of Study: The Effectiveness of Single Joint Hybrid Assistive Limb (HAL-SJ) Robotic Exoskeleton in Improving Functional Outcomes among Workers with Wrist Fractures: A Randomized Controlled Trial

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can withdraw from the study at any time without giving a reason and this will not affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the researcher instructions related to my participation in the study.
- All personal details will be treated as CONFIDENTIAL.
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness:

Signature: I/C number:

Name: Date:

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APPENDIX D4

BORANG PERSETUJUAN PESAKIT (MALAY)

Tajuk Penyelidikan: Keberkesanan Eksoskeletal Robotik Single Joint Hybrid Assistive Limb (HAL-SJ) dalam Meningkatkan Kefungsian di Kalangan Pekerja yang Mengalami Kepatahan Tulang Pergelangan Tangan: Percubaan Kawalan Rawak

Dengan menandatangani di bawah, saya mengesahkan bahawa:

- Saya telah diberi maklumat tentang penyelidikan di atas secara lisan dan bertulis and saya telah membaca dan memahami segala maklumat yang diberikan dalam risalah ini.
- Saya telah diberikan masa yang secukupnya untuk mempertimbangkan penyertaan saya dalam penyelidikan ini dan telah diberi peluang untuk bertanyakan soalan dan semua persoalan saya telah dijawab dengan sempurna dan memuaskan.
- Saya juga faham bahawa penyertaan saya adalah secara sukarela dan pada bila-bila masa saya bebas menarik diri daripada penyelidikan ini tanpa harus memberi sebarang alasan dan ianya sama sekali tidak akan menjejaskan rawatan perubatan saya pada masa yang akan datang. Saya tidak mengambil bahagian dalam mana-mana penyelidikan lain pada masa ini. Saya juga memahami tentang risiko dan manfaat penyelidikan ini dan saya secara sukarela memberi persetujuan untuk menyertai penyelidikan ini di bawah syarat-syarat yang telah dinyatakan di atas. Saya faham bahawa saya harus mematuhi nasihat dan arahan daripada penyelidik berkaitan dengan penyertaan saya dalam penyelidikan ini.
- Saya faham bahawa segala maklumat dan data peribadi akan dianggap sebagai SULIT.
- Saya akan menerima satu salinan 'Risalah Maklumat Peserta dan Borang Persetujuan atau Keizinan Peserta' yang telah lengkap dengan tarikh dan tandatangan untuk dibawa pulang ke rumah.

Subjek:

Tandatangan: Nombor K/P:

Nama: Tarikh :

Penyelidik yang mengendalikan proses menandatangani borang keizinan:

Tandatangan: Nombor K/P:

Nama: Tarikh :

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Saksi tidak-berpihak/adil:

Tandatangan: Nombor K/P:

Nama: Tarikh :

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APPENDIX E

SOCIODEMOGRAPHIC QUESTIONNAIRE

ID: _____ Date: _____

Please complete the following questionnaire by providing the answers in the space provided:	
Age	
Gender	Male / Female
Marital Status	Married/ Single/ Divorced
Occupation	
Educational Level	UPSR/ PMR/ SPM/ STPM/ Sijil/ Diploma/ Degree/ Master/ PhD No formal education
Hand Dominance	Right/ Left/ Ambidextrous
Date of Injury	
History of Present Injury	
Mechanism of injury	
Medical/ Surgical Management	Conservative/ Surgery/ Conservative & Surgery
Types of Medical/ Surgical Interventions	
Date of Surgery	
Types of Wrist Fracture	Extra-articular/ Partial Articular/ Complete Articular
Employment Status	Employed/ Unemployed
Salary	
Medical Leave	Yes / No
SOCSO Compensation Scheme	Employment Injury / Invalidity

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APPENDIX F

CLINICAL DATA RECORD SHEET

1) Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure

	Initial Assessment Date:	Reassessment Date:
DASH Score		

2) LAM Assessment on Stages of Employment Readiness (LASER) Questionnaire

	Initial Assessment Date:	Reassessment Date:
LASER Score		

3) Visual Analogue Scale (VAS)

	Initial Assessment Date:	Reassessment Date:
VAS Score		

4) Grip Strength

	Initial Assessment Date:	Reassessment Date:
1st Trial		
2nd Trial		
3rd Trial		
Average		

5) Lateral Pinch Strength

	Initial Assessment Date:	Reassessment Date:
1st Trial		
2nd Trial		
3rd Trial		
Average		

6) Active Range of Motion – Wrist

	Initial Assessment Date:	Reassessment Date:
Extension		
Flexion		
Supination		
Pronation		
Radial Deviation		
Ulnar Deviation		

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7) Active Range of Motion – Hand

		Initial Assessment Date:	Reassessment Date:
Thumb	MCPJ Flexion		
	IPJ Flexion		
Index Finger	MCPJ Flexion		
	PIPJ Flexion		
	DIPJ Flexion		
Middle Finger	MCPJ Flexion		
	PIPJ Flexion		
	DIPJ Flexion		
Ring Finger	MCPJ Flexion		
	PIPJ Flexion		
	DIPJ Flexion		
Little Finger	MCPJ Flexion		
	PIPJ Flexion		
	DIPJ Flexion		

8) Purdue Pegboard Test

Initial Assessment Date:

	1st Trail	2nd Trial	3rd Trial	Average
Right Hand				
Left Hand				
Both Hand				
R + L + B				
Assembly				

Reassessment Date:

	1st Trail	2nd Trial	3rd Trial	Average
Right Hand				
Left Hand				
Both Hand				
R + L + B				
Assembly				

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APPENDIX G1

DISABILITIES OF THE ARM, SHOULDER AND HAND (DASH) OUTCOME MEASURE

DISABILITIES OF THE ARM, SHOULDER AND HAND

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

to be continued…

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continuation…

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = ____ ([(sum of n responses / n) - 1] x 25, where n is the number of completed responses.)

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

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APPENDIX G2

DISABILITIES OF THE ARM, SHOULDER AND HAND (DASH) OUTCOME MEASURE (MALAY VERSION)

TANGAN, BAHU DAN LENGAN KURANG UPAYA

Sila nyatakan kebolehan anda melakukan aktiviti-aktiviti pada minggu lepas dengan membulatkan nombor berdasarkan nombor berdasarkan jawapan yang sesuai.

	Mudah	Kurang mudah	Sederhana susah	Sangat susah	Tidak boleh langsung
1. Membuka penutup balang yang baru atau yang ketat.	1	2	3	4	5
2. Menulis.	1	2	3	4	5
3. Memutar kunci.	1	2	3	4	5
4. Menyediakan makanan.	1	2	3	4	5
5. Menolak pintu yang berat.	1	2	3	4	5
6. Meletakkan barang di atas rak yang lebih tinggi daripada kepala anda.	1	2	3	4	5
7. Melaksanakan kerja-kerja rumah yang berat (cth. Membasuh dinding lantai).	1	2	3	4	5
8. Berkebun.	1	2	3	4	5
9. Mengemas tempat tidur.	1	2	3	4	5
10. Membimbit bakul membeli-belah atau beg bimbit.	1	2	3	4	5
11. Membawa barang berat (melebihi 10 paun/ 4.5 kg).	1	2	3	4	5
12. Mengganti mentol lampu siling.	1	2	3	4	5
13. Mencuci atau mengeringkan rambut anda.	1	2	3	4	5
14. Membasuh belakang tubuh.	1	2	3	4	5
15. Menyarung baju.	1	2	3	4	5
16. Menggunakan pisau untuk memotong makanan.	1	2	3	4	5
17. Aktiviti-aktiviti rekreasi yang memerlukan daya yang rendah (cth. Bermain kad terup, mengait, dll.)	1	2	3	4	5
18. Melakukan aktiviti rekreasi di mana anda terpaksa menggunakan daya atau impak tangan, bahu atau lengan (cth. Bermain golf, bermain, tenis, menukul dll.)	1	2	3	4	5
19. Aktiviti-aktiviti rekreasi yang memerlukan anda menggerakkan lengan secara bebas (bermain piring terbang '*frisbee*', badminton, dll.)	1	2	3	4	5
20. Kemampuan untuk bergerak (bergerak dari satu tempat ke satu tempat).	1	2	3	4	5
21. Aktiviti seksual.	1	2	3	4	5

to be continued…

continuation…

TANGAN, BAHU DAN LENGAN KURANG UPAYA

	Tidak pernah	**Jarang-jarang**	**Kadang-kadang**	**Selalu**	**Sentiasa**
22. Pada minggu lepas, setakat mana masalah tangan, bahu atau lengan anda mengganggu aktiviti sosial harian anda bersama keluarga, kawan-kawan, jiran atau kumpulan? (bulatkan nombor)	1	2	3	4	5
	Tiada halangan	**Sedikit terhalang**	**Sederhana terhalang**	**Sangat terhalang**	**Tidak boleh langsung**
23. Pada minggu lepas, adakah pekerjaan atau aktiviti-aktiviti harian yang lain terhalang disebabkan oleh masalah tangan, bahu atau lengan?(bulatkan nombor)	1	2	3	4	5

Sila nyatakan tahap keterukan simptom-simptom berikut pada minggu lepas. (Bulatkan nombor)

	Tiada	**Sedikit**	**Sederhana**	**Teruk**	**Sangat teruk**
24. Sakit tangan, bahu atau lengan. (semasa berehat)	1	2	3	4	5
25. Sakit tangan, bahu atau lengan apabila melakukan aktiviti-aktiviti tertentu.	1	2	3	4	5
26. Sesemut (menyucuk-nyucuk) pada tangan, bahu atau lengan.	1	2	3	4	5
27. Rasa lemah pada tangan, bahu atau lengan.	1	2	3	4	5
28. Rasa kaku pada tangan, bahu atau lengan.	1	2	3	4	5
	Mudah	**Kurang mudah**	**Sederhana susah**	**Sangat susah**	**Terlalu sukar sehingga saya tidak dapat tidur**
29. Pada minggu lepas, nyatakan kesukaran anda untuk tidur akibat kesakitan pada tangan, bahu atau lengan?(bulatkan nombor)	1	2	3	4	5
	Sangat tidak setuju	**Tidak setuju**	**Tidak pasti**	**Setuju**	**Sangat setuju**
30. Saya berasa tidak ada kemampuan, tidak yakin, atau tidak berguna disebabkan oleh masalah tangan, bahu atau lengan.	1	2	3	4	5

KURANG UPAYA DASH/ SKOR SIMPTOM = $\left(\left[\frac{\text{jumlah dari nilai yang dipilih}}{\text{soalan dijawab}}\right]-1\right)\times 25$

Skor DASH tidak boleh dikira jika terdapat lebih daripada 3 butiran yang tidak dijawab.

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APPENDIX G3

DISABILITIES OF THE ARM, SHOULDER AND HAND (DASH) OUTCOME MEASURE (CHINESE VERSION)

上肢功能障碍评定量表

请根据过去一个星期您从事如下活动的能力来打分，在下面合适的分数上画圈。

		毫无困难	有点困难	中度困难	非常困难	无法完成
1.	打开一个紧的或新的罐子。	1	2	3	4	5
2.	书写。	1	2	3	4	5
3.	转动钥匙（开锁、发动引擎）。	1	2	3	4	5
4.	准备一顿饭。	1	2	3	4	5
5.	推开一扇沉重的门。	1	2	3	4	5
6.	在高过您头顶的架子上放置物品。	1	2	3	4	5
7.	做繁重的家务活（如：刷墙，擦地板）。	1	2	3	4	5
8.	种植或整理园子。	1	2	3	4	5
9.	铺床。	1	2	3	4	5
10.	提购物袋或公文包。	1	2	3	4	5
11.	提重物（超过4.5千克）。	1	2	3	4	5
12.	换高过头顶的灯泡。	1	2	3	4	5
13.	洗或吹干您的头发。	1	2	3	4	5
14.	洗后背。	1	2	3	4	5
15.	穿套头毛衣。	1	2	3	4	5
16.	用刀子切食物。	1	2	3	4	5
17.	几乎不需要费力就能完成的休闲活动（如：打扑克牌，织毛线等）。	1	2	3	4	5
18.	需要手，手臂或肩膀使用些力量才能完成的休闲活动（如：高尔夫球、使用锤子做活、网球等）。	1	2	3	4	5
19.	需要灵活使用手臂才能完成的休闲活动（如：玩飞盘，打羽毛球等）。	1	2	3	4	5
20.	完成交通需求（从一个地方到另一个地方）。	1	2	3	4	5
21.	性活动。	1	2	3	4	5

to be continued…

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continuation…

上肢功能障碍评定量表

	一点儿也不	轻度	中度	重度	极度
22. 在过去的一星期内，您的手，手臂或肩部对您在与家人，朋友，邻居和组群的正常社交活动中产生了何种程度的影响？（在数字上画圈）	1	2	3	4	5

	毫不受限	轻度受限	中度受限	非常受限	不能完成
23. 在过去的一星期中，您的手，手臂或肩部问题是否限制了您的工作或者日常活动？（在数字上画圈）	1	2	3	4	5

请为过去一个星期里下列症状的严重程度打分。（在数字上画圈）

	无	轻度	中度	重度	极度
24. 手臂，肩部或手疼痛。	1	2	3	4	5
25. 当进行某项特定活动时手臂，肩部或手疼痛。	1	2	3	4	5
26. 手臂，肩部或手的刺痛感（针刺样）。	1	2	3	4	5
27. 手臂，肩部，手无力。	1	2	3	4	5
28. 手臂，肩部，手僵硬。	1	2	3	4	5

	毫无困难	有点困难	中度困难	非常困难	太困难了以致于我无法入睡
29. 在过去的一星期中，由于您手臂，肩部或手疼痛给您带来了何种程度的睡眠困难？（在数字上画圈）	1	2	3	4	5

	强烈不赞同	不赞同	不赞同也不反对	赞同	强烈赞同
30. 由于手臂，肩部，手的问题，我觉得能力很差，很没自信，很没用。（在数字上画圈）	1	2	3	4	5

DASH功能障碍/症状得分=[（n个作答得分的平均分）-1]×25，n代表已答题目的数量
如果有3个以上遗漏项目，DASH分数不予计算。

Chinese (Simplified) translation courtesy of Dr. Le Qi, Hand Surgery, China-Japan Union Hospital of Jilin University, China.

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APPENDIX H1

LAM ASSESSMENT OF STAGES OF EMPLOYMENT READINESS (LASER)

Name: …… Gender: ☐ Male ☐ Female
Date: ……

	This questionnaire is to help us better understanding your needs. Each statement describes how a person might feel when staring a job service program with good will Industries. Please indicate the level of agreement you have with each statement. In case, make your choice in term of how you feel right now, not what you have felt in the past or would like to feel.	Strongly Disagree 1	Disagree 2	Undecided 3	Agree 4	Strongly Agree 5
1	I think I might be ready to look for some kind of job.					
2	I am doing something to get ready to look for a job					
3	It might be worthwhile to work on finding a job					
4	I am not able to work. I do not see why I have to be here.					
5	I am finally doing something about finding a job.					
6	I have been thinking that it might be time for me to find a job.					
7	Getting myself ready to find a job is pretty much a waste of time because I can ‘t work anyway.					
8	I guess being out of work is not good, but there is nothing I can do about it right now.					
9	I know I need to get a job and really think I should work on finding one.					
10	People tell me that I should get a job, but I don’t think so.					
11	Anyone can talk about wanting to find a job, but I am actually doing something about it.					
12	All this talk about work is boring. Why can’t people just leave me alone?					
13	I am actively doing something to find a job					
14	It is a pretty much a waste of time getting ready to find a job because I ready don’t want to work.					

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Lam Assessment of Stages of Employment Readiness (LASER)
Scoring Sheet

Date of Assessment:

PRE CONTEMPLATION STAGE	COMTEMPLATION	ACTION STAGE
4	1	2
7	3	5
8	6	11
10	9	13
12		
14		
Total	Total	Total

Date of Assessment:

PRE CONTEMPLATION STAGE	COMTEMPLATION	ACTION STAGE
4	1	2
7	3	5
8	6	11
10	9	13
12		
14		
Total	Total	Total

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APPENDIX H2

LAM ASSESSMENT OF STAGES OF EMPLOYMENT READINESS (LASER) (MALAY VERSION)

PENILAIAN PERINGKAT KESEDIAAN PEKERJAAN LAM (L.A.S.E.R)

Nama: _____ Jantina: _____

Tarikh: _____

Borang soal selidik ini adalah untuk membantu lebih memahami keperluan klien. Setiap pernyataan menerangkan bagaimana perasaan seseorang itu mungkin apabila memulakan program perkhidmatan pekerjaan dengan industri yang muhibah. Sila nyatakan tahap persetujuan anda dengan setiap kenyataan berikut. Dalam setiap kes, sila buat pilihan anda berdasarkan terma seperti bagaimana perasaan anda sekarang, bukan apa yang anda telah dirasai di masa lalu atau ingin rasai.

	Sangat tidak setuju 1	Tidak setuju 2	Tidak pasti 3	Setuju 4	Sangat Bersetuju 5
1. Saya rasa mungkin saya sudah bersedia untuk mencari beberapa jenis pekerjaan					
2. Saya melakukan sesuatu untuk mendapatkan pekerjaan					
3. Ia mungkin agak berbaloi untuk mencari pekerjaan					
4. Saya tidak mampu bekerja. Saya tidak nampak mengapa saya perlu mencari pekerjaan					
5. Saya akhirnya melakukan sesuatu untuk mendapatkan pekerjaan					
6. Saya telah berfikir bahawa ia mungkin adalah masa yang sesuai bagi saya untuk mencari pekerjaan					
7. Mempersiapkan diri saya untuk mencari pekerjaan adalah sangat membuang masa kerana saya sudah tidak boleh bekerja					
8. Saya rasa tidak mempunyai pekerjaan dalam tempoh yang agak lama adalah tidak bagus, tetapi tiada apa yang boleh saya lakukan sekarang					

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9. Saya tahu saya perlu untuk mendapatkan pekerjaan dan saya fikir patut untuk mencari satu pekerjaan					
10. Orang memberitahu saya bahawa saya perlu mendapatkan pekerjaan, tetapi saya tidak fikir begitu					
11. Sesiapa sahaja boleh bercakap tentang mahu untuk mencari pekerjaan, tetapi saya benar-benar melakukan sesuatu mengenainya					
12. Semua perbincangan ini adalah membosankan. Mengapa orang lain tidak meninggalkan saya sendirian sahaja?					
13. Saya secara aktif melakukan sesuatu untuk mencari pekerjaan					
14. Ia adalah sesuatu yang membuang masa bersedia untuk mencari pekerjaan kerana saya benar-benar tidak mahu bekerja lagi					

PENILAIAN PERINGKAT KESEDIAAN PEKERJAAN LAM (L.A.S.E.R)
(borang pemarkahan)

Tarikh Penilaian:

Peringkat Pra-Jangkaan	**Peringkat Jangkaan**	**Peringkat Tindakan**
4.	1.	2.
7.	3.	5.
8.	6.	11.
10.	9.	13.
12.		
14.		
Jumlah:	Jumlah:	Jumlah

Tarikh Penilaian:

Peringkat Pra-Jangkaan	**Peringkat Jangkaan**	**Peringkat Tindakan**
4.	1.	2.
7.	3.	5.
8.	6.	11.
10.	9.	13.
12.		
14.		
Jumlah:	Jumlah:	Jumlah

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APPENDIX H3

LAM ASSESSMENT OF STAGES OF EMPLOYMENT READINESS (LASER) (CHINESE VERSION)

姓名：_____ 性別：❑男 ❑女 今天日期：_____ 出生日期：_____

	此問卷可幫助我們更了解你的需要。每句句子描述了一個人開始求職服務計劃時的感覺。請在適當的方格用剔號（✓）指出你對每句句子的同意程度。請依照你現在的感覺去決定您/你的選擇，而非您/你過去或將來的感覺。	☹ 非常不同意	☹ 不同意	😐 不確定	☺ 同意	☺ 非常同意
1.	我覺得我已經準備好去搵一份工作。					
2.	我正開始行動去準備搵工。					
3.	我認爲花功夫在搵工上是值得的。					
4.	我根本無工作能力，我不明白爲何要參加這計劃。					
5.	我終於開始爲搵工做一些功夫。					
6.	我想現在是我搵工的適當時機。					
7.	我根本沒有工作能力，所以爲自己做好準備去搵工是浪費時間的。					
8.	雖然我覺得無工做是不太好，但現在我是無能爲力。					
9.	我知我需要搵一份工，我亦認爲我必須努力搵工。					
10.	其他人告訴我應該要搵工，但我並不同意。					
11.	任何人都可以口講自己想搵工，但我就不同，我實際上正在努力搵工。					
12.	所有這些關於搵工的問題都好悶，爲什麼不讓我自己一個人靜一靜？					
13.	我正在積極地搵工。					
14.	我根本不想返工，爲搵工做準備工夫根本是浪費時間。					

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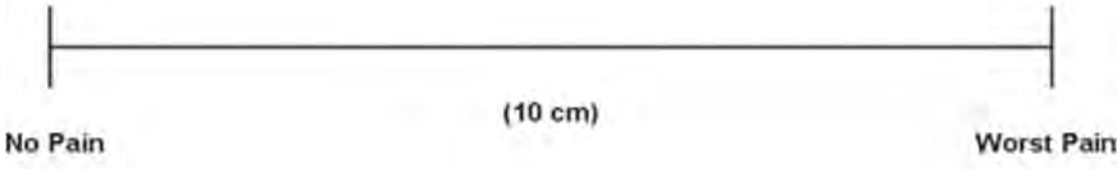
APPENDIX I1

VISUAL ANALOGUE SCALE



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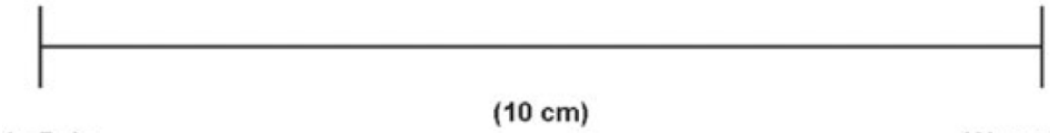
APPENDIX I2

VISUAL ANALOGUE SCALE (MALAY VERSION)



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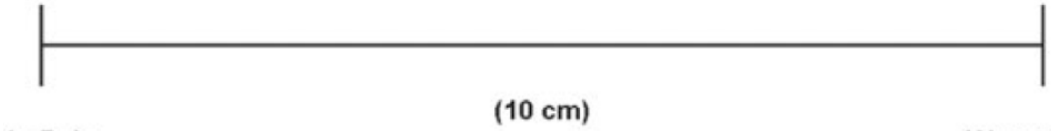
APPENDIX I3

VISUAL ANALOGUE SCALE (CHINESE VERSION)



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APPENDIX J1

LIST OF PRESENTATION AND PUBLICATION

1.	Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton therapy in improving functional outcomes among workers with wrist fractures: Study protocol for a randomized controlled trial	Published in PLOS ONE

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APPENDIX J2

SINGLE JOINT HYBRID ASSISTIVE LIMB (HAL-SJ) ROBOTIC EXOSKELETON THERAPY IN IMPROVING FUNCTIONAL OUTCOMES AMONG WORKERS WITH WRIST FRACTURES: STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

PLOS One

STUDY PROTOCOL

Single Joint Hybrid Assistive Limb (HAL-SJ) robotic exoskeleton therapy in improving functional outcomes among workers with wrist fractures: Study protocol for a randomized controlled trial

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Data availability statement: Given the protocol nature of this article, no datasets were generated or analyzed during the preparation of the protocol. The results will be published in a scientific journal.

Abstract

Introduction

Robotic technologies have been developed for motor rehabilitation and such robots have shown favourable results when compared with equivalent doses of usual clinical therapy. Recently, robotic interventions have been suggested to be applied in orthopaedic rehabilitation with upper extremity disorders, especially those related to hand and wrist. This study aims to determine the effectiveness of combined conventional therapy and HAL-SJ robotic therapy in restoring the wrist functionality following the fractures as compared to the standard conventional therapy solely.

Methods and analysis

Workers with wrist fractures will be randomized in two groups, i.e., the control group (conventional therapy) and intervention group (combination of conventional therapy and robotic HAL-SJ intervention). All participants will receive 5-day/week therapy sessions for four weeks. Primary outcomes of the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure and secondary outcomes of range of motion, grip and pinch strengths, fine and gross hand dexterity as well as pain and the Lam Assessment of Stages of Employment Readiness (LASER) will be assessed at baseline assessment and upon completion of the therapy program after 4 weeks. Data from the baseline and post intervention outcome measures will be analysed using a Repeated Measures ANOVA to compare the therapy effectiveness of both control and intervention groups.

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Competing interests: I have read the journal's policy and the authors of this manuscript have the following competing interests: Author Yoshiyuki Sankai holds a patent related to the technology discussed in this manuscript and is serving as the President and Chief Executive Officer of Cyberdyne Inc. company which manufactures and distributes the Single Joint Hybrid Assistive Limb robotic exoskeleton.

Results

Participants recruitment and data collection are in progress

Discussion

Wrist fractures can produce some residual disability and pain that may impact the functionality of a person. The application of robotic technology in facilitating upper limb movement and functional recovery training is extensive and shows positive outcomes in the field of neurorehabilitation. However, there is a lacking of published evidence about the effectiveness of robotic intervention in orthopaedic rehabilitation, especially in the field of hand therapy.

Conclusion

Participants recruitment and data collection are still ongoing

Clinical trial registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (registration number: ACTRN12622000413729).

Introduction

Work-related hand injuries contributed to 24.9% of all industrial accidents seen at the emergency departments and orthopaedic clinics in Malaysia [1]. Approximately 98.6% of workers with traumatic hand injuries returned to work after a median absence of 45.5 days [2]. Hand injury costs had brought cumulative economy impact not only to patients, but their family, employer, and society [3].

Decreased wrist flexion and/or extension after trauma or surgery can be a challenging problem [4]. A study in UK reported that majority of patients had some degrees of disability one year after distal radius fracture with 16% had moderate to very severe disability and were not working [5]. In addition, patients who have high self-reported pain/disability and occupational demand at baseline have an average of 9.2 weeks of work loss following distal radius fracture [6].

The goal of restoring wrist motions is to reduce impairments and enhance functional performance for activities of daily living, work, and leisure. Improper rehabilitation program after wrist injury may significantly impair the overall upper extremity function [7]. A study by MacDermid et al. [6] indicates that both injury and patient factors can impact the management and outcomes after distal radius fracture. Although optimal physical parameters, including strength, range of motion (ROM), and function are achievable within 3–6 months of conservative or surgical management, some patients require longer duration to complete the rehabilitative phase.

With respect to the employability issues of the workers with wrist fractures, the advocation of matching treatment to the patient's stage of employment readiness appears to be a more effective approach to service provision [8]. A timely and

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goal-oriented treatment-matching approach in the work program will deliver better outcomes in term of cost effectiveness, employment, and service quality.

Robotic technologies developed for motor rehabilitation have shown to produce favourable results when compared with equivalent doses of usual clinical therapy [9,10]. Compared to manual therapy, robotic intervention can potentially provide greater impact on impairment due to easy deployment, applicability across of a wide range of motor impairment, high measurement reliability, and the capacity to deliver high dosage and high intensity training protocols for a longer duration, irrespective of the skills, and fatigue level of the therapist [11]. Given the current concepts of robotic intervention are focused on providing motor control/learning, practice-induced neuroplasticity, intensity, and task specific training, the application of robotic intervention in upper limb orthopaedic rehabilitation, especially concerning the hand and wrist has been suggested [12].

The Single Joint Hybrid Assistive Limb (HAL-SJ) is one of the robotic devices that can be used for upper limb rehabilitation. The Hybrid Assistive Limb (HAL) represents a cyborg-type robot designed to amplify, enhance, and assist physical abilities, thereby advancing and elevating human capabilities through the cutting-edge science of "Cybernics". Cybernics constitutes a burgeoning interdisciplinary field focusing on the integration of neuroscience, robotics, systems engineering, information technology, "kansei" engineering, ergonomics, physiology, social science, law, ethics, management, economics, and more, within the realms of cybernetics, mechatronics, and informatics [13]. The newly developed wrist joint attachment to the HAL-SJ can assist voluntary articulatory movements of the wrist joint including wrist flexion and extension, and forearm supination and pronation. Investigating the outcome of HAL-SJ among upper limb injured workers, especially those with wrist fractures shall provide further evidence on the effectiveness and feasibility of robotic interventions in the field of hand therapy and upper limb rehabilitation.

Objectives

The primary objective of this study is to determine the effectiveness of Single Joint Hybrid Assistive Limb (HAL-SJ) robotic therapy in improving functional level, physical performance, and work readiness among workers with wrist fractures after 4 weeks of intervention.

Hypotheses

A 4-week combined conventional therapy and Single Joint Hybrid Assistive Limb (HAL-SJ) robotic therapy provides greater functional and impairment levels improvement among workers with wrist fractures as compared to those receiving conventional therapy alone during the same intervention period.

Method

Research design

This is a randomized controlled trial (RCT) design where the effects of the study treatment (intervention) are compared with those of a control treatment after the patients were being randomly assigned to the two groups, i.e., the control group and the intervention group. The protocol for this study is guided by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist consisting of a 33-items. The checklist for this study is detailed in S1 File. The SPIRIT Schedule of Enrolment, Interventions, and Assessment is shown in Fig 1 while the flow for this study is detailed in Fig 2 beginning with participant enrollment, group allocation, baseline assessment, intervention and ending with reassessment. The study protocol with information sheet, consent form, demographic questionnaire, and data collection form are included in the S2 File.

Participants: Recruitment and eligibility criteria

The target participants for this study are Social Security Organisation (SOCSO) insured workers with wrist fractures who meet both the inclusion and exclusion criteria and are receiving rehabilitation management at PERKESO Rehabilitation Centre. The inclusion criteria are wrist fractures affecting individual or combined distal radius, distal ulna, distal radioulnar,

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SPIRIT Schedule of Enrolment, Interventions, And Assessments

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	
TIME POINT	*Baseline* $-t_1$	0	*Day 1* t_1	*4-week follow-up* t_2
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Conventional Therapy (Physiotherapy & Occupational Therapy			←	→
HAL-SJ Robotic Intervention			←	→
ASSESSMENTS:				
Disabilities of the Arm, Shoulder and Hand Outcome Measure (DASH)	X			X
LAM Assessment on Stages of Employment Readiness	X			X
Visual Analog Scale (pain)	X			X
Grip Strength	X			X
Pinch Strength	X			X
Range of Motion	X			X
Canadian Occupational Performance Measure	X			X
Purdue Pegboard	X			X
Block and Box Test	X			X

Fig 1. SPIRIT schedule.

https://doi.org/10.1371/journal.pone.0322191.g001

and/or radiocarpal joint, as well as extraarticular fracture, partial articular fracture, and/or complete articular fracture. The exclusion criteria are: associated peripheral nerve injuries, neuropathy, and/or tendon injuries to the affected upper limb; associated neurological conditions related to the central nervous system; cognitive impairment or psychiatric conditions; severe and uncontrolled medical conditions such as cardiovascular disorders, respiratory disorders, cancer; skin disorders such as eczema, psoriasis, open wounds, etc., of the affected forearm and hand that prevent electrode placements; severe contracture of the affected wrist joint; and those with forearm size that is not suitable for wearing the HAL-SJ robotic exoskeleton. The recruitment period for this study has been started on 21 June 2021 and will end by 20 June 2025.

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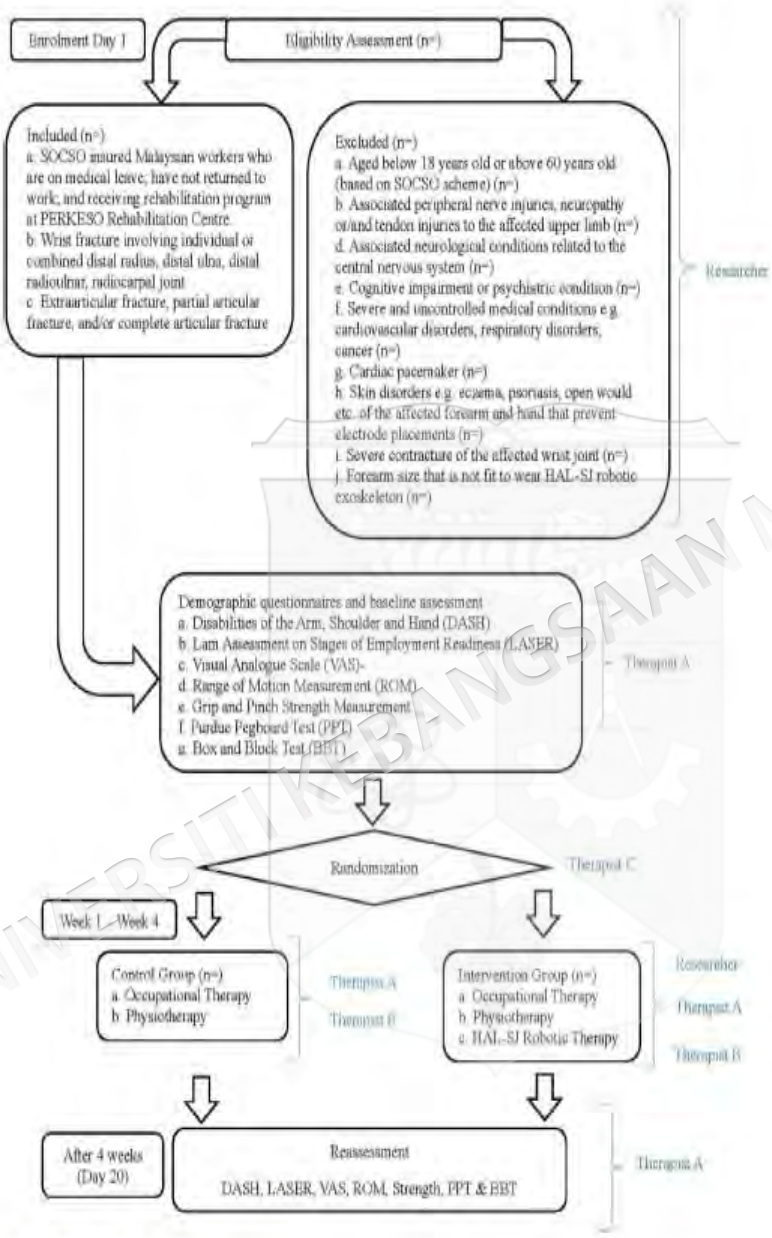

Fig 2. Study flow.

https://doi.org/10.1371/journal.pone.0322191.g002

Sampling size

The sample size for each hypothesis was calculated using G*Power analysis. Since this is a novel study without reference from previous research, the sample size was determined using ANOVA repeated measures, within-between interaction, with a Cohen's f effect size set at 0.25 for a medium effect, an alpha error of 0.05, and 80% power. The results indicated

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that a total of 34 participants would be required. Factoring in a 10% dropout rate, the necessary sample size increased to 38 participants with 19 participants allocated to the interventional group and 19 participants to the control group.

Randomization

All patients with wrist fractures referred to PERKESO Rehabilitation Centre will be randomly assigned to the control and intervention groups by Therapist C, an independent therapist who is not involved in the assessment or intervention process. Simple randomization with allocation concealment will be used to prevent the researcher from influencing which participants are assigned to the intervention group. After completing the baseline assessment process, each participant will receive a sealed opaque envelope containing an equal number of random allocation cards designated with the alphabet "C" (Control group) and "I" (Intervention group). Therapist C will record the group allocation for each participant. Selected participants will be informed about the study and included only after giving their informed consent.

Blinding

The baseline assessment of each participant will be conducted by Therapist A before the randomization process to maintain the blinding of the respective therapists and participants. The researchers will not participate in any baseline or outcome assessment processes throughout the study. The group allocation for each participant will be revealed upon the completion of the randomization process by Therapist C.

Research team

This study involves various clinicians and administrative staff from the PERKESO Rehabilitation Centre, including the Researcher (primary author EWT), Therapist A (an Occupational Therapist), Therapist B (a Physiotherapist), Therapist C (an independent therapist), and a case manager. All patients with wrist fractures referred to the PERKESO Rehabilitation Centre will be categorized through the admission database by the case manager. The Researcher will then conduct eligibility screening for each participant based on the inclusion and exclusion criteria. As a certified HAL-SJ operator accredited by Cyberdyne Inc., the Researcher will assume the roe of delivering the robotic intervention for participants in the intervention group. Therapist A will serve as the baseline and outcome assessor and will conduct conventional occupational therapy interventions. Prior to group allocation through the randomization process by Therapist C, Therapist A will perform baseline assessments for all enrolled participants. Meanwhile, Therapist B will be responsible for conducting the conventional physiotherapy interventions outlined in the study (Fig 2).

Informed consent, registration, baseline assessment and group allocation

The study flow will be elucidated to the selected participants upon confirmation of their eligibility for the study. An information sheet (S2 File) detailing general information, purpose, procedures, risks and benefits, as well as data confidentiality, will be provided and explained to each participant. Participants will only be included in the study after signing the informed consent forms. Following this, baseline assessment and collection of demographic data for each participant will be conducted by Therapist A. Subsequently, participants will be allocated into either the control or intervention group by Therapist C through simple randomization with allocation concealment (Fig 2).

HAL-SJ robotic exoskeleton

HAL-SJ robotic exoskeleton is certified by ISO 13485:2016 (certificate number: 1757.181211) and EC (registration number: DD 601417310001) for rehabilitation and physical therapy usage. The upper limb HAL-SJ is a wearable movement support robot that detects bioelectrical signals on the skin surface and assists joint movements by controlling and operating an actuator placed outside the respective joint. The power units of HAL generate power assist torque by amplifying

the wearer's own joint torque estimated from his/her bioelectrical signals, and the support motions are consequently controlled. It is a safe device that can be used for rehabilitation intervention as approved by the FDA, EC and MDA. It may cause several minor problems: (a) skin allergy or reddening of area where electrode is affixed, however, the reddening should disappear shortly after the electrode was taken off; (b) abrasion of areas that contact the device, e.g., cuffs and straps; and (c) muscle and joint soreness (due to post exercise effect). The researcher of this study, who is a certified HAL-SJ operator accredited by Cyberdyne Inc. will take necessary precaution and careful supervision throughout the entire HAL-SJ robotic exoskeleton session to minimize these problems. The HAL-SJ robotic exoskeleton that will be used is shown in Figs 3 and 4.

Study protocol

The design of this study is an interventional, parallel, superiority randomized clinical trial on a consecutive convenience sample of 38 participants using 1:1 ratio. The study protocol involves a combination of conventional therapy and HAL-SJ robotic therapy. Each participant from both the control and intervention groups will undergo two conventional therapy sessions daily, consisting of an occupational therapy session and a physiotherapy session, on a 5-day/week basis. Each occupational therapy and physiotherapy session will last for 90 minutes, respectively. Additionally, the intervention group

Fig 3. Single Joint Hybrid Assistive Limb (wrist extension).

https://doi.org/10.1371/journal.pone.0322191.g003

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Fig 4. Single Joint Hybrid Assistive Limb (forearm rotation).

https://doi.org/10.1371/journal.pone.0322191.g004

will receive a 60-minute HAL-SJ robotic therapy session conducted by the researcher daily, following the conventional therapy sessions. All participants will receive these 5-day/week therapy sessions for a duration of 4 weeks.

Study protocol for conventional therapy

Both the control and intervention groups will undergo conventional therapy, which comprises occupational therapy and physiotherapy interventions aimed at wrist fracture rehabilitation. This therapy encompasses various interventions such as pain management, range of motion exercises, progressive strengthening exercises, functional activities training, as well as work conditioning and work hardening activities.

In the initial week, the interventions prioritize restoring joint mobility and pain management. Occupational therapy interventions during this phase encompass active and passive ROM exercises for the digits, elbow, and shoulder, active ROM exercises for the wrist and forearm rotation, tendon gliding exercises, and dexterity exercises. Physiotherapy interventions involve joint mobilization, soft tissue mobilization, retrograde massage, heat/cold modalities, ultrasound therapy, and electrical stimulation.

The conventional therapy program from the first week will be sustained into the second week of intervention, with the inclusion of functional activities training from occupational therapy. Additionally, physiotherapy will introduce isometric and isotonic strengthening exercises during this phase.

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During the third week, the focus shifts to a graded strengthening program. This includes isometric and isotonic strengthening exercises, progressive resisted exercises, as well as open and closed kinetic chain exercises. All interventions conducted during the first and second weeks will be maintained throughout the third week of the conventional intervention phase.

In the fourth week of the conventional therapy program, interventions will involve work simulation, work conditioning, and work hardening activities. All interventions from previous weeks will be continued based on the individual's condition.

Study protocol for HAL-SJ Robotic Therapy

The HAL-SJ Robotic Therapy protocol will utilize the gentle mode of the HAL-SJ exoskeleton It comprises four phases that will progress over the 4-week intervention period, adjusting according to four parameters: assist gain, assist level, flexion/extension signal balance level, and active/relax phase duration. Each intervention session will include four types of wrist exercises: wrist extension, flexion, supination, and pronation. The protocol entails three sets of exercises, with 50 repetitions for each specific wrist movement (extension, flexion, supination, and pronation), performed with an active/relax phase duration of 10 seconds/10 seconds.

The assist level will remain constant at x1 level throughout the 4-week intervention period. However, the assist gain and the flexion/extension balance signal will be adjusted based on the individual's progress from the first week to the fourth week of the intervention period.

During the first week, the intervention will be carried out with the highest assist gain set at 75–100%, while maintaining the assist level at x1. Simultaneously, the flexion/extension balance signal level will be maintained at 100% flexion/100% extension. In the second week of the intervention, the assist gain will be reduced to 50–75%, while the flexion/extension signal balance level remains at 100% flexion/100% extension. As the intervention progresses into the third week, the assist gain will be further reduced to 25–50%, while the flexion/extension signal balance level will be adjusted based on the desired wrist exercise movements. During wrist extension or supination, the flexion/extension signal balance level will be set at 50% extension (supination)/100% flexion (pronation), and vice versa. In the fourth week of intervention, the assist gain will be set to the lowest level at 0–25%. During this phase, the flexion/extension signal balance level will be regulated to 25% for the desired wrist movement while the remaining 100% signal will be adjusted for the antagonistic movement.

Outcome measures

The primary outcome measure is Disabilites of the Arm, Shoulder and Hand (DASH) Outcome Measure for gauging the upper extremity functional improvement. The DASH assesses physical function and symptoms for various musculoskeletal conditions of the upper extremity [14]. It has extensively researched psychometric properties [15] with validity and responsiveness in both proximal and distal disorders [16]. Focusing on disability level, each item has five response options and total score can be computed using a provided formula, i.e., total score = ([(sum of n responses)/n]-1)×25 with a higher score indicating greater disability [17].

There are 6 secondary outcomes. Firstly, ROM, including both active and passive ROM of the forearm, wrist and fingers are assessed. Assessment begins with wrist flexion, extension, radial deviation and ulnar deviation as well as supination and pronation using a wrist goniometer. This is followed by assessments on the same wrist and forearm joints to evaluate the end feel. For fingers, active and passive ROM of proximal interphalangeal joint, and distal interphalangeal joint are assessed using a finger goniometer. Grip and pinch (lateral pinch, tripod pinch, and tip-to-tip pinch) strengths are secondary outcomes measured using the respective Jamar (using a dynamometer (handle 2) and B&L Engineering Pinch Gauge measured three times using a position recommended by the American Society of Hand Therapists [18].

Another secondary outcome measures are fine and gross hand dexterity as measured using the Purdue Pegboard Test (PPT) and the Box and Block Test (BBT) respectively. The PPT is a valid and reliable standardized instrument with five subtests. The first three subtests involve placing the maximum number of pins into holes on the pegboard using the dominant hand, the non-dominant hand, and then both hands simultaneously, all within a 30-second time frame. The fourth is not an actual test but involves a mathematical calculation. The fifth test involves using alternate hands to assemble components including pins, collars, and washers, within a 60-second timeframe [19]. Meanwhile, the BBT is widely used across various clinical populations due to its ease and efficiency of implementation [20,21]. It involves transferring 125 2.5 cm^3 wooden blocks, arranged in various orientations, from one side of a partition to another using the testing hand as quickly as possible within a 1-minute timeframe. The participant's score corresponds to the number of blocks successfully transported over a 15.2-cm tall partition in one minute [20,21]. It has high inter-rater and test-retest reliability, with intra-class correlation coefficients ranging from 0.85 to 0.97 [22–24]. Normative data for the BBT in adults were published in 1985, based on a sample of 628 individuals without disabilities spanning ages 20–70+ years [20].

Pain is a secondary outcome measured using Visual Analogue Scale (VAS). It is a single-item tool that captures the entire pain construct at once. Consisting of a 100mm horizontal line with two opposing labels, "no pain" and "severe pain," participant indicates his/her pain level by marking a score along the scale using a vertical line. Due to its ease of use, the VAS is applicable across a variety of practice and research settings [25].

Readiness to work as measured using the Lam Assessment on Stages of Employment Readiness (LASER) is a secondary outcome of this study. LASER is a common instrument used to assess the psychological readiness of workers to return to work following an extended period of unemployment due to disability [8,26]. LASER comprises 14 items aligned with Prochaska's stages of change model, delineating behaviors within three stages of work readiness, i.e., the pre-contemplation (6 statements), contemplation (4 statements), and action stages (4 statements). The different sub-scores representing the corresponding stages, forming a continuous measure. The highest sub-score reflects a subject's inclination towards the corresponding stage. Subjects in the pre-contemplation (PC) stage do not perceive unemployment as an issue and may lack interest in working or believe they are unable to work. Subjects in the contemplation (C) stage begin weighing the pros and cons of working but haven't taken any action such as job searching yet. Subjects in the action (A) stage have made the decision to work by actively seeking employment and addressing many barriers related to returning to work and they would have the best employment outcomes [8,26].

Given that outcome measures commonly employed for wrist fractures include wrist range of motion (ROM) measurement, grip/pinch strength measurement (using a dynamometer and pinch gauge), pain measurement (Visual Analogue Scale), and the Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure [27], all of these outcome measures will be utilized in this study. Additionally, both the Purdue Pegboard Test and Box and Block Test will be employed to assess functional performance in terms of hand dexterity, while readiness to work will be evaluated using the LAM Assessment on Stages of Employment Readiness (LASER) Questionnaire. All the baseline and outcome assessments will be conducted by Therapist A who is an experienced occupational therapist in the field of hand therapy.

Statistical analysis

Data will be analyzed using the IBM® SPSS® Statistics version 29. Descriptive statistics for categorical data, including gender, marital status, hand dominance, types of medical management and intervention, type of wrist fractures, educational level, employment status, and type of SOCSO compensation scheme, will be expressed in frequency and percentage. Descriptive statistics for continuous data, including age, the scores of a primary outcome measure of DASH, and the secondary outcomes measures, including ROM, grip and pinch strength, pain, hand dexterity, and work readiness, will be used expressed in mean, standard deviation, maximum, and minimum if the data is normally distributed or in median and inter-quartile range if the data is not normally distributed. The Shapiro-Wilks test will be used to test the normality of the continuous data. All statistical tests will be performed using two-sided tests at the 0.05 significance level.

A Repeated Measures ANOVA will be used to analyze the mean differences in treatment outcomes within and between the groups at baseline and after 4 weeks of intervention. ANOVA assumes that the data in each group are normally distributed and that the variances are equal across groups (homogeneity of variance). If the data is not normally distributed, a transformation will be applied, including log, square root, or Box-Cox transformation. If the data cannot be transformed to meet ANOVA assumptions, a non-parametric alternative, i.e., the Kruskal-Wallis test, will be conducted.

A Repeated Measures ANOVA is used for independent observations in this study by comparing the means across the independent groups, i.e., control and intervention groups. With respect to this, the data in this study is balanced where it has equal sample sizes across the control and intervention groups. A Repeated Measures ANOVA compares the mean differences between groups that have been split on two "factors" (also known as independent variables), where one factor is a "within-subjects" factor and the other factor is a "between-subjects" factor. For example, in this study, a Repeated Measures ANOVA is used to measure a dependent variable (functional outcome) over two time points (baseline and after 4 weeks of interventions), i.e., where "time" is the "within-subjects" factor), but also when the subjects (participants) have been assigned into two separate groups when they undergo difference interventions (i.e., the control and intervention group). These groups form the "between-subjects" factor. The within-subjects factor is time while the between-subjects factor consists of the types of interventions. The primary purpose of a Repeated Measures ANOVA is to understand if there is an interaction between these two factors on the dependent variable. Since we are using the ANOVA for analysis, we do not include random effects where it treats all groups as fixed effects.

With respect to Repeated Measures ANOVA analysis, the independent factors in this study are the combination of robotic intervention with conventional therapy and the conventional therapy alone with DASH scores (primary outcome) and all six secondary outcomes act as an dependent variable, respectively. This study will assess the main effects of time and group and their interaction effect. The change in the pre- and post-functional level (DASH scores) (main effect 1) among workers with wrist fractures between the intervention and control groups (main effect 2) will be compared and analyzed. The study will also explore the difference in functional level between pre- and post-interventions in both control and intervention groups (interaction effect).

Other key assumptions will be assessed, i.e., sphericity and homogeneity of variances. The Mauchly's test of sphericity will be used to determine whether the variances of the differences between all pairs of levels of a within-subjects factor are equal. If the p-value is significant ($p < 0.05$), the assumption of sphericity is violated. If sphericity is violated, the degrees of freedom of the F-statistic will be adjusted using correction Greenhouse-Geisser or Huynh-Feldt corrections, making the test more conservative [28]. For the homogeneity of variances, Levene's test will be used to evaluate whether the variances of the dependent variable are equal across groups. If the p-value is significant ($p < .05$), it indicates a violation of the assumption of homogeneity of variances [29,30].

The results will be expressed as mean differences between groups, along with their corresponding two-sided 95% confidence intervals. Statistical significance will be determined by p-values, which will be reported to three decimal places. For p-values less than 0.001, the notation "<0.001" will be used.

This study will adopt the principle of intention-to-treat (ITT) analysis. The ITT principle is a cornerstone in RCT analysis, emphasizing that all randomized participants in an RCT should be analyzed according to their assigned treatment group, regardless of treatment completion, discontinuation, or adherence to the study protocol. This process has once been described as "once randomized, always analyzed" [31–33].

Standard statistical methods for analyzing RCT data typically incorporate baseline measurements as covariates. However, when a participant has a recorded baseline measurement but is missing all subsequent follow-up data, the ITT principle implies that they should still be included in the analysis based on their assigned group. This poses a methodological challenge that requires careful consideration [32]. A common challenge in clinical trials is evaluating data from patients who drop out or cannot complete the full study [32,34–38].

If there is any missing data occurrence happened, this study will use the baseline observation carried forward (BOCF) method to handle patient dropouts. The BOCF uses the baseline observation and handles missing data from early treatment discontinuation. For participants who discontinued participation in the trial, their baseline observation will be considered their final response, irrespective of the reason for withdrawal or their scores at the time of withdrawal. For participants who completed the intervention, the BOCF endpoint was their last recorded observation [35]. This method has been proposed as a more reliable and preferred imputation strategy over the last observation carried forward (LOCF) method [35,36,39]. The LOCF method may yield biased estimates of treatment effects and compromised statistical tests of the null hypothesis of no treatment effect [40]. The LOCF method is also prone to substantial misrepresentation of trial results and is an unsuitable choice for primary analysis [41].

Besides, it is essential to consider both treatment-related and non-treatment-related reasons for dropout in the BOCF approach. Treatment-related reasons for discontinuation comprised adverse events and insufficient efficacy. Non-treatment-related reasons encompassed failure to meet inclusion criteria, protocol deviations, loss to follow-up, patient-initiated withdrawal (e.g., work-related conflicts, transportation difficulties), and investigator-initiated withdrawal (e.g., site closures, unreliable patient behavior) [35].

Monitoring, ethics and dissemination of information

The study has obtained ethical approval from the Research Ethics Committee of Universiti Kebangsaan Malaysia (JEP-2021–201) and the Scientific Committee of PERKESO Rehabilitation Centre (PRPTAR.600-5(48)). Besides, it has been registered at the Australian New Zealand Clinical Trials Registry (ANZCTR) with registration number: ACTRN12622000413729.

Participation in this study is entirely voluntary, and individuals have the right to withdraw from the study at any point without facing any pressure or coercion. Each participant will receive an information sheet detailing the study. Those who choose to participate will be provided with an informed consent form, which they must sign. Both the Information Sheet and Informed Consent Form are available in S2 file.

The privacy and anonymity of research participants are rigorously protected, and all information or data collected for this research will only be disclosed with explicit consent or as mandated by law. Each participant's name is securely stored in a password-protected database, associated solely with a study identification number, which is also utilized on all participant data sheets.

The findings of this study will be compiled into a report and distributed to PERKESO Rehabilitation Centre and Universiti Kebangsaan Malaysia. Upon completion and conclusion of the study, the raw materials will be kept in a locked file cabinet located in the Researcher's office. Electronic data will be safeguarded and accessible only through a password known solely to the Researcher. Following five years from the completion of the study, all materials will be shredded and disposed of by the Researcher.

The trial results will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The manuscript detailing the trial will be submitted to a peer-reviewed international scientific journal for publication. Additionally, the findings may be presented at national conferences and scientific meetings.

Results

This study was commenced on 15th March 2022. Currently, the data collection process for protocol implementation is still ongoing.

Discussion

Wrist fractures can produce residual disability and pain that may impact the functionality of a person. The application of robotic technology in facilitating upper limb movement and functional recovery training is extensive in the field of

neurorehabilitation [42–51] but limited in the field of orthopaedic rehabilitation particularly in hand therapy practice. Given the current concepts of robotic intervention are focused on providing motor control/learning, practice-induced neuroplasticity, intensity, and task specific training, robotic intervention for orthopaedic hand and wrist disorders has been suggested [12]. Recent work has served as the introducing point to incorporate robotic devices in the rehabilitation program of traumatic wrist injuries. The study has shown that robotic-based rehabilitative approach is effective and comparable to the traditional therapy approach on individuals with wrist injuries [52].

This randomized controlled trial aims to investigate the effectiveness of combined conventional therapy and HAL-SJ robotic therapy in restoring the wrist functionality following the fractures as compared to the standard conventional therapy solely. Investigating the outcome of HAL-SJ among upper limb injured workers, especially those with wrist fractures shall provide further evidence on the effectiveness and feasibility of robotic interventions in the field of hand therapy and upper limb rehabilitation.

The effectiveness of the study protocol has been evaluated by examining the functional and impairment levels of the impacted hand. To compare wrist functionality and work readiness between control and intervention groups, the DASH and LASER outcome measures are employed. Additionally, the VAS, goniometric measurement, isometric strength assessment, Purdue Pegboard, and Box and Block Tests offer comparable data on impairment outcomes such as pain, strength, and hand dexterity for both groups.

Subsequent investigations ought to focus on assessing the effectiveness of HAL-SJ robotic therapy independently in restoring wrist functionality subsequent to traumatic wrist fractures, without integrating conventional therapy methods.

Here are several extra factors to contemplate -

- While a power analysis was conducted, it is important to note that the participants in this study might not entirely reflect the broader population of individuals with wrist fractures.
- The inclusion criteria did not rule out potential participants with associated fractures or traumas to other body parts.

Supporting information

S1 File. SPIRIT checklist.
(PDF)

S2 File. Study protocol. Study protocol with information sheet, consent form, demographic questionnaire, and data collection form.
(PDF)

S3 File. Study protocol approved by ethics committee. Study protocol approved by the Research Ethics Committee of Universiti Kebangsaan Malaysia (JEP-2021–201).
(PDF)

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