EFFICACY OF TELEREHABILITATION IN IMPROVING GRIP STRENGTH

by

Sam Prasanna Rajkumar James

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Doctoral Advisory Committee:

Dr. Sankar Sengupta, Ph.D., Chair
Dr. Megan Conrad Ph.D., Co-Chair
Dr. Gary McDonald Ph.D.
Dr. Brian Dean, Ph.D.

To
The God Almighty,
my family and my friends.

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Sam James

ABSTRACT

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SAM PRASANNA RAJKUMAR JAMES

Advisers: Dr. Sankar Sengupta and Dr. Megan Conrad, Ph.D.

Handgrip strength is essential to perform day-to-day tasks. People lose handgrip strength due to aging, diseases, and other conditions. According to neuroplasticity principles, grip strength can be improved using repetitive tasks and exercises. People often are not motivated enough to adhere to meaningless repeated movements to improve grip strength exercises. This study describes developing an innovative smartphone-based telerehabilitation system that includes an innovatively designed grip strength device (eGripper) and a phone application to play games. This telerehabilitation system encourages patients to play a game while improving grip strength.

eGripper was a repurposed dynamometer that sends grip strength data to an android phone. The raw grip strength data stream was used as a control variable to play games. In this study, the grippyBird game was designed, where customizations can be done from a remote therapist dashboard.

Thirty-four participants participated in validity and reliability experiments to measure this device against the “gold” standard Jamar dynamometer. The test results substantiate that eGripper has acceptable concurrent validity and inter-instrumental reliability. A randomized clinical trial with an experimental and control group measured

efficacy and compliance. Findings from the clinical trial showed significant improvements in grip strength and compliance between groups. A formative and summative usability testing was performed. Formative usability used focus groups and informal interviews with a few therapists and patients during the design stage. Four experimental participants did a summative usability experiment with two surveys.

An eGripper telerehabilitation system to resolve the issues of HEP compliance was developed for this study. The use of a game instead of repetitive exercises motivated participants to be compliant in performing their HEP more regularly. Future research is needed to continue developing both the eGripper and associated games to help patients with poor hand strength improve their ability to grip.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF FIGURES—Continued

LIST OF ABBREVIATIONS

HEP	Home Exercise Program
ADL	Activities of Daily Living
QOL	Quality of Life
GRIFT	Grip Force Tracking Device
PCB	Printed Circuit Board
MCU	Microcontroller Unit
ADC	Analog to Digital Converter
GPIO	General Purpose Input Output
HTML	Hypertext Markup Language
CSS	Cascading Style Sheet
JS	JavaScript
ASHT	American Society of Hand Therapists
ICC	Intraclass Correlation Coefficient
PI	Principal Investigator
SUS	System Usability Scale
SEQ	Suitability Evaluation Questionnaire

CHAPTER ONE

INTRODUCTION

Problem Statement

Think about how much we rely on a firm hand grip every day. Hand grip helps people open doors, grip a glass of water, hold a gallon of milk, brush their teeth, and drive a car (*Give Grip Strength a Hand*, 2016). Muscles in the forearm and hand generate this grip. Many clinical disorders, such as stroke, brain injury, and myopathy, can cause weakness of the forearm and hand muscles, resulting in a weak grip. Exercise can improve grip strength (Eng, 2004), but people must do these exercises consistently. With regular exercise, grip strength takes an average of five months to recover after an initial stroke (Sunderland et al., 1989). During this time of recovery, grip strength exercises should be goal-oriented and repetitive to yield better results (Langhorne et al., 2009). Therefore, therapists frequently give their patients paper-based home exercise programs to continue the grip strengthening regimen at home. To get consistent results, patients should follow and comply with their home exercise programs, although research has found that 50% to 70% of patients fail to comply with these home exercise programs (Beinart et al., 2013). Noncompliance with home exercise programs occurs because they are boring, give no feedback, and do not upgrade or downgrade the exercises based on the patient's progress (Palazzo et al., 2016). In contrast, hospital-based rehabilitation patients receive tailored exercises and regular therapy feedback that meet patient needs. Noncompliance with home exercise programs can weaken muscles and result in an

inability to grip objects, leading to difficulty performing activities of daily living (ADL) and may result in depression, immobility, increased caregiver burden, and increased morbidity (Gobbens, 2018).

Telerehabilitation uses communication and information systems to provide rehabilitation services to patients in remote locations (McCue et al., 2010). This service can improve exercise compliance by providing supervision and encouragement from the therapists remotely. Tchero et al. (2018) concluded that telerehabilitation is the best alternative to hospital-based rehabilitation care for stroke patients, especially in remote areas. Sarfo et al. (2018) suggested that telerehabilitation interventions have better or similar effects compared to hospital-based rehabilitation interventions. People adhere better to home exercise programs provided on an app with remote support than paper handouts (Lambert et al., 2017). Another method of increasing continued engagement with home exercise programs is game-based rehabilitation, defined as using video games to improve physical and cognitive skills in patients with deficits. Studies have found that game-based rehabilitation improves muscle strength through better participation, fun, and exercise engagement (Chen et al., 2015). Games provide high-intensity repetitions with motivation, enjoyment, and immediate feedback (Dodakian et al., 2017).

Research in game-based telerehabilitation has progressed through several technological advancements (Lange et al., 2009a). These programs have several advantages, including patients can practice therapy in their own homes, take breaks from intensive therapy, attend to family duties, and exercise at convenient times. Games are fun and encourage more practice of therapeutic movements. Most telerehabilitation

research uses a personal computer, custom-designed motion tracking system, and video conferencing system, although packaging the telerehabilitation system in a bulky and heavy device seems impractical and not portable (Dodakian et al., 2017). The commercial gaming systems used in telerehabilitation research are not portable and are expensive, ranging from $300 to $2,000. Existing game-based telerehabilitation focuses on gross upper-body motor movements, balance, and cognition. Researchers use commercial gaming systems (e.g., Wii, Kinect, and PlayStation) for therapy unsuitable for therapeutic purposes because they focus on providing complex motor tasks that are demanding, exhausting, and challenging to practice specific movements. Additionally, games used in telerehabilitation research are not customized for individual patients' abilities and lack specialized grip dynamometers to control the games.

Many smartphones that use the android operating system provide game-based telerehabilitation service delivery advantages. In the U. S., 81% of the population uses smartphones (Pew Research Center, 2018). In this study, we are proposing a design of a smartphone-based telerehabilitation system that uses games to improve grip strength among patients with weak grip strength. These games can be delivered as an app through the smartphone, requiring a commercially available electronic dynamometer to play games.

Research Objectives

This research focuses on providing an alternative service delivery method to rehabilitate and improve exercise compliance, specifically handgrip strength. As mentioned above, telerehabilitation technologies and games will be used to deliver

rehabilitative services. Moreover, affordable smart grip strength dynamometers are not available to use with games. Therefore, the research objectives are to:

- design an affordable smart hand dynamometer to exercise using games that are customizable to individual patients' grip strength levels,
- test the system for validity and reliability,
- test the usability of the system
- study the clinical feasibility of this system.

These research objectives are carried out in three phases described below.

Phase 1 – System Design

In phase 1 of this study, a research question was asked before designing the telerehabilitation system -

RQ1: Is it feasible to repurpose an off-the-shelf electronic hand dynamometer to send the load cell data using Bluetooth for rehabilitation purposes and use it as a controller to play games to improve grip strength?

The system device consists of a commercially available electronic dynamometer. The dynamometer is repurposed to stream its raw load cell via Bluetooth to the smartphone. A simple flappy bird-style game called grippyBird was designed to play with the dynamometer data. The patient's data is collected through the internet on a remote server to monitor and track progress in a therapist dashboard.

Phase 2 – System Evaluation

The newly designed system was tested against the Jamar dynamometer, the gold standard, to evaluate the telerehabilitation system for validity and reliability. We wanted

this new system to have valid measurements and produce reliable results. The usability of the system also was measured. After the institutional review board's (IRB) approval, we recruited 34 healthy subjects to collect the data for validity and reliability tests on this experiment. The following research question and associated hypothesis were developed for this experiment:

RQ2: To what extent is there a 2.5-pound difference in eGripper observations and Jamar dynamometer observations as a measure of validity and reliability of the eGripper?

H_{02}: Differences in observations of grip strength do not exceed 2.5 pounds between the eGripper and Jamar dynamometer.

H_2: Differences in observations of grip strength exceed 2.5 pounds between the eGripper and Jamar dynamometer.

Phase 3 – Clinical Trial

To conduct a clinical trial of the telerehabilitation system, we recruited eight patients with weak grip strength in a local hospital to measure the system's efficacy. The patients were divided into experimental and control groups, with both groups doing the prescribed exercises for four weeks. The experimental group used the newly designed system, with the control group using paper-based exercises and trackers.

RQ3: Will there be at least a 5-pound difference in improvements in grip strength between the experimental group using eGripper versus the control group using traditional paper-based handouts for home exercise programs?

H_{03}: Differences in observations of grip strength do not exceed 5 pounds between the experimental and control groups.

H_3: Improvement in observations of grip strength exceeding 5 pounds between the experimental and control groups.

RQ4: To what extent are the home exercise programs compliant between the experimental group using eGripper and the control group using traditional paper-based handouts?

Research Contributions

This research's results are expected to improve grip strength and compliance with home exercise programs in the experimental group using the eGripper. Some of the contributions of this research include:

- A novel application was developed to remotely monitor and modify home exercise programs with follow-up from therapists.
- New data were obtained for the concurrent validity and inter-instrument reliability of the eGripper system.
- Clinical insights were gained regarding the eGripper system's feasibility and efficacy in improving grip strength.
- New empirical data on the usability of the eGripper from the user’s perspective were obtained.
- New knowledge of how much this eGripper system contributes to home exercise compliance.

CHAPTER TWO

LITERATURE REVIEW

Chapter two presents a comprehensive review of the literature regarding home exercise programs and noncompliance, telerehabilitation, and grip strength. The following topics are included in this review:

Home Exercise Program and the Importance of its Compliance

A home exercise program (HEP) is a set of practical, economical, and personalized exercises prescribed by a therapist to be continued at home to enhance their functional recovery. HEP includes activities and tasks to strengthen muscles and increase joint range of motion, flexibility, endurance, balance, and activities of daily living (Anar, 2016). HEP should be continued for various reasons, like reinforcing newly learned or re-learned skills at the clinic to improve muscle memory, which can help build new skills further and improve strength, endurance, balance, and functions. The benefits of home programs include decreased disability, reduced falls, increased ability, and improved overall functions and quality of life. HEP also promotes the rapid progression of therapy to advanced levels. Chronic and progressive patients can benefit from consistent HEP in the long term to maintain strength and make functional gains long after clinical visits (Cegielski et al., 2017).

Non-Compliance to HEP

HEP compliance is a substantial problem, with factors affecting it multi-dimensional, including psychological and patient-centered, that vary between individuals

(Jin et al., 2008). Noncompliance to a home exercise program is as high as 50 to 65% for general musculoskeletal conditions (Bassett, 2003). In patients with lower back pain, non-compliance with home exercise is as high as 50-70% (Argent et al., 2018; Beinart et al., 2013). When patients have poor HEP compliance, their recovery journey can be delayed, and become prone to debility.

One essential responsibility of therapists is to provide HEP to their patients. When providing HEP, a therapist must consider these personal and psychological factors when designing an effective, personalized home exercise plan. Patients who firmly adhere to their prescribed exercises are considerably better at achieving their goals and demonstrate a more substantial increase in physical and motor function (Gaikwad et al., 2016; Palazzo et al., 2016). Overall, a strong need exists to identify potential barriers to HEP compliance and design strategies to combat those barriers.

Strategies to Improve HEP Compliance

Therapists are using various proactive strategies to improve patients' compliance with HEP. These strategies can have an impact on patients and can aid them in learning how to overcome noncompliance to HEP (Gaikwad et al., 2016). Supervised coaching with reinforcement also increases the probability of HEP compliance (O'Brien et al., 2021). Positive feedback and appreciation from the therapist and a rapid decrease in symptoms can boost patients' morale and compliance rates (Jack et al., 2010). The therapist should collaborate with patients to set exercise goals and monitor them regularly to encourage HEP compliance. Therapists also can incorporate automatic reminder systems to schedule patient exercise routines. For more interaction and real-time

monitoring, inertial measurement unit (IMU) sensors with audio can be a compliance facilitator and give patients live therapy sessions on physical activities and exercises (Jack et al., 2010). Jack et al. stressed that interactive systems could help patients perform tasks correctly and self-analyze their efficacy most reliably and efficiently. Compliance can be improved when therapists compliment patients on their achievements at each session. Education is an intervention that can affect patients' perceived threats and barriers by stressing the importance of compliance with HEP. Patients should be provided with written information and verbal instructions to improve compliance. To achieve high compliance rates, a therapist should develop a practical and comprehensive self-management plan incorporating the above practices, patient education, and behavior management (Peek et al., 2016).

Game-Based Rehabilitation

Game-based rehabilitation is a novel concept in rehabilitation, where patients in the rehabilitative services actively participate in a manner that invokes their motor and mental abilities. Game-based rehabilitation, also known as activity-based neuroplasticity, enhances motor learning by replicating real-life movements (Gandhi et al., 2021). Virtual reality is used in game-based rehabilitation to improve function and activities of daily living (Paquin & LeBlanc, 2013). Standards of rehabilitation protocols, including less dependence on rehabilitation personnel, increased intensity, frequency of activities, and creative treatment delivery, are improved with game-based rehabilitation (Silva et al., 2020). Its feasibility, motivation, and simplicity can be creatively and positively applied in rehabilitating post-stroke individuals (Gandhi et al., 2021). The advantage of game-

based rehabilitation programs is how therapy can be customized for each patient by using varied objects associated with daily living to the patient's needs (Silva et al., 2020). Task variability can improve motor performance rapidly (Srikesavan et al., 2016). The use of visual feedback, sensory feedback, and cognitive functions make game-based rehabilitation helpful and allows precise movements and inclusion of task dynamics during the therapy, thus promoting neuroadaptation in recovery (Gandhi et al., 2021).

Game-based exercises are also designed to engage cerebral palsy patients in physical activities using an exciting and entertaining environment (Daoud et al., 2020). Cerebral palsy is a non-progressive neurological disease characterized by motor impairments in the upper limbs, physical disability, and coordination deficits in early childhood (Golomb et al., 2010). An important factor in assessing the effectiveness of this system is intense observation of functional movements of patients while playing the games. These games aim to engage the patient in correct shoulder physical exercises, such as flexion, abduction, and adduction (Daoud et al., 2020). Kinetic sensors track patients' 25 skeleton joints in achieving human interaction in game-based rehabilitation (Daoud et al., 2020). The computerized assessment method is used to assess the correctness of arm movements by analyzing the data received by the Kinetic sensor during each game-playing session (Daoud et al., 2020). Bryanton et al. (as cited in Daoud et al., 2020) found that the Immersive Rehabilitation Exercise System (IREXS) could potentially engage cerebral palsy patients in targeted physical exercises for shoulder movements in an entertaining environment. The results reported in this study suggested

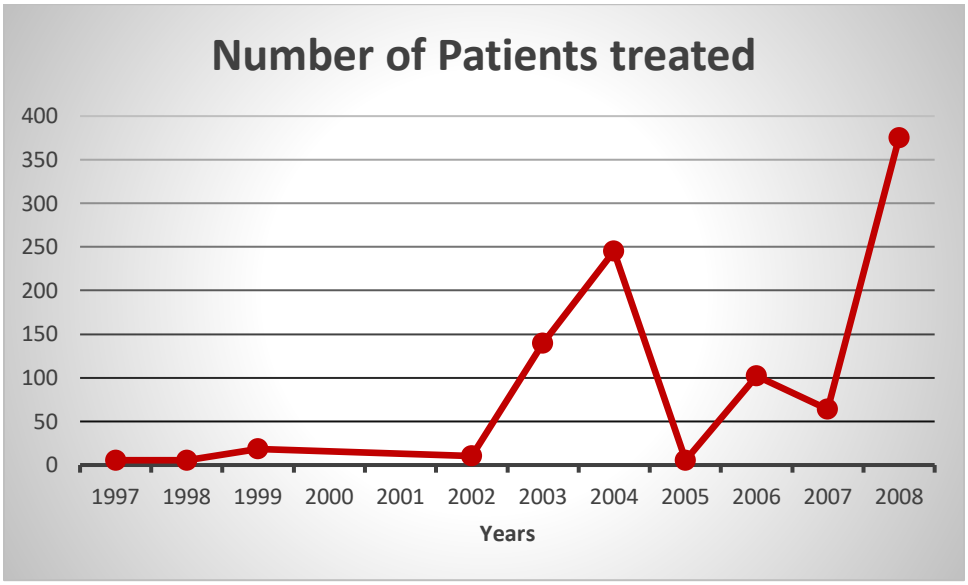
the feasibility of Bespoke Games in rehabilitation for cerebral palsy patients (Daoud et al., 2020)

Telerehabilitation and Different Modes of Delivery

Telerehabilitation is a new healthcare delivery modality that provides medical care to patients with rehabilitation needs via telecommunication or the internet (McCue et al., 2010). Through this rapidly growing technique, the physical therapist-patient relationship has evolved. Patients living in remote areas can easily access the therapist, and a therapist can easily control the rehabilitation through this technology. Compared to traditional rehabilitation, the cost of health care providers, travel expenses, and patient hospital stays has been dramatically reduced (McCue et al., 2010). The acute phase of diseases can be managed effectively through patient-rehabilitator interaction. This interaction facilitates the quick management of injuries, increasing patient efficacy to a satisfactory level. Telerehabilitation needs a computer, smartphone, or tablet with an internet connection and a device for one-to-one patient interaction. In the coronavirus (COVID-19), health care services prioritized telehealth as a safe delivery system to provide outpatient care (Kichloo et al., 2020). Telerehabilitation can be helpful for patients with brain injuries, musculoskeletal conditions, multiple sclerosis, osteoarthritis, motor disabilities, and surgical therapies. According to international publications on telerehabilitation, from 1998 to 2008, a significant increase occurred in development of these new communications and computer technologies (Gajarawala & Pelkowski, 2021). The emerging needs of people have increased the acceptance of this technology, as shown in Figure 1.

Figure 1

Acceptance of Telerehabilitation over Time.



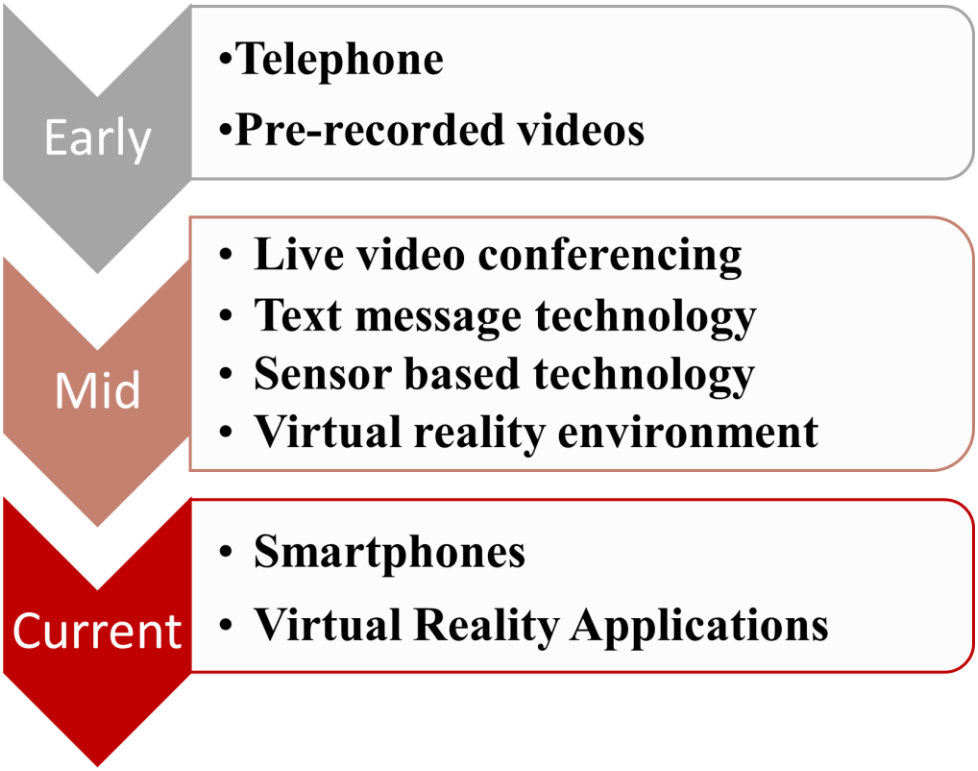
Note: Image source: Peretti, A., Amenta, F., Tayebati, S. K., Nittari, G., & Mahdi, S. S. (2017, July 21). Telerehabilitation: Review of the State-of-the-Art and Areas of Application. *JMIR Rehabilitation and Assistive Technologies*, *4*(2), e7. https://doi.org/10.2196/rehab.7511

Modes of Telerehabilitation Service Delivery.

According to early research, which started with small pilot studies, clinicians provided prescriptions and follow-up visits by telephone (Winters, 2002). In 1980, pre-recorded videos were introduced for client interaction. In the 1990s, video call conferencing with patients was introduced (McCue et al., 2010) as a powerful tool for providing patient consultations, diagnostic assessments, and treatments through audio and video interactions. These technological developments enable the patient to comply with HEP.

Figure 2

Progression of Telerehabilitation Technology



With the development of force sensors and remote monitoring technologies in telerehabilitation, therapists can measure a patient's range of motion and gait remotely (Attygalle et al., 2008). Environmental sensors gather information about patients' residences and their feelings about the home environment. Virtual reality is a successful entry into the healthcare delivery system, allowing therapists to interact in a computer-generated real-time environment during therapy, surgeries, and education (Lange et al., 2009a). Smartphones have also revolutionized the world of telerehabilitation, as half of the smartphone users use medical apps to get health consultations (Barrios et al., 2021; Bhamra et al., 2021; Espinoza et al., 2016; Ienaga et al., 2020).

Telerehabilitation for Assessment and Treatment

A positive effect was obtained for patients who had experienced strokes and were being treated at home for levels of social activity, activities of daily living, motor capacity, manual dexterity, and walking (Holmqvist et al., 1998). A significant decline was observed in the readmission rate, with patient satisfaction favoring the home treatment group.

Legg et al. (2004) concluded in a systematic review of randomized clinical trials of rehabilitation provided at home that therapy improved the ability to undertake personal activities of daily living and reduced the risk of deterioration in ability. In-home treatment reduces the incidence of delirium, the duration of rehabilitation, and costs in a frail elderly population. Patients who received therapy in their homes took the e initiative to set and achieve rehabilitation goals versus patients who received treatment in hospitals.

Espinoza et al. (2016) analyzed the accuracy of a hand dynamometer connected to a smartphone to assess rheumatoid arthritis (R.A.) disease activity by measuring hand grip strength. The authors presented an innovative health technology where they could remotely assess hand grip strength through a smartphone. The innovation consists of a digital dynamometer from Vernier Software and Technology, a smartphone, and a mobile application. The dynamometer interfaced with the mobile app and sent the measurement variables to a private database. This prospective study analyzed 82 R.A. patients that measured power, pinch, and tripod grips. The obtained data were significantly correlated against the disease activity score (DAS28), a standard criterion to measure disease activity. Espinoza et al. stated that the smartphone hand dynamometer device is a self-

assessment tool and does not depend on the healthcare professional for assessment. The device monitors the R.A. disease activity precisely, allowing clinicians to guide treatments using this device so that the patient can be quickly trained to perform the grip strength measure.

Dodakian et al. (2017) designed a home-based telerehabilitation system to evaluate stroke patients. Their telerehabilitation system consists of a 2' by 4' table, a Dell Laptop with a webcam added with a fish-eye lens, a USB modem for wireless internet, a USB-based blood pressure cuff, and a custom-made USB-based mat for contact-sensitive switches for input for the rehabilitation games. The study used a wrist splint with an accelerometer and a Music Glove. Their research goals were to assess the system's feasibility, measure patients' compliance with assigned treatment sessions, and quantify arm motor gains using their newly designed system. Twelve stroke patients were recruited for the pilot test, each reporting a compliance rate of 96.9% for at least 30 minutes a day for 28 days (Dodakian et al., 2017). They recorded at least 25,000 arm movement repetitions per person over the 28 days, indicating a significant gain in the arm function ($p < 0.0015$).

Neuendorf et al. (2018) designed a robotic ball for upper extremity training in stroke patients. The hardware consists of an electric motor and inertial sensors enclosed in a polycarbonate casing housing for the ball. The ball was connected to a smartphone. The study recruited 12 stroke patients who completed 45 minutes of training daily over 12 weeks. The findings of the study indicated a significant improvement in grip strength ($p < 0.005$) and unilateral dexterity ($p < 0.002$).

A telemonitoring system consisting of a Bluetooth pulse oximeter that records heart and SpO2 at 1 Hz was constructed by Bonnevie et al. (2019). The data were stored in a local database, transferred via Global Systems for Mobile Communications (GSM) to a remote monitoring place, and saved in a second database. A total of 105 participants with chronic respiratory disease were referred for pulmonary rehabilitation using this system. Most participants (98%) agreed that the system was easy to use and was willing to use it throughout pulmonary rehabilitation. The system transmitted 98% usable data and introduced minimal artifacts. Finally, the researchers concluded that the telemonitoring system was effective and acceptable for use in home telerehabilitation by people with chronic respiratory disease.

Integration of telerehabilitation and game-based rehabilitation

Telerehabilitation and game-based rehabilitation are two major research areas in their respect. Integrating both systems can have a mass-level service provision that is cost-effective and efficient. This integration concept looks progressive and attractive, but the compliance rate and specialized training are substantial hurdles to advancement. Patients with upper limb deficits can access virtual reality game-based rehabilitation through telerehabilitation. With the added possibility of adapting this platform to a home environment, telerehabilitation with remote supervision by a therapist would make this form of rehabilitation widely applicable, especially for individuals who lack access to rehabilitation facilities or have difficulty traveling regularly to a rehabilitation facility. Game-based telerehabilitation can emphasize task specificity, intensity, and training volume and may be more acceptable to patients (Burdea et al., 2020).

HEP via Telerehabilitation.

In an outpatient setting, a home exercise program (HEP) is advised for patients to target specific problems. Patients in home environments accomplish this scheduled program with the assistance of a therapist. The therapist can be in touch with patients through videoconferencing on smartphone healthcare applications (Chen et al., 1999). These supervised treatment sessions can help achieve short-term and long-term treatment goals and improve overall rehabilitation rates. Continuation of these monitored sessions builds intrinsic motivation and a positive response to the treatment. According to a pilot study of Lung Transplant Go (LTGO), a home exercise program was delivered through telerehabilitation. This intervention was delivered through a Versatile and Integrated System for Telerehabilitation (VISYTER) to lung transplant patients focusing on aerobic and strengthening exercises(Choi et al., 2016). Under the supervision of this program, patients improved their balance, walking distance, and lower body strength. Participants responded highly positively to this intervention, with no adverse events reported. They found the program acceptable, reliable, and feasible.

Grip strength and its importance

Grip strength is a biomarker for aging, overall strength, mobility status, bone mineral density, upper limb function, malnutrition, fractures, falls, sleep problems, depression, diabetes, cognitive impairment, multimorbidity, and quality of life (Bohannon, 2019a). Grip strength is a recommended standalone measurement for identifying the risk of the poor health status of older adults. According to research, grip strength is cross-sectionally associated with the strength of other body muscles, with

hand dynamometry measuring the overall strength practically (Bohannon, 2019a). Zhang et al. (2017) have reported a significant correlation between a 6-minute walk and grip strength. Kim et al. (2012) (as cited in Bohannon, 2019a) suggested that hand grip strength and bone mineral density increase the risks for fragility fractures. Grip strength can be a potential marker for malnutrition. Zhang et al. (2020) reported that a positive relationship existed between low grip strength and the risk of malnutrition. Grip strength can predict diseases because diabetic patients may have limited strength in lower limbs due to neuropathy. McGrath et al. (2020) reported that a 5kg decrease in grip strength had been associated with cardiovascular disease (CVS). Grip strength is also associated with multimorbidity, with an increase in comorbidities related to a decrease in grip strength. Improving grip strength can improve the quality of life among the "Chinese oldest old's" (Xie & Ma, 2021).

Grip Strength vs. ADL

Muscle weakness can affect grip strength and ability to complete activities of daily living (ADL). An independent and joint association has been found between grip strength and activities of daily living disability (Snih et al., 2004). Aging alters adipose tissue and muscle mass, changing body composition, and leading to functional limitations and ADL disability among older adults (Tanaka et al., 2021). According to cross-sectional and longitudinal studies, muscle weakness is predictive of ADL disability in Mexican Americans because of the prevalence of diabetes among older adults(Peterson et al., 2016). Thus, adopting strategies for strengthening muscles can help to decrease disability associated with completing ADL tasks and increase activities of daily living.

Grip Strength vs. Functioning:

Skeletal muscles help in mobility, locomotion, and daily activities and are the most important component at the tissue-organ level of body composition. Muscle and bone loss at older ages can result in impaired functional performance. Osteoporosis sarcopenia resulting from reduced bone mass can result in higher falls and fragility fractures. A decrease in muscle mass deteriorates muscle strength, thus affecting physical fitness, daily activities, and quality of life.

Grip Strength vs. Quality of Life (QOL):

The World Health Organization (WHO 2022) defined "quality of life (QOL) as an individual's perception of their position in life in the context of the culture and value systems in which they live and with their goals, expectations, standards and concerns" (para. 1). According to demographic data, the older population is increasing rapidly. It is expected to reach nearly 1.5 billion people older than 65 years worldwide by 2050 (Xie & Ma, 2021). This demographic trend challenges communities, government, and public health services to preserve the high health-related quality of life during old age. Increased vulnerability to diseases and adverse somatic changes in old age can negatively affect QOL. Health-related QOL is a multidimensional construct that depends on psychosocial, physical, and social health. Physical fitness is an essential predictor of health related QOL, with muscle and bone mass influencing grip strength. Occupational therapies, such as squeezing a spray bottle or rolling out dough, can improve grip strength and hand function and increase the quality of life.

Neuroplasticity's influence on improving grip strength

"Neuroplasticity can be defined as the brain's ability to change, remodel and reorganize for better ability to adapt to new situations" (Demarin et al., 2014). It forms neuronal synapses that strengthen the brain's structure and function, enabling a person to perform specific tasks frequently and fluently. When people can see and imitate a movement, that may stimulate mirror neurons to drive visuomotor neuroplasticity (Dobkin, 2004). The neuroplastic principles predict that neurons can be remodeled and reorganized to achieve the required task.

Homunculus is a functional representation of motor and sensory cortices according to the functions of the limbs. Smaller muscles and fine motor areas have a larger area of representation in the brain. The motor homunculus depicts that the area of the brain specialized for hands is huge see Figure 3 Gross body movements can recover faster than fine movements. This phenomenon occurs because a larger brain area needs to be recovered.

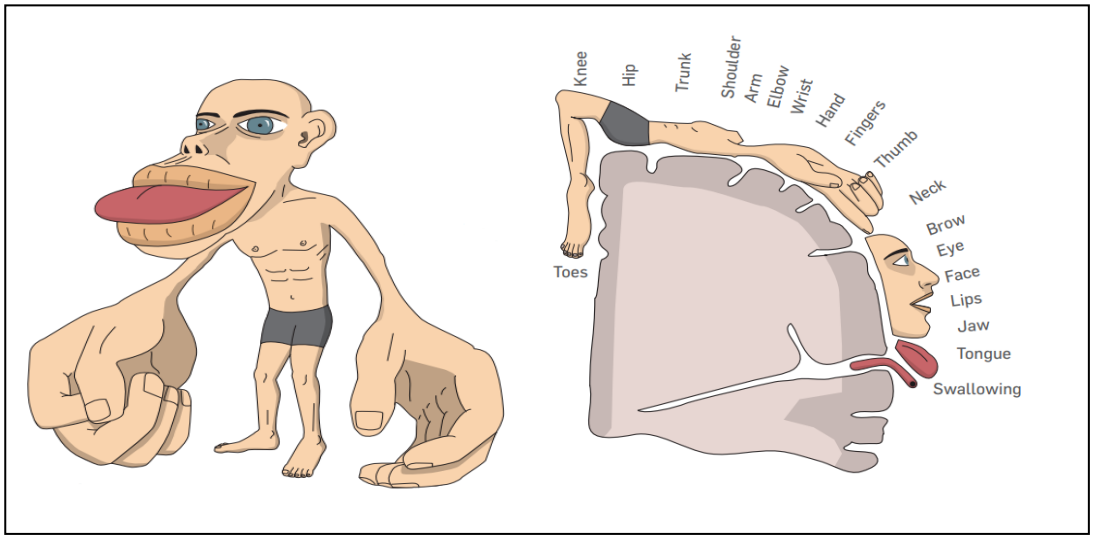
The Inpatient Rehab Facilities

Inpatient rehab facilities (IRFs) in acute care hospitals, as a rule of thumb, focus on gross motor and functional mobility skills such as bed-mobility skills, trunk control, pre-gait skills, and transfers which enable patients to ambulate. This process hustles the discharge and reduces the length of stay at the hospital, decreasing the costs of inpatient stay. Moreover, on the other hand, IRFs usually give a minor input to hand functions such as fine motor skills and grip strength because it takes a significantly longer time to

recover than lower extremity motor function (Dobkin, 2017). Rand and Eng's (2017) study suggested that grip strength improves up to 64% one-year post-stroke.

Figure 3

Motor Homunculus - Hands have a larger area than the arms and forearms



Note: Image Source: Brainmapper © Dr. Rebekah Corlew and Theo Walker (CC BY-NC-SA 4.0)

The Third-Party Payers

Third-party payers such as Medicare, Medicaid, and other insurance companies require rehabilitation therapists to have direct contact service delivery with patients for therapy to make payments. They usually do not reimburse inpatient rehab stays just to improve hand function skills. Due to these reimbursement cost limitations, direct contact therapy visits are often limited, and home-based exercise programs are prescribed. The patients, however, can do the exercises without help from a therapist. It may be hard for them to comply with the home exercise program for various reasons, such as the inability to perform individual movements, acquire appropriate feedback, and have poor pain tolerance. The compliance rate with home exercise programs drops as time passes.

Diseases and Conditions Affect Grip Strength

Stroke

Stroke is a leading cause of disability by losing functional abilities like getting out of bed, taking a bath or shower, using the toilet, dressing, preparing meals, and eating (Nowak & Hermsdörfer, 2009). Generally, patients survive the initial insult to their brain, but it leaves a long-term impairment on their activity limitation and reduced participation in daily activities (Eng, 2004). Upper extremity weakness results in about 70% of stroke survivors (Harris & Eng, 2010). In stroke, the brain loses control over muscle contractions, so people lose muscle tone and strength, resulting in motor impairment and limitations in functional abilities. There is a direct correlation between motor impairment and independence of performing functions (Yang et al., 2006). The maximal voluntary contraction force of the muscle is significantly reduced after a brain injury. Up to 40% of the survivors never regain functional use of the upper limb to perform daily activities (Harris & Eng, 2010). Loss of this muscle function is remediated with high intensity, a repetitive and practical task-oriented practice that should be meaningful for the patients (Barker et al., 2008). Studies have demonstrated that lower extremity functions have recovered faster in 3-4 weeks (Dobkin, 2004) while improving hand functions takes a long time (Sunderland et al., 1989).

Multiple Sclerosis

Multiple sclerosis is an autoimmune disease that affects the central nervous system and causes demyelination, inflammation, gliosis, and neuronal loss (Pellegrino et al., 2018). It presents symptoms like numbness and tingling, focal weakness, tremors,

fatigue, spasticity, vision impairment, cognitive dysfunction, and bladder and bowel incontinence (Mayo Clinic, 2022). The gradual progress in disease causes permanent disability in 10-15 years (Cree et al., 2016). As it affects mainly the upper body, the patient needs to use more force to hold on to move a thing due to decreased grip strength (Vanbellingen & Kamm, 2016). Higher healthcare-related costs are associated with problems with hand functions. These problems indicate the significance of finding the best treatments to improve hand impairments and the quality of life for people with multiple sclerosis.

Parkinson's Disease

Parkinson's disease is a neurodegenerative disease characterized by generalized slowing of movements with a symptom of resting tremor or rigidity (Radder et al., 2017). Other associated symptoms are sleep dysfunction, loss of smell, excess salivation, mood swings, and constipation. Weakness reported in this disease strongly influences muscle strength, and the patient would not be able to carry out daily living activities due to decreased grip strength (Garg & Dhamija, 2020). Parkinson's patients experience a loss of grip strength leads to functional limitations (Barichella et al., 2016).

Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease of joints characterized by chronic inflammatory arthritis and extra-articular involvement of synovial joints (Alomari et al., 2012). It involves the morning stiffness of multiple joints of both hands, restricting mobility (Williams et al., 2018). Pain and swelling of hands and wrist joints diminish hand strength and cause movement impairment, progressive muscle mass, and loss of

strength with age (Higgins et al., 2018). Males and females with Rheumatoid arthritis have lower grip strength than their healthy counterparts (Žura et al., 2021).

Spinal Cord Injuries

Cervical spinal cord injury is the most severe type of spinal cord injury as being close to the brain. It comprises cervical vertebrae from C1 to C7. The injury in this region usually results in tetraplegia or quadriplegia, i.e., complete, or partial loss of sensation below the shoulder/neck. The drastic decline in upper extremity function, primarily in the hands, significantly impairs grip strength and hand dexterity, thus affecting the quality of life and the capacity for independent living.

Carpal Tunnel Syndrome

Carpal tunnel syndrome is a painful and progressive compressive neuropathy. The median nerve inside the wrist is crushed by swollen flexor tendon. The symptoms include pain, numbness, or tingling in the hands and fingers. This sensation is more pronounced in the thumb, middle, and index finger causing a noticeable decrease in grip strength as the disease progresses.

Tennis Elbow

Lateral epicondylitis is an overuse injury involving the origin of the common extensor tendon at the elbow joint. The pain at the lateral epicondyle during power grip occurs because the extensor carpi radialis longus and the extensor carpi radialis brevis must work to counteract the flexion moment generated at the wrist by the digital and wrist flexors. Due to elbow position, the motor units for the wrist cross the elbow, and their length and muscle tension are affected, causing a reduction in grip strength.

Wrist Fractures

Wrist fractures occur when one of the two long bones in the forearm, i.e., radius or ulna, breaks close to the wrist. Distal radius fractures are more common as the radius is the most broken bone due to high-energy accidents. The fracture occurs about 1 inch from the end of the bone and results in pain, tenderness, swelling, and numbness in the fingers due to nerve injury, thus restricting hand dexterity and grip strength. To prevent permanent nerve damage, the doctor should address it quickly.

Clinical Conditions

We saw those neurological conditions like stroke, spinal cord injury, amyotrophic lateral sclerosis, and musculoskeletal conditions such as rheumatic arthritis, carpal tunnel syndrome, and muscular dystrophy were the common conditions in which grip strength was affected. One out of 15 studies did not mention experimental subject testing, while others had at least two subjects. One study by Jaspers et al. assessed 196 children's grip strength, and others used adult subjects. Among the experimental subjects, 146 had a stroke in five studies, 196 had rheumatoid arthritis in two studies, 17 spinal cord injuries, ten systemic cases of sclerosis, five muscular dystrophies, five amyotrophic lateral sclerosis, and five carpal tunnel syndromes were observed (see Table 1).

Table 1

Different clinical conditions and the number of subjects included in the study

System	Clinical conditions	# of subjects	Studies
Neurological	Stroke	146	Burdea et al., 2019; Park et .al, 2019; Rinne et .al, 2016; Park et .al, 2013, Vu et al, 2018
	Spinal Cord Injuries	17	Hoffman et al., 2017
	Amyotrophic lateral sclerosis	5	Geman et al., 2016
Musculoskeletal	Rheumatoid Arthritis	196	Salaffi et al., 2021
	Muscular Dystrophy	5	Geman et al., 2016
	Carpal Tunnel Syndrome	5	Geman et al., 2016

We classified the studies' intended usage of handgrip devices. A couple of studies stated that they had used the devices for treatment only, six studies designed their device for assessment of handgrip strength only, and the rest of seven studies intended for both evaluation and treatment of grip strength (see Table 2).

Table 2

Intentions of the devices

Intention	Studies
Evaluation	Noh et al., 2016; Jaspers et al., 2018; Vu et al., 2018; Salaffi et al., 2021; Chethna et al., 2020; Hoffman et al., 2019
Treatment	Park et al., 2019; Park et al., 2013;
Evaluation & Treatment	Roman et al., 2020; Rinne et al., 2016; Jaber et al., 2012; Mohan et al., 2013; Burdea et al., 2019; Pani et al., 2014; Geman et al., 2016

Types of Sensors Used for Grip Strength Measurement

Load cell – Strain-Gauge Type Sensors

A load cell is a force-transducer, a piece of metal wherein a strain gauge is attached. It transforms any mechanical force, such as a load, weight, tension, or compression, into another measurable physical variable, usually an electrical signal. The electrical signal changes proportionally to the force applied to the sensor. In the case of our device, the handgrip force is converted to a change in resistance. Load cells are susceptible to tiny changes of force. Typically, feeble grip strength of about 1 to 2 pounds of force is not easily measured with a standard JAMAR dynamometer from its mechanical dials. In this review, we listed the different types of load cells, from commercially available to patented ones used by various researchers such as

- N-type Strain Gauge Based Force Sensor,
- PW6KRC3 is a single point load cell by HBM (Datasheet: PW6KRC3), Vernier HD- BTA Strain Gauge (Datasheet: Vernier HD- BTA)
- Rinne et al. (2016) have a patented force-sensing mechanism called Flexible Metal Blade System. (US Patent document: Flexible Metal Blade System)

Resistive type sensors

Force Sensitive Resistor (FSR) is a variable resistor that changes its resistance depending on the force applied. These sensors are relatively affordable and straightforward to use in the applications, but their responsiveness slightly changes from sensor to sensor. So, when using FSRs, we should only expect a range of responses. In the case of grip strength, even if there are slight variations (about 0.5 to 1 lbs.), it does not

make a significant clinical difference (Bohannon, 2019b). Two research groups (Park et al., 2013; Salaffi et al., 2021) have used this sensor. The Salaffi group designed a cylindrical hand dynamometer and used 5 FSRs for individual fingers.

- Interlink 402 –Force Sensor (datasheet: Interlink 402)

Piezoresistive Type Sensors

Piezoresistive sensors are also called "Quartz Force Sensors." This sensor is used to measure force in dynamic applications. Load cell type sensors are used for static applications. The quartz force sensors have quick response, durability, toughness comparable to solid steel, extended ranges, and the ability to measure quasi-static forces. A hand gripping force is applied to the quartz crystal sensor, producing a proportional voltage signal. Some of the piezoresistive sensors used in the review were

- Flexiforce A201-a Piezoresistive force sensor by Tekscan (Datasheet: Flexiforce A201)
- FC22 Compressive force sensors by Measurement Specialties (Datasheet: FC22)

Pressure type sensors

Pressure-based force sensors are usually made as single monolithic silicon chip type sensors with a diaphragm with strain-gauge for pressure detection. Some chips come with integrated electronics such as a multiplexer, analog to digital converter, digital filters, and memory.

- MS5535C - Pressure Sensor Intersema Sensorielle SA (Datasheet: MS5535C)
- MPXM2202A - Pressure Sensor, Freescale Semiconductor (Datasheet: MPXM2202A)

Capacitive type

They are also called “Force sensing Capacitors” they change their capacitance when a force or stress is applied to the sensor. This change of capacitance is measured using capacitance to digital converters. In our review, Geman et al. (2016) used three capacitive force sensors to develop a novel device to measure grip strength in peripheral neuropathic patients. The study did not mention any specific manufacturer for the sensors, but we added a commercially available capacitive force sensor datasheet for reference. (Datasheet: SingleTact)

Displacement Sensor

The displacement sensor will measure the distance between an object and the sensor. One research group (Hoffman et al., 2017) has developed a spring-loaded dynamometer with a displacement sensor attached to one of its handles. They calculated the grip strength by detecting the displacement between the stationary and moveable handles and converting it into a distance. Using the distance moved, they converted into grip force using Hooke’s law ($F = -k \cdot x$)

Again, this research group did not mention the displacement sensors used in their novel device. Different types of displacement sensors are available commercially, including optical, linear proximity, and ultrasonic displacement sensors.

Fiber Bragg Grating (FBG) Sensor

The fiber Bragg grating sensor is also called an “Optical Strain-gauge.” This sensor is constructed using an optical fiber, where a microstructure grating is present within the core of the optical fiber. When light is passed through it, a specific light is

reflected. When a force such as grip strength is applied to its handles, there will be a slight shift in the reflected light's wavelength. One research team in India developed a dynamometer to measure grip strength using this FBG sensor (Chethana et al., 2020).

Device Handle Profiles

Studies were identified that had used various handles for grip strength measurement devices, including:

- *Cylindrical Profile*: The commonly used one is the cylindrical-shaped handle; 6 out of 15 studies have designed and used this handle.
- *Spherical Profile*: The spherical profile is the second most used handle. Three studies used ball-type profiles, and two others used variations of this type – pear-shaped and bulb-shaped profiles.
- *Straight Profile*: Most commercially available hand dynamometers have this straight profile handles. They have two handles – one fixed and another moveable. A mechanism is present between these two, such as a spring, hydraulic cylinder, or load cell sensor.

They have mentioned that commercially available dynamometers, such as JAMAR and Takei, have a straight profile handle that does not ergonomically fit the natural shape of the hand. The dynamometer handle movement only allows the fingers towards the palm, causing inaccuracies in measuring the grip strength.

Wireless Networking Protocols

A wireless network protocol should be used when delivering or collecting data through telerehabilitation. Devices like this handgrip dynamometer should use Bluetooth

communication between the nodes for a faster and smoother data flow. Our review has identified four studies that used Bluetooth to send data from the sensor to the computer or data acquisition system. One study mentioned using the HC-05 Bluetooth transceiver module for sending and receiving data from the sensor to the computer. HC-05 module has a small footprint and consumes low power, and it can be embedded into the dynamometer housing. HC-05 module establishes a serial port connection with the host computer. The other research group used GSM/GPRS for data transfer.

Gaming Capabilities

In making games for play with the gripping device, the device should have wireless capabilities to provide telerehabilitation services. The games should be easily playable and able to win with little effort; this will make the rehabilitation program more successful. We found in our review that eight studies incorporated gaming capability, and four had gaming and wireless communication capabilities. Jaspers et al. (2018) developed a portable grip force tracking system (GRIFT) to quantify mirror movements in children. The GRIFT system was incorporated with a computer game; the game's goal is to jump the astronaut over meteorites flying across the screen. When the child squeezes the GRIFT system with either hand, the system gets active and controls the position of an astronaut on the screen. A higher grip strength force translates the astronaut higher up on the screen to avoid collision with the meteorite. In this way, they could repeatedly engage the child in squeezing the hand gripper to measure the mirror movements in the children. The experiment done by Rinne et al. (2016) is like the movement of an object on the

screen; here, they control the vertical movement of the object using the grip strength analog signal.

Jaber's team mentioned the possibility of adding "serious games" to this system so that the grip ball could motivate a user to do exercises when linked to the gaming system. They also added that the grip ball could remotely evaluate the grip strength. Another team from India (Mohan et al., 2013) also mentioned using virtual reality games to engage patients in therapy. In a study by Roman et al., when the subject squeezes the cylindrical hand dynamometer, the subject can manipulate the movement of a bullet on the screen to move through a ring. The subjects get visual feedback on how hard they exert the force on the device based on the bullet's movement. The subject also performs a cognitive task with a level of hand force applied to the device. They designed this graphical user interface with LabView.

Vu et al. (2018) designed a system to assess both hands' grip strength sustainability and coordination. To measure this, their team designed a game-like interface in LabView; when the left-hand dynamometer is squeezed, the target, a "red ball" on the screen, moves vertically, and the ball falls if there is no grip signal. The right dynamometer's grip strength signal can move the ball horizontally to the right, and if no signal is received, it will move left. The ball will be in the original spot with no force signal from either dynamometer. The subject must squeeze both dynamometers to bring the ball to the target location. A visual trace and feedback are seen on the screen. Burdea and his team (2019) developed custom rehabilitation games using the Unity3D game engine; they also made it easy to play with the remaining skills and made games

winnable by all. They achieved this by calibrating the baseline grip strength prior to the gameplay and using 25% baseline for momentary grip and 10% of the maximum grip strength for sustained activities in the gameplay and manipulating the game avatars and objects.

Table 3

Studies with Title, Publication, and Population in which grip strength was measured

Article Type	Author	Title	Journal Name	Population
Conference	Mohan et al., 2013	A Sensorized Glove and Ball for Monitoring Hand Rehabilitation Therapy in Stroke Patients	2013 Texas Instruments India Educators' Conference	2 Healthy Subjects
Conference	Park et al., 2013	A rehabilitation device to improve the hand grasp function of stroke patients using a patient-driven approach.	IEEE ... International Conference on Rehabilitation Robotics: [proceedings]	2 Healthy Subjects and one stroke
Conference	Chethana et al., 2020	Design and Calibration of Fiber Bragg Grating Sensor for Analysis of Real-Time Skeletal Hand Muscle Strength	2020 IEEE International Conference for Innovation in Technology (INOCON) Bengaluru, India. Nov 6-8, 2020, Design	10 Healthy Subjects
Conference	Roman et al., 2020	A Novel Hardware and Software Interface for a Grip Force Tracking System	11th International Conference and Exposition on Electrical and Power Engineering (EPE 2020)	2 Healthy Subjects

Table continued

Table 3 - Continued

Article Type	Author	Title	Journal Name	Population
Conference	Geman et al., 2016	A novel device for peripheral neuropathy assessment and rehabilitation	2016 International Conference and Exposition on Electrical and Power Engineering (EPE)	5 Amyotrophic Lateral Sclerosis, 5 Muscular Dystrophy, 5 Carpal Tunnel Syndrome
Peer-reviewed	Jaber et al., 2012	Design and validation of the Grip-ball for measurement of handgrip strength	Medical Engineering and Physics	No Subjects
Peer-reviewed	Noh et al., 2016	Development Of Arduino-Based Hand Dynamometer Assistive Device	Journal of Mechanics in Medicine and Biology	25 Healthy adults
Peer-reviewed	Jaspers et al., 2018	GriFT: A Device for Quantifying Physiological and Pathological Mirror Movements in Children	IEEE Transactions on Biomedical Engineering	196 Children
Peer-reviewed	Pani et al., 2014	A device for local or remote monitoring of hand rehabilitation sessions for rheumatic patients	IEEE Journal of Translational Engineering in Health and Medicine	10 Rheumatoid Arthritis and 10 Systemic Sclerosis

Table continued

Table 3 - Continued

Article Type	Author	Title	Journal Name	Population
Peer-reviewed	Salaffi et al., 2021	Handgrip Strength Features in Rheumatoid Arthritis Patients Assessed Using an Innovative cylindrical-shaped Device: Relationships with Demographic, Anthropometric, and Clinical Variables	Journal of Medical Systems	186 Rheumatoid Arthritis patients
Peer-reviewed	Park et al., 2019	Game-based hand resistance exercise versus traditional manual hand exercises for improving hand strength, motor function, and compliance in stroke patients: A multi-center randomized controlled study	NeuroRehabilitation	50 Stroke
Peer-reviewed	Rinne et al., 2016	Democratizing Neurorehabilitation: How Accessible are Low-Cost Mobile-Gaming Technologies for Self-Rehabilitation of Arm Disability in Stroke?	PLoS ONE	87 Stroke Subjects

Table 4

Device Name, Sensor Types, and Characteristics

Sensor Types	Sensors	Device name	Wireless capability	Gaming Capability	Microcontroller &Signal Acquisition & Sampling	Author, Year
Load cell - Strain-gauge	N-type strain gauge - Strain Gauge Based Force Sensor	Novel device - Hand Dynamometer	Possibility mentioned	Not Mentioned	Arduino Uno R3 & AD524	Noh et al., 2016
	Compressive force sensors (Measurement Specialties FC22) - 0-23Kg accuracy	GriFT (Grip Force Tracking device) - cylindrical dynamometer	Not Mentioned	Yes	NI-DAQ USB-6009	Jaspers et al., 2018
	PW6KRC3 and PW2F-2 - Strain Gauge type	Grip Force Tracking System (GFTS)	Bluetooth	Yes	Digital Signal Controller PW2F-2	Roman et al., 2020
	Vernier HD- BTA Strain Gauge	BiGRA	Not Mentioned	Yes	National Instrument NI USB-6009 DAQ	Vu et al., 2018
	Flexible Metal Blade System Strain Gauge type	Adapted Power-grip controller	Bluetooth	Yes	Not Mentioned.	Rinne et al., 2016

Table continued

Table 4 - Continued

Sensor Types	Sensors	Device name	Wireless capability	Gaming Capability	Microcontroller &Signal Acquisition & Sampling	Author, Year
Capacitive based	three capacitive force sensors	A novel device	Not Mentioned	Not Mentioned	AD7746 capacitance to digital converter	Geman et al., 2016
Pressure-based	MS5535C - Pressure Sensor	Grip-Ball	Bluetooth	Possibility mentioned	PIC 18LF13K22 & 15 Hz	Jaber et al., 2012
	Intersema Sensorielle SA.					
	MPXM2202A - Pressure Sensor, Freescale Semiconductor	Sensorized ball	Not Mentioned	Possibility mentioned	PIC 18LF4620 CMCdaq	Mohan et al., 2013
	Pressure sensor	BrightArm duo	Not Mentioned	Yes	Not Mentioned	Burdea et al., 2019
	Pressure Sensor	TPS100 System	Bluetooth	Yes	Not Mentioned	Park et al., 2019

Table continued

Table 4 - Continued

Sensor Types	Sensors	Device name	Wireless capability	Gaming Capability	Microcontroller &Signal Acquisition & Sampling	Author, Year
Resistive type	5 FSR 402 – Force Sensor	Innovative Cylindrical shaped device	Not mentioned	Not Mentioned	Arduino Mega 2560	Salaffi et al., 2021
	an FSR-402 by Interlink	a hand grasp rehabilitation device	Not Mentioned	Not Mentioned	TMS320F2801 digital signal processor (DSP).	Park et al., 2013
Piezoresistive	an FSR-402 by Interlink	a hand grasp rehabilitation device	Not Mentioned	Not Mentioned	TMS320F2801 digital signal processor (DSP).	Park et al., 2013
Fiber Bragg Grating sensor	Fiber Bragg Grating sensor	Fiber Bragg Grating sensor-based Hand Grip Device	Not Mentioned	Not Mentioned	FBG interrogator (SM i130-700 and 1KHz	Chethana et al., 2020
Displacement	Displacement Sensor	MediSens Handgrip device	Not Mentioned	Not Mentioned	MSP 430 32Hz	Hoffman et al., 2017

CHAPTER THREE

DESIGN AND DEVELOPMENT OF A TELEREHABILITATION SYSTEM

Chapter 3 explains "phase one" of the research study, i.e., a detailed explanation of the design and development of the telerehabilitation system to answer the first research question: Is it feasible to design and develop a game-based telerehabilitation system to monitor and deliver home exercise programs on a smartphone along with repurposed electronic hand dynamometer to improve grip strength?

Proposed Telerehabilitation System

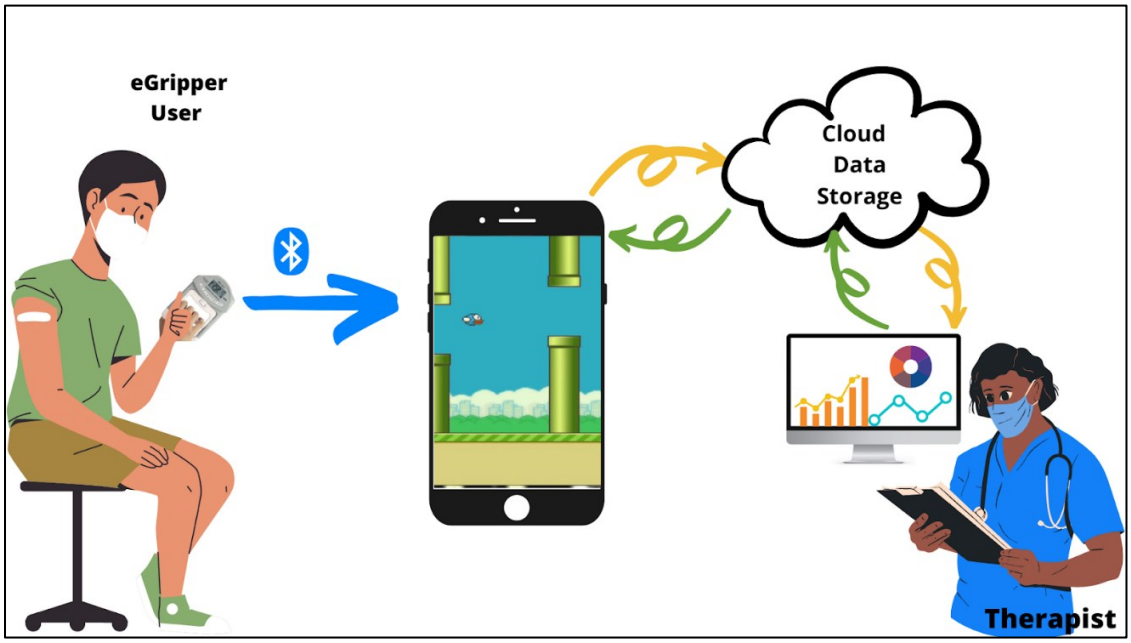
This research question was approached first by formulating a research goal to design and develop an innovative telerehabilitation system to incorporate HEP into interactive games to improve grip strength. Before designing the system, the process flow of the telerehabilitation system was identified. The process starts with the end-user, i.e., the patient, using the hand grip dynamometer that generates the data and sends it to the android smartphone via Bluetooth serial port. The smartphone has a game app where the character will move whenever the end-user squeezes the dynamometer. While the end-user is playing the game, the app sends the data to a remote cloud server for storage. A therapist can retrieve the stored data for analysis and change the game parameters according to the end-user's strength level. A therapist can set a goal; once the patient achieves the goal, the therapist can review and upgrade the goal.

This research goal to develop an innovative telerehabilitation system was divided into hardware and software components. An existing electronic hand dynamometer was

repurposed, and firmware was developed to acquire and send grip strength data via Bluetooth as a hardware component. The software includes a customized gaming environment for patients to play and a remote therapist dashboard to monitor grip strength and associated parameters and adjust exercises /gaming variables.

Figure 4

Proposed Telerehabilitation System



Note: The process flow starts from the end user, the patient shown as "eGripper User," squeezing the eGripper that sends processed data to the android phone to play games. The android phone sends the data to the cloud storage and receives customized patient game parameter data from the cloud storage to initialize the game. A therapist dashboard pulls data from the same cloud storage and displays the patient's clinical data. A therapist can alter the game according to the patient's functional status.

Hardware Prototype Design

In stage one, the goal was to acquire and measure the patient's grip strength and transmit the data to a smartphone. An electronic hand dynamometer with a strain-gauge-

based load cell sensor and a microcontroller with Bluetooth capability to send the raw data were needed to achieve this. A commercially available electronic hand dynamometer with the requirements (Figures 5a and 5b) was bought from eBay. The hand dynamometer was disassembled to expose the built-in electronic circuitry and the load cell sensor (Figures 5a and 5b). Before designing the custom printed circuit board (PCB) for this project, the initial feasibility was checked by building a pre-prototype assembly using existing breakout modules of a microcontroller and an analog-to-digital converter. The following section describes the load cell sensor and various hardware modules used in this project.

Figures 5a and 5b

(a) A commercially available hand dynamometer (b) A load cell inside the dynamometer

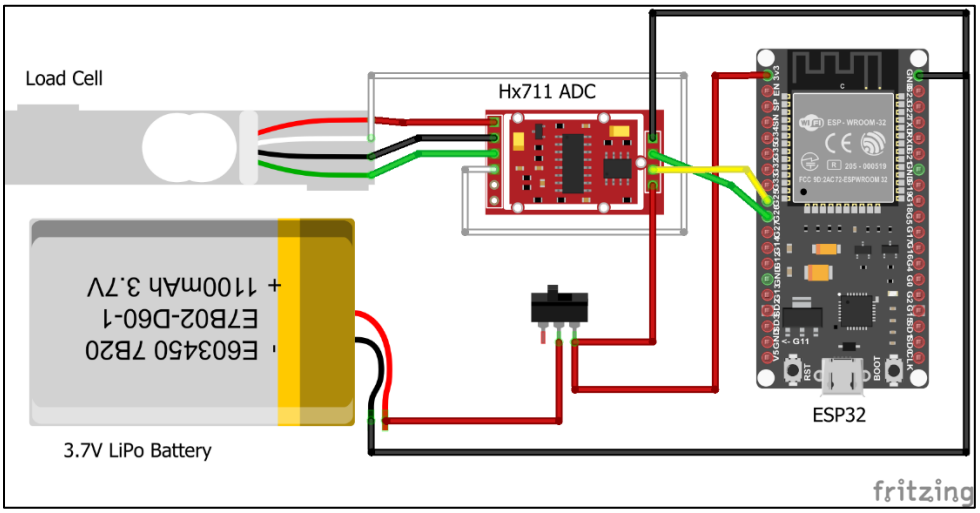
Load Cell Sensor

A load cell is a force transducer; it converts an applied force, such as grip strength, into a measurable electrical signal. The electrical signal generated by the load

cell is directly proportional to the grip strength applied on the dynamometer's handles. Different types of load cells exist - hydraulic, pneumatic, and strain gauge-based load cells. Strain-gauge-based load cells are known for their accuracy and cost-effectiveness and are commonly used for force measurements. Load cells are typically made up of a metal body, and strain gauge(s) were attached to it in a Wheatstone bridge configuration, and an external voltage power them through the red wire (+) and black wire (-).

Figure 6

Pre-prototype assembly



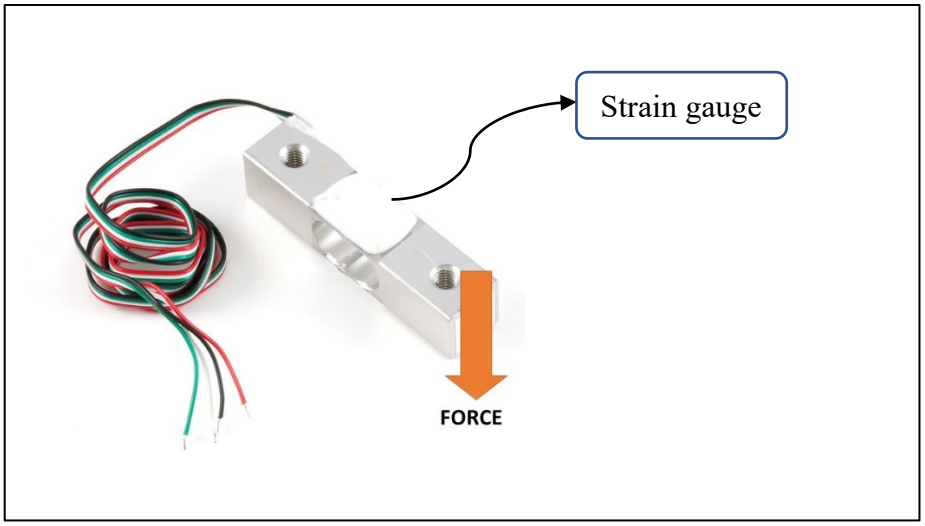
When a force is applied to the load cell, a change of resistance in the strain gauge causes a voltage difference directly proportional to the force applied. This voltage difference signal is obtained from green (-) and white (+) signal wires to measure the generated force. The load cell sensor is extracted from the device housing and disconnected from its built-in circuit board.

The manufacturer of the hand dynamometer mentioned that the load cell has a maximum loading capacity of 90kg/198 lbs. The average healthy subject's maximum grip

strength does not exceed 150lbs, and patients with weak grip strength will have lower values, so using this is an ideal sensor for our hardware prototype. The existing electronic circuitry from the hand dynamometer has a numerical LCD (liquid crystal display) panel to show grip strength in kg or lbs. units. Since we do not have the schematics of the existing circuit to know where to tap in to extract its raw output for transmitting the data through Bluetooth, because of this limitation, we designed our PCB (printed circuit board) to obtain the raw data to send it to the smartphone via Bluetooth.

Figure 7

Strain-gauge in the load cell

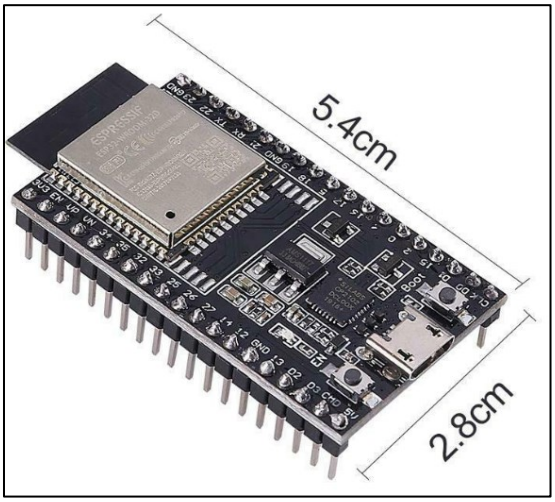


Espressif's ESP32 Microcontroller Unit (MCU)

We used Espressif's ESP32-WROOM-32E, a feature-rich 32-bit microcontroller (MCU) with integrated Wi-Fi and Bluetooth connectivity. It has a rich set of peripherals, ranging from capacitive touch sensors, Hall sensors, a secure digital card interface for memory storage, Ethernet, high-speed SPI, UART, I2S, and I2C. It is mainly used for mobile, wearable, and IoT applications due to its ultra-low power consumption.

Figure 8

The preassembled plug-and-play ESP32 module



It can function reliably in various environments, with an operating temperature ranging from -40°C to +125°C. The integrated chip has a low-power coprocessor to save power for tasks that do not require computing power, such as monitoring peripherals. The prepackaged breakout module has multiple general-purpose input-output (GPIO) ports. It comes with a built-in voltage regulator, USB (universal serial bus) to TTL (transistor-transistor logic) converter, and other components which will make this module ready to plug and play.

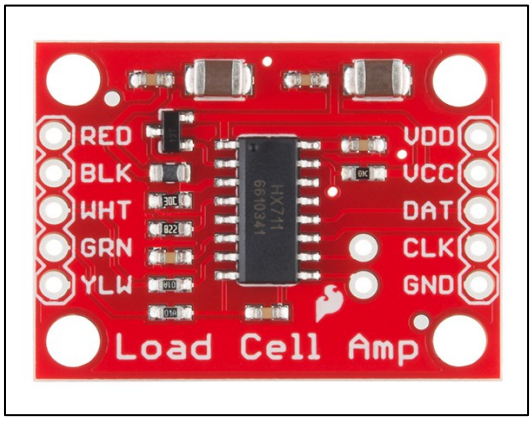
HX711 ADC module

An HX711 is a commercially available, 24-bit precision ADC module for weighing scale applications. HX711 can directly interface with the Wheatstone bridge of the load cell. HX711 has a low-noise programmable gain amplifier (PGA), and two channels, A and B, can be selected through an input multiplexer. HX711 can be programmed with a gain of 128 or 64 for a full-scale differential input voltage of ±20mV

or ±40mV, respectively. The output from the load cell, i.e., the voltage difference, is in the millivolts range. The microcontroller's GPIO ports cannot read or detect in mV ranges. The ADC will amplify the voltage difference and be converted to digital output for easier transmission from ADC to ESP32 microcontroller.

Figure 9

HX711 Load cell Amplifier



Power supply

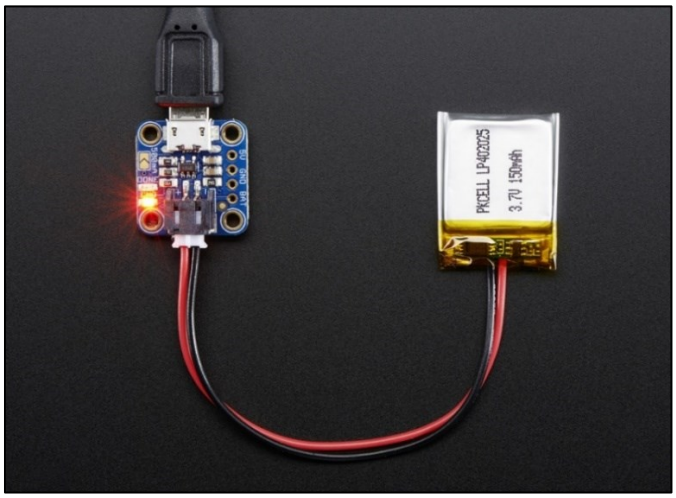
We used a 3.7-volt rechargeable lithium battery pack with 2000mAH to power our assembly (Figure 10). It is connected to Adafruit's micro LiPo charger, which has a small form factor. It is easy to use with any micro-USB cable and a rechargeable 3.7V LiPo battery plugged into the JST (Japan Solderless Terminal) plug. This battery charger has two LEDs; one indicates the battery is charging, and another indicates that it is fully charged and ready to use.

The load cell has four wire terminals; on one end, each terminal was connected to the four nodes of the Wheatstone bridge (Figure 7), and the other was connected to the HX711 ADC. The ADC receives the input from the load cell, and the ADC's digital

output and clock pins are connected to GPIO ports IO26 and IO25, respectively, in ESP32.

Figure 10

Charger Circuit and Power Supply



The ESP32 is programmed with a custom firmware program to send the clock input to the ADC to send the digital output (explained in the following section). Once the ESP32 receives the digital output data, it sends the data to the android phone through its built-in Bluetooth module. The android phone receives the digital output data through its serial port; A Serial Bluetooth Terminal app by Kai Morich was used to read the load cell sensor raw data. Since the prototype circuit was newly assembled, the raw data obtained from the Android Bluetooth serial terminal will have an eight-digit number which makes no sense until it is processed.

A preliminary calibration was performed to make the raw data a meaningful output. This calibration setup is explained in the next chapter. After testing for feasibility, a custom printed circuit board (PCB) was designed as the main prototype module. The

PCB was designed in EasyEDA, an online PCB design tool; please see the PCB design in Figure 11 and the schematics in Figure 12.

Figure 11

Custom printed circuit board (PCB) prototype

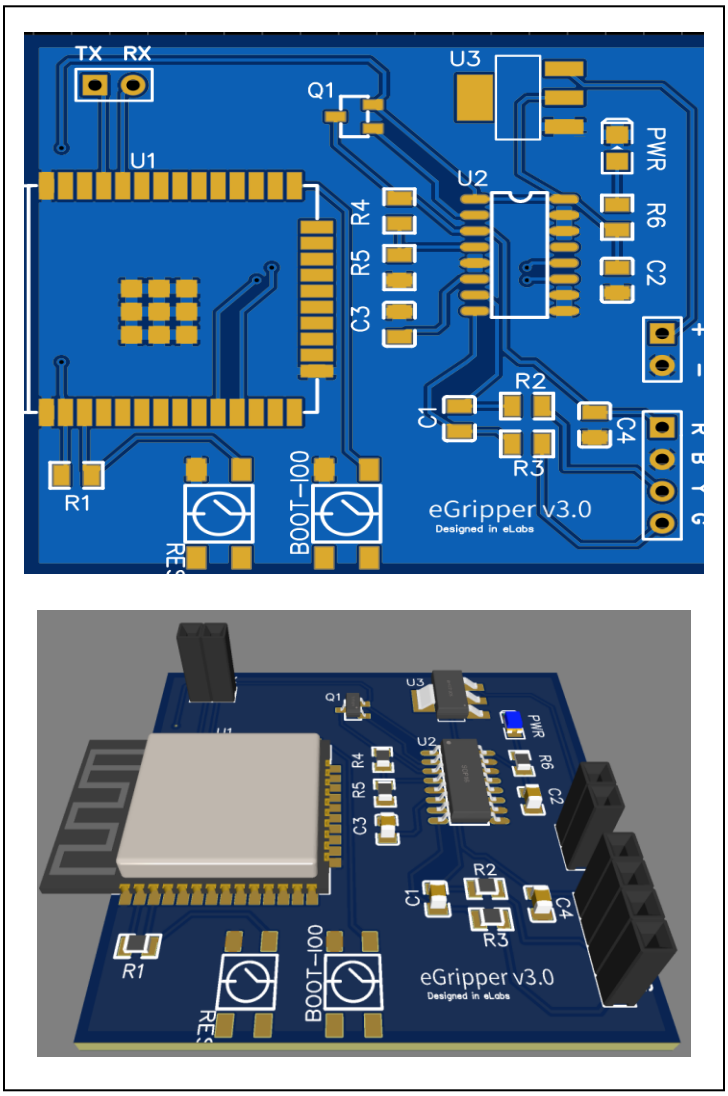
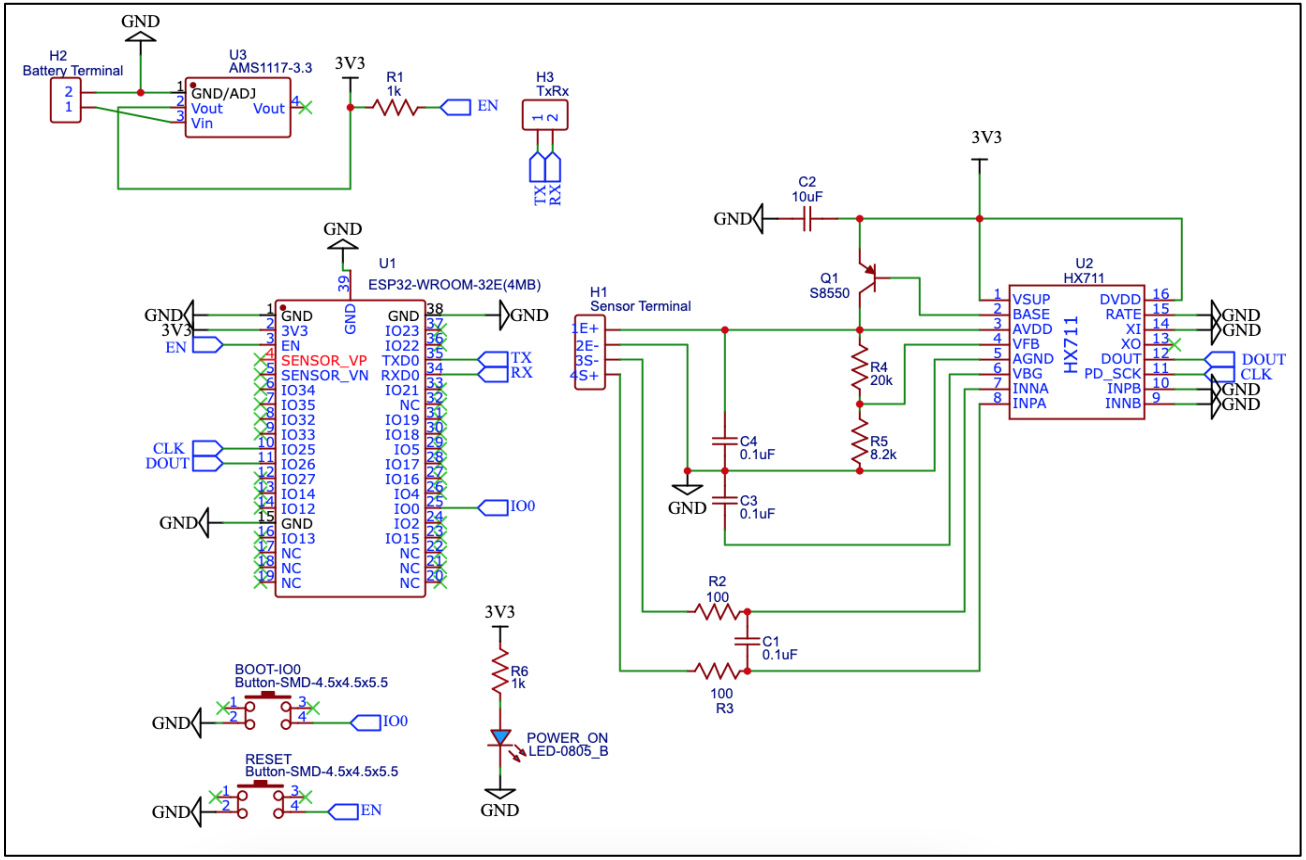


Figure 12

PCB Schematics



Firmware development

The firmware for the ESP32 microcontroller was programmed in embedded C language, and it has two purposes. One was receiving and processing the load cell's raw data from the hand dynamometer. The other purpose was to send the processed data to the android phone over Bluetooth communication protocol. As mentioned in the previous section, the newly assembled circuit sends the raw data to the Android Bluetooth serial terminal with an eight-digit number which makes no sense until it is processed. The firmware was built using Microsoft's Visual Studio Code, a code editor, and PlatformIO – an integrated development environment (IDE) for embedded systems. This firmware uses three external libraries for coding – Arduino, BluetoothSerial, and Q2HX711. Each library was installed through the PlatformIO IDE. Arduino library is used for ESP32 GPIO operations to send and read data to and from HX711 and other mathematical operations for manipulating raw data to convert it to meaningful data. The BluetoothSerial library, as the name says, is used to send the processed data to the Android phone via the Bluetooth serial port. Q2HX711 library is used to manipulate the pins and access digital output data from the HX711 ADC.

After including the external libraries, an instance of the BluetoothSerial object was created as AndroidBT. The pin configurations of HX711 are defined, and the global variables are declared. A "zero" float type variable holds the initial raw data, and subsequent raw data reads after every 500 milliseconds were subtracted from the zero variable to give the absolute change in value. The new data is captured in a "temp" variable, and the temp is divided by 5000, a calibration factor, to get the exact weight in

pounds and stored in the “weight” variable and sent to the android phone via Bluetooth serial port. The following section explains the process of obtaining the calibration factor.

Figure 13

Firmware code is written in embedded C language

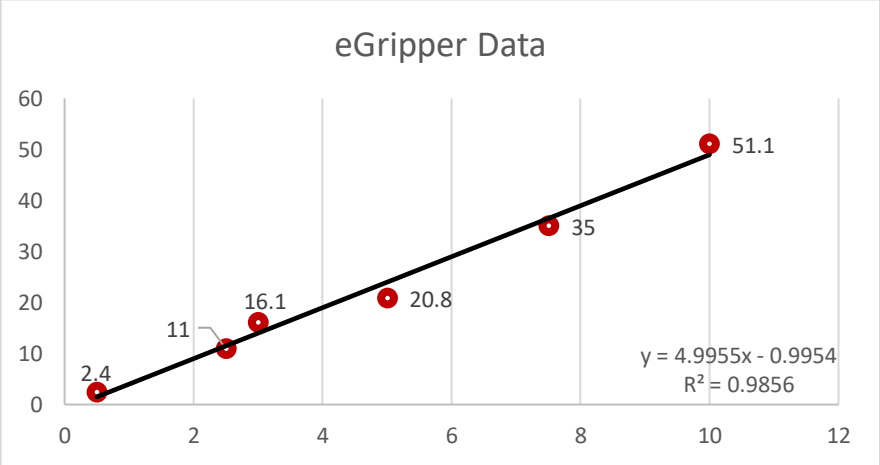
```
#include <Arduino.h>
#include <Q2HX711.h>
#include <BluetoothSerial.h>

#if!defined(CONFIG_BT_ENABLED) ||
!defined(CONFIG_BLUEDROID_ENABLED)
#error Bluetooth is not enabled! Please run `make menuconfig` to
and enable it
#endif

BluetoothSerial AndroidBT;

const byte hx711_data_pin = 26;
const byte hx711_clock_pin = 25;

Q2HX711 hx711(hx711_data_pin, hx711_clock_pin);
float zero;
float temp;
float weight;
void setup() {
Serial.begin(115200);
AndroidBT.begin("eGripper-XX"); //Bluetooth device name
Serial.println("The device started, now you can pair it with
bluetooth!");
delay(100);
zero = hx711.read();
zero = hx711.read();
Serial.print("Zero:");
Serial.println(zero);
}
void loop() {
delay(500);
temp = (zero - hx711.read());
weight = (temp/4995.5); // divided by Calibration Factor
AndroidBT.println(weight)
      }
```

Estimating the Calibration Factor

The eGripper's newly designed circuit needs to be calibrated and zeroed. Initially, the raw output from the eGripper was measured without any weights; after that, a few known weights were loaded on the platform, and the raw output with known weights was measured. The initial output without any weights was subtracted from the output with known weights. Since the device's resolution was in three orders of magnitude, minor weight changes were largely amplified, so the raw output was divided by 1000 to get the correct order of magnitude for the output in pounds. After this correction factor, a few known weights of 0.5, 2.5,3, 5, 7.5, and 10 lbs. were loaded, and their outputs were recorded in Microsoft® Excel. The linear regression was computed with the known weights vs. its corresponding output data. The regression equation showed 4.9955 as the multiplier of the weights. The final step in processing the raw data was to divide the output by 4.9955 to yield the corrected values. These calibration and conversion factors were hardcoded in the firmware in the ESP32 for accurate output values.

Figure 14

Calibration Factor - see the regression equation y=4.9955x



Software design

The software design consists of firmware, a smartphone app, a game, and a dashboard.

App Development

Two smartphone apps were developed using Apache Cordova - an open-source mobile development framework, and web technologies – HTML (Hypertext Markup Language), CSS (Cascading Styling Sheets), and JavaScript for feasibility and testing. It was deployed for android devices only.

The primary function of the first app was to receive the Bluetooth serial port data from the eGripper and display it on the screen. The app has a connect button; when pressed, it will connect to the eGripper device via a Bluetooth serial port. After connecting, the raw data from the eGripper gets processed in the microcontroller's firmware and sent to the android phone. The android app displays the processed data on the screen. The app also has a max grip strength placeholder, displaying the max grip strength. It will be updated whenever the person squeezes more than the current value.

The second app is a customized game. In this app, the processed data from the eGripper is transmitted for game character manipulation. Game development mechanics are explained in the following section. Whenever the patient is playing the game, the app pushes data into the google firebase cloud server for storage. The administrator dashboard retrieves the data to display the clinical parameters.

Game Development

The game was developed using P5JS, a visual JavaScript library to sketch 2D art. P5JS library was used for its simplicity and ease of use. A small game was programmed from scratch with a few lines of code. Integrating games into webpages and using Bluetooth data as an input can be difficult and time-consuming, but with P5JS, it was effortless to integrate with HTML and JavaScript. A simple flappy bird-style game, "grippyBird," with one level of control, i.e., moving the bird high up in the air, was developed.

Game mechanics

The mechanics of the grippyBird game is that a bird will fly on midlevel in the air and encounter obstacles such as electrical posts in varying shapes and sizes. The goal is to avoid the electrical posts so the bird will be alive and keep flying and dodging the obstacles.

The process flow for the grippyBird game starts when a patient squeezes the eGripper, and the load cell data is transmitted to the android phone. The data is sent to the game program as a streaming variable that makes the grippyBird character fly high to avoid obstacles. Once the character is high in the air, gravity brings the bird to mid-level. The game's therapeutic goal was to make the patient squeeze the eGripper repeatedly to avoid obstacles and score points. The obstacles come in varying sizes and speeds to keep the patients engaged in the game. The score will be reduced during the gameplay if the player hits an obstacle.

The therapist can customize the grippyBird game's parameters, such as set how much grip strength is needed to make the bird fly higher, how much score can be added or reduced if an obstacle is dodged and hit respectively, adjust the speed of the obstacle and levels. A customizable time limit can be set to reduce muscle fatigue in patients.

Figure 15

eGripper and GrippyBird Game

Administrator Dashboard Development

The administrator dashboard was programmed with HTML, CSS, and JavaScript web technologies. This dashboard aimed to retrieve the eGripper data and display it as a graph for the frequency of squeezes. It will also display the maximum grip strength during the session and the number of repetitions performed.

An administrator dashboard was designed for therapists to monitor, track patients' progress, and modify game parameters to alter the exercise regimen. The dashboard displays the patient's progress in clinical parameters such as muscle strength, endurance, usage time, and overall compliance with the prescribed home exercise program.

CHAPTER FOUR

TESTS OF RELIABILITY AND VALIDITY

Chapter four describes the experimental setup and procedures for reliability and validity tests of the repurposed hand dynamometer measured against the gold standard Jamar dynamometer and the known weights. The research question and associated hypothesis for this phase of the study are:

RQ2: To what extent is there a 2.5-pound difference in eGripper observations and JAMAR dynamometer observations as a measure of validity and reliability of the eGripper?

H_0: Differences in observations of grip strength do not exceed 2.5 pounds between the eGripper and JAMAR dynamometer. $H_0: |eGripper - Jamar| \leq 2.5$

H_a: Differences in observations of grip strength exceed 2.5 pounds between the eGripper and JAMAR dynamometer. $H_a: |eGripper - Jamar| > 2.5$

Reliability

Clinicians frequently measure grip strength and depend on measurement data to make decisions. These decisions are determined by the extent to which clinicians can rely on tests, instruments, or devices that provide as accurate and relevant clinical data as possible to map patients' traits or behaviors. The main attribute of measurement is reliability, that is, how consistent and error-free a measurement is, and reliability can be stated as the reproducibility or dependability of a measurement (Portney & Watkins, 2015). A reliable examiner can measure repeated outcomes with consistent results;

similarly, the reliable instrument is assumed to measure with predicted consistency (Portney & Watkins, 2015). Validity estimates the extent to which an instrument measure is free from error (Vogt & Johnson, 2016). Mathiowetz (2002) reported that nine studies had examined the concurrent validity and the inter-instrument reliability of seven different grip strength devices.

Inter-instrumental reliability is an experiment that compares a novel instrument with the gold standard. Here the eGripper is tested against the Jamar dynamometer. This inter-instrument reliability experiment is conducted with healthy participants measuring their grip strength with the two instruments within minutes apart.

Traditionally, the correlation coefficients like Pearson product-moment correlations and Spearman rho were used to establish the relationship between the instruments, and t-tests were used to measure the agreement between the instruments (Portney & Watkins, 2015). Recently, the intraclass correlation coefficient (ICC) has been suggested as a more reliable test as it measures the degree of association and agreement between instruments with a single value (Portney & Watkins, 2000). An excellent ICC score is 0.90 or above; 0.75 to 0.90 is considered good; 0.50 to 0.75 is moderate, and anything less than 0.50 is poor (Portney & Watkins, 2015).

Validity

Validity is the device's ability to measure what it intends to measure (Portney & Watkins, 2015). Validity represents the value given to a score and how the value obtained should be used and interpreted. Validity also emphasizes the value of measurements in clinical decision-making. Concurrent validity is a study to measure the device's

(eGripper) output to be validated against the criterion measure (Jamar dynamometer; Portney & Watkins, 2015). Measuring the agreement between two instruments is considered a concurrent validity: for instance, the eGripper measures grip strength in the same way as the 'gold standard' Jamar dynamometer. Another type of concurrent validity is assessed when known weights are suspended from the handle of a dynamometer. Fess (1987) describes this method as checking dynamometer calibration. The Pearson product-moment correlation is used to obtain a correlation coefficient between the weights suspended from the two dynamometers that measure this concurrent validity. Fess (1987) suggested that $r \geq 0.9994$ is considered acceptable.

Methodology

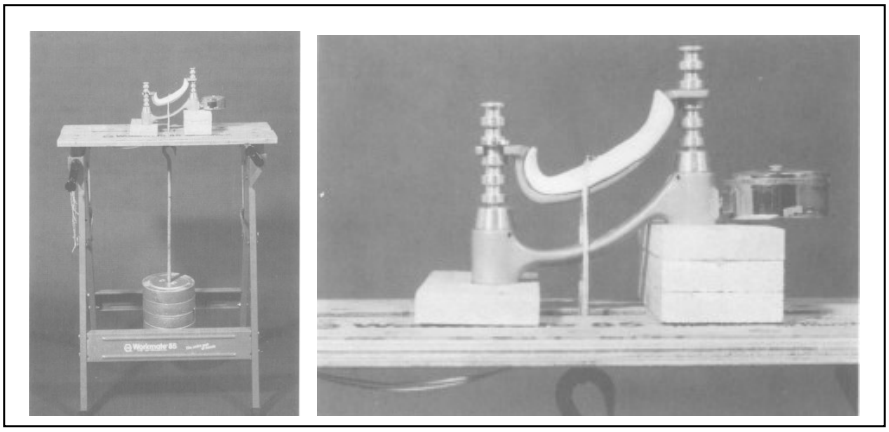
Experimental Setup for Validity

According to Fess (1987), the eGripper was set up for the validation experiment (Figure 16 and 17). Due to the unavailability of a split-top workbench, a foldable ladder was used to stabilize the eGripper and suspend weights. The eGripper's stationary handle was stabilized on top of the ladder between the top two steps, and a flat piece of a metal bar was placed across the steps. The eGripper is further steadied using two bar clamps on each side of the eGripper. All measures were taken to ensure the eGripper's stationary handle was stable, and the movable handle was free to move without obstructions. An easy-hang Velcro strap with a hook was suspended from the moveable handle, where a wooden platform was hung to load weights. The eGripper was zeroed prior to placing the weights on the platform. The weights from 0.5 to 130 lbs. were gradually loaded on the wooden platform. The weights loaded on the platform were sensed by eGripper, the

output was sent to the android app via Bluetooth, and values were recorded from the android app.

Figure 16

Fess's (1987) Experimental Setup to Calibrate and Measure Concurrent Validity



Note: Image source: Fess, E.E. (1987). A method for checking Jamar dynamometer calibration. Jour. of Hand Therapy, 1, 28-32.

Figure 17

Our Experimental Setup According to Fess (1987) for Calibration and Measure Concurrent Validity

Sample Size Estimation

A priori power analysis was conducted in Minitab (Minitab Inc. State College, PA) to estimate the sample size. A power analysis was conducted in Minitab® to determine the appropriate sample size; using the following settings: statistical test that was used was a paired t-test, the difference between means was 2.5 lbs., expected standard deviation was 5 lbs., power and alpha levels were set at .80 and 0.05 respectively, and alternate hypothesis was not equal to H_0. The power analysis results indicated that 34 subjects needed to be tested to reject the null hypothesis. (Figure 18).

Figure 18

Minitab Power and Sample Size Analysis Results for Reliability and Validity Experiments

Power and Sample Size - Reliability Experiment

Paired t Test

Testing means paired difference = 0 (versus ≠ 0)

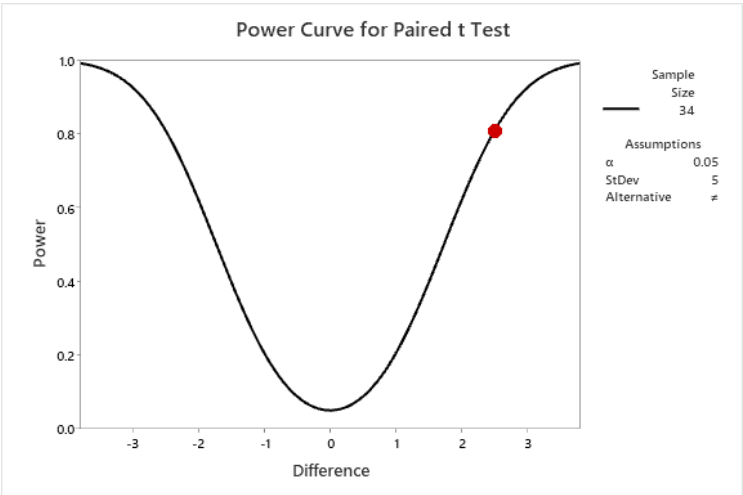
Calculating power for mean paired difference = difference

α = 0.05 Assumed standard deviation of paired differences = 5

Results

Difference	Sample Size	Target Power	Actual Power
2.5	34	0.8	0.807778

The sample size is for each group.



Participants

Thirty-four volunteers participated in the study to provide grip strength data. The study recruited healthy participants aged 18 years or older who did not have pain in their hands or impairments such as arthritis, fracture, or carpal tunnel syndrome. One participant with pain in their thumb was not included in the sample. Participants ranged from 27 to 62 years old, with a mean (standard deviation) age of 41.4(10.7). Fourteen male and 20 female adults participated in the study, of whom 29 were right-handed, five were left-handed, and one was ambidextrous.

Table 5

Study participants characteristics

Participants Characteristics	
Mean Age	41.4
SD Age	10.7
Min age	27
Max age	62
Males	14
Females	20
Right-handed	29
Left-handed	4
Ambidextrous	1

Instruments

A hydraulic Jamar dynamometer and a newly repurposed eGripper were used for this experiment. Jamar is known as the "gold standard" in hand dynamometry and has excellent validity and reliability scores (Ashford et al., 1996; Fess, 1987; Flood-Joy & Mathiowetz, 1987; Mathiowetz, 2002; Mutalib et al., 2022; Peters et al., 2011) The

purpose of this experiment was to establish the measures of validity and reliability for the eGripper device.

Procedure

The institutional review board (IRB) approved this study, and the necessary permission was obtained from where the study was held (see Appendix A for a copy of the IRB and the permission letters). This inter-instrument experiment was conducted in the rehab gym at Select Specialty Hospital, Pontiac. The study procedures were explained to all participants, and informed consent was obtained before the experiment. The participants were instructed with the standard verbal instructions to avoid confusion. (See Appendix B). The grip strength was tested according to the American Society of Hand Therapists (ASHT) recommendations. The participants were seated on a straight-back chair with both feet on the floor. They were positioned as such that their shoulder will be adducted and neutrally rotated, elbow flexed at 90°, forearm in a neutral position, and wrist between 0° and 30° dorsiflexion and between 0°and 15° ulnar deviation (see Figure 19).

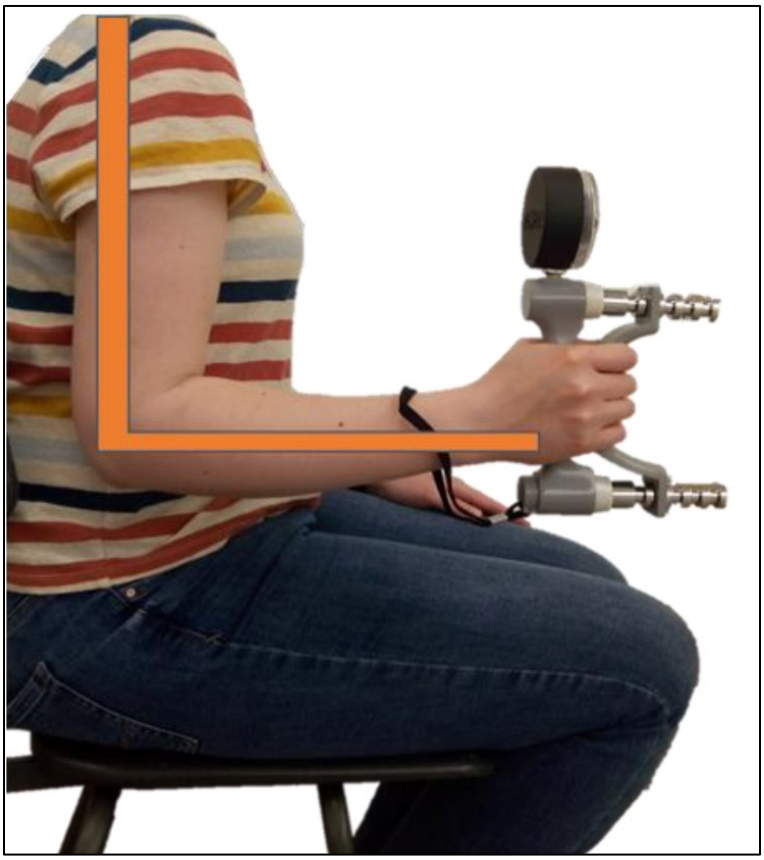
The participants were asked to squeeze the dynamometer as hard as possible to elicit maximal grip strength. They were given tryouts for both devices and enough time to recover before the start of the experiment. Providing tryouts familiarized them with the expectations of the experiment and reduced their anxiety.

Once they were ready for the experiment, three trials were obtained using both devices with each hand for 12 trials per participant. The participants rested between trials for approximately 30 seconds and two minutes before switching hands and devices to

avoid fatigue bias. While the right hand was resting, the subject did trials on his left hand and vice versa. The initial hand and the dynamometer tested were randomized to avoid learning effects, fatigue, and device bias.

Figure 19

ASHT recommendation for grip strength testing



Note: Image source: Bardo, A., Kivell, T. L., Town, K., Donati, G., Ballieux, H., Stamate, C., Edginton, T., et al. (2021). Get a Grip: Variation in Human Hand Grip Strength and Implications for Human Evolution. Symmetry, 13(7), 1142. MDPI AG. https://doi.org/10.3390/sym13071142.

Data Analysis

For the concurrent validity with the Jamar dynamometer, a paired t-test was performed, with a 2.5 lbs. difference between pairs and a 0.05 significance level.

Pearson's correlation coefficient (r) was estimated for concurrent validity with known weights; in addition, a percentage difference between Jamar and eGripper was calculated using the difference between means divided by the average of means. ICC (1,1) levels of agreement against "the gold standard" were calculated for inter-instrumental reliability.

Findings

RQ2: To what extent is there a 2.5-pound difference in eGripper observations and JAMAR dynamometer observations as a measure of validity and reliability of the eGripper?

H_{02}: Differences in observations of grip strength do not exceed 2.5 pounds between the eGripper and JAMAR dynamometer.

H_2: Differences in observations of grip strength exceed 2.5 pounds between the eGripper and JAMAR dynamometer.

The known weights versus eGripper data were plotted (Figure 20), and the trend line and the r value are 0.9994 was calculated. A paired t-test was performed on the grip strength data between the Jamar and eGripper devices. The testing of paired t-test assumptions for normality was performed using Shapiro-Wilk's normality test and found no significant difference from a normal distribution. The p-value for paired t-test for mean grip strengths found insufficient evidence to support a significant difference between the Jamar dynamometer and eGripper device. Bland-Altman plots were done to show agreement between both devices. Based on these findings, the null hypothesis of no difference between the eGripper and Jamar dynamometer was retained.

Figure 20

Regression Plot for Known Weights vs. eGripper

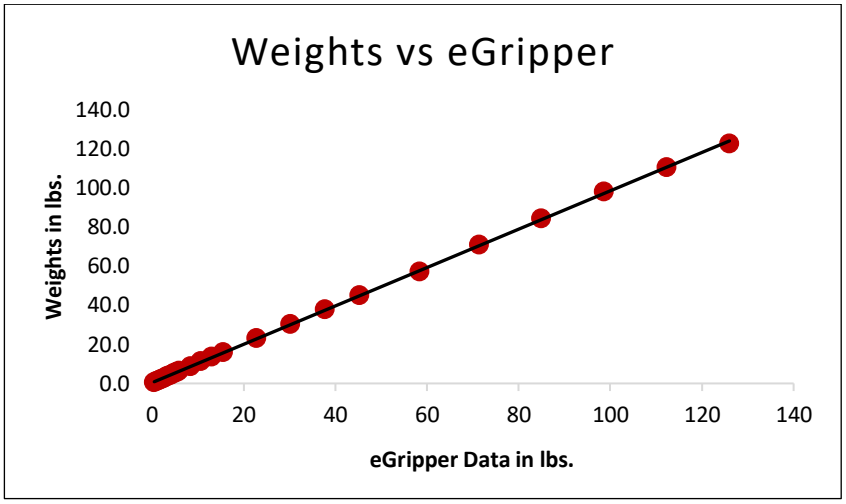


Table 6

Results of Paired t-Tests Comparing Jamar and eGripper

	Jamar Right	***eGripper Right***	***Jamar Left***	***eGripper Left***
Mean	69.61	66.36	71.33	69.32
SD	26.83	26.12	27.68	26.84
Pearson Correlation	0.94		0.98	
df	33.00		33.00	
t Stat	0.49		-0.47	
P(T<=t) two-tail	0.63		0.64	
t Critical two-tail	2.03		2.03	
ICC	0.94		0.97	

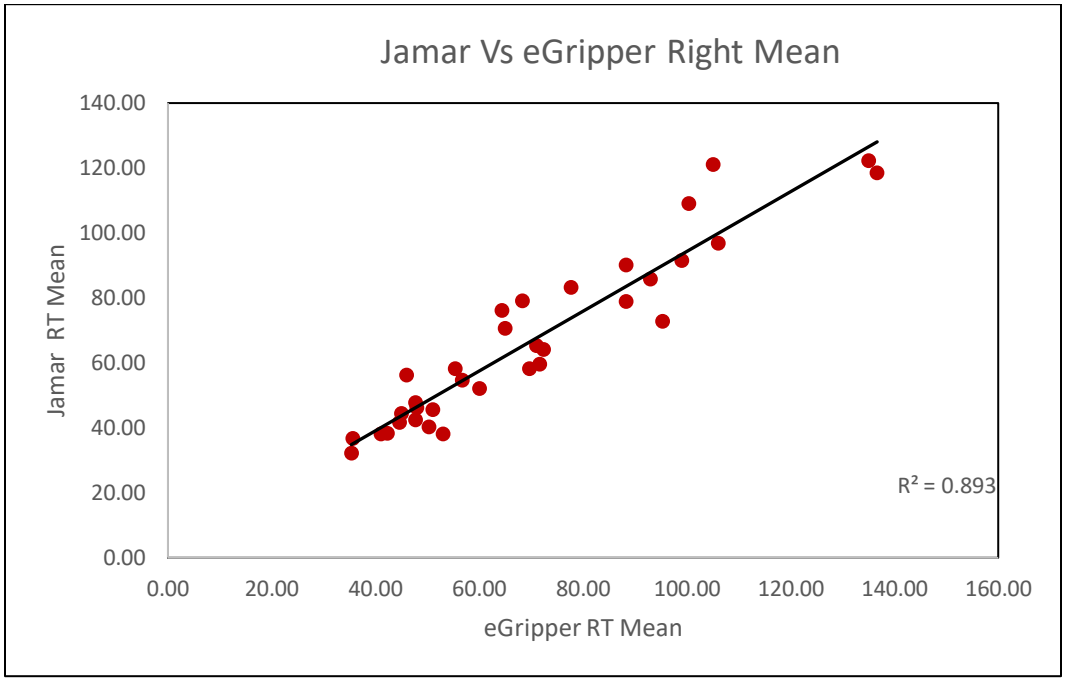
Table 7

Concurrent validity with known weights for all four devices

Devices	**Correlation coefficient**
eGripper 1	0.999926
eGripper 2	0.999962
eGripper 3	0.999922
eGripper 4	0.999926

Figure 21

Regression plots for Right and Left Jamar vs. eGripper dynamometers



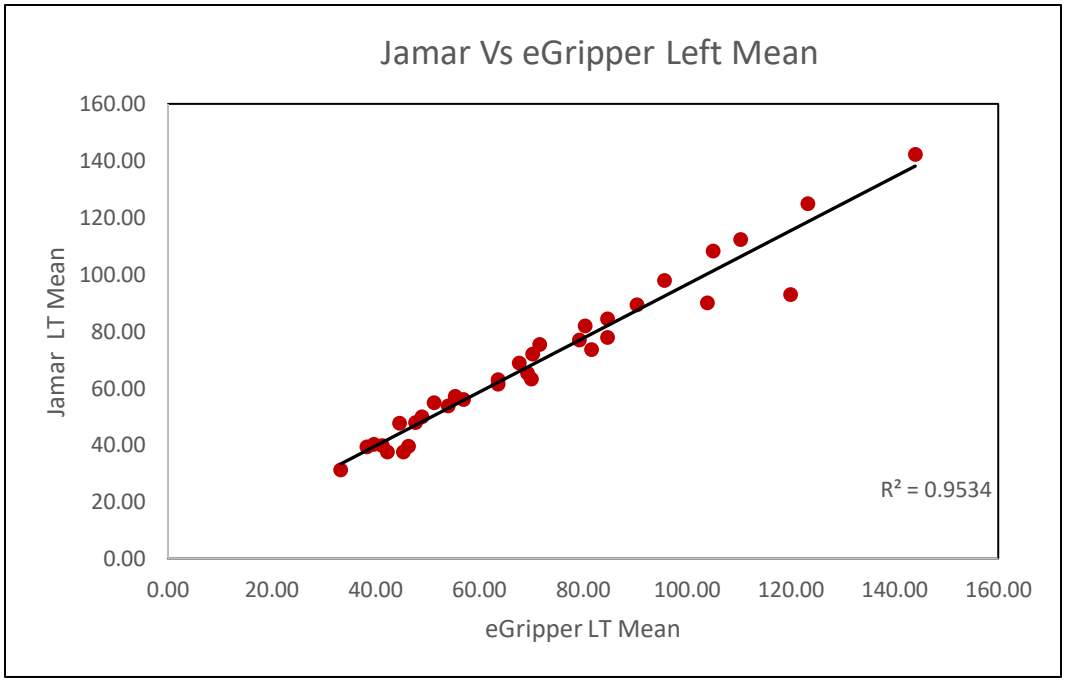
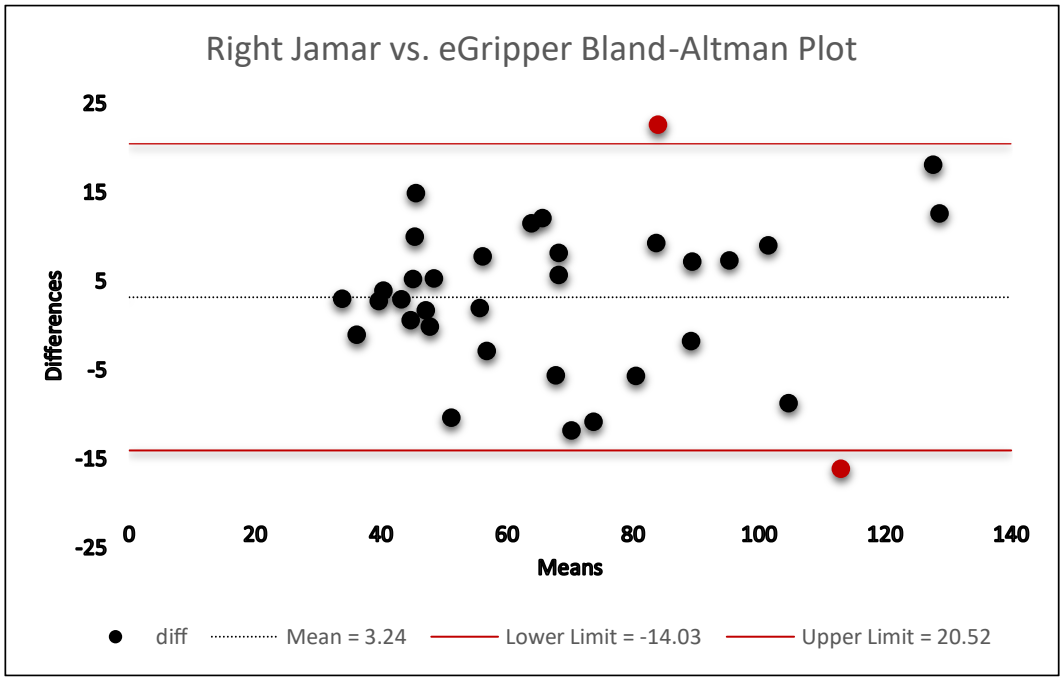
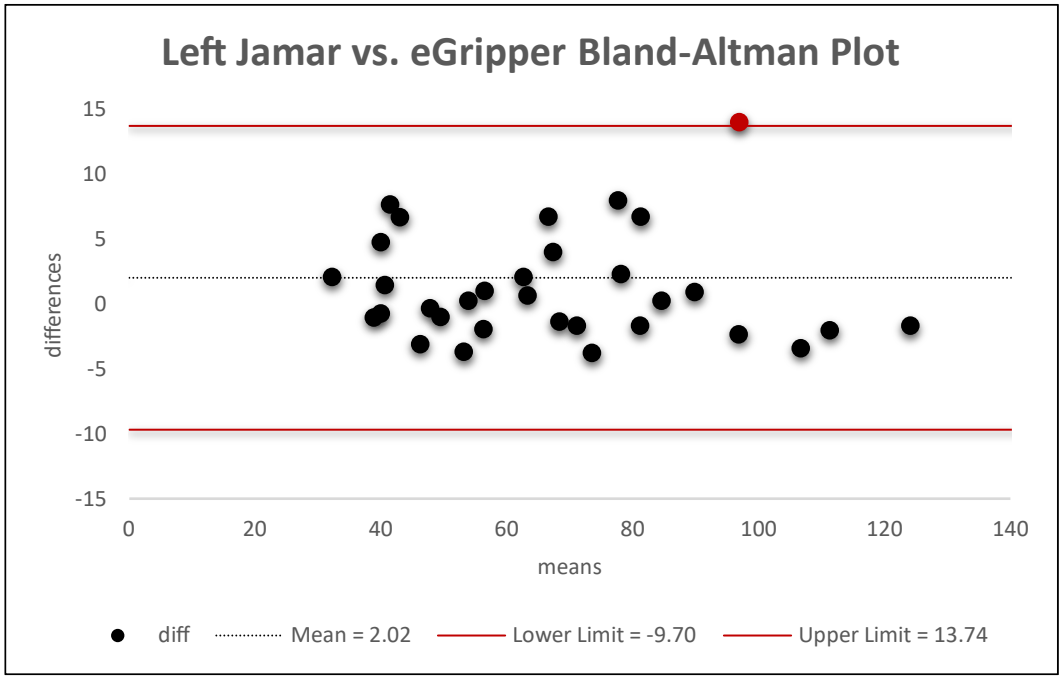


Figure 22

Bland-Altman plots for Right and Left Jamar vs. eGripper dynamometers





CHAPTER FIVE

RANDOMIZED CLINICAL TRIAL

Chapter five discusses the methodology of this research's third phase of the randomized clinical trial. In this clinical trial, two research questions were tested.

RQ3: Will there be at least a 5-pound difference in improvements in grip strength between the experimental group using eGripper versus the control group using traditional paper-based handouts for home exercise programs?

H_{03}: Differences in observations of grip strength do not exceed 5 pounds between the experimental and control groups.

H_3: Improvement in observations of grip strength exceeding 5 pounds between the experimental and control groups.

RQ4: To what extent are the home exercise programs compliant between the experimental group using eGripper and the control group using traditional paper-based handouts?

Methodology

Experimental Design

This clinical experiment was a randomized controlled trial using a pretest-posttest control group experiment. This study randomly assigned participants to either the experimental or control group. All participants completed a pre and post-test grip strength measurement. The control group followed the paper-based HEP, with the experimental

group using the eGripper telerehabilitation system for four weeks. The participants were followed up at the end of their fourth week.

Sample Size Estimation

A priori power analysis was conducted in Minitab® (Minitab Inc. State College, PA) to estimate the sample size; using the input settings - the 'two sample with t-test was selected,' the difference between means was 5 lbs., expected standard deviation was set to 2.5 lbs., power, and alpha level set to .80 and 0.05 respectively. The alternate hypothesis is not equal to H_0. The power analysis resulted in 4 participants per group needed to reject the null hypothesis (Figure 23).

Figure 23

Power and Sample Size - Clinical Experiment

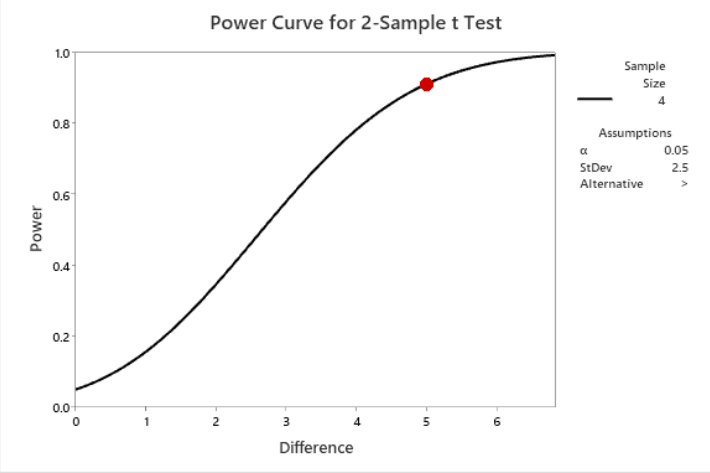
Power and Sample Size - Clinical Experiment

2-Sample t Test
Testing means 1 = mean 2 (versus >)
Calculating power for mean 1 = mean 2 + difference
α = 0.05 Assumed standard deviation = 2.5

Results

Difference	Sample Size	Target Power	Actual Power
5	4	0.80	0.801534

The sample size is for each group.



Participants

Eight participants were recruited for this study. Four participants were randomly assigned, either to the experimental or control group. The inclusion criteria for this clinical study were patients with poor grip strength measured with a JAMAR dynamometer, with a minimum of 10 pounds of force in either hand. Participants had to be at least 18 years old, male, or female, and be able to follow simple instructions in English. The exclusion criteria were patients with cognitive or perceptual impairments and less than 10 pounds of grip strength.

Procedures

The participants for this study were recruited from three locations, one from a local hospital in Pontiac, MI, and two from outpatient clinics in Warren, MI. The principal investigator (PI) also was an occupational therapist (OT) employed at a local hospital.

The PI performed an initial OT evaluation and screened the patient for the selection criteria when admitted to the hospital. If a patient met the inclusion criteria, the PI provided the patient with a research flyer and explained the purpose of this clinical trial. After the patients read and understood the study protocol and if they expressed their willingness to participate, the PI obtained their informed consent and enrolled them in the study.

Patients from outpatient clinics were evaluated by their respective staff therapists. If a patient met the inclusion criteria, their respective staff provided their patients with a copy of the research flyer with the PI's contact information. If a patient was interested in

participating in the study, they contacted the PI to express their interest. The PI then met with the potential research participant and clarified the clinical trial's purpose. When a patient agreed to participate after reading the research protocol, the PI obtained their informed consent and enrolled them in the study. After the enrollment, each participant was randomly allocated a control and an experimental group using the random function in Microsoft Excel®.

Before beginning the experiment, each participant was tested for grip strength in the same procedure described in chapter four (see Figure 19) as their pretest data. The control group participants received paper-based HEP instructions (Appendix E), handouts, and a paper-based tracker. The experimental group received the eGripper and a customized grippyBird game to play with the eGripper. The duration of the experiment for both groups was four weeks. The PI monitored the experimental group at regular intervals and provided necessary feedback and gradations to the exercise program from the remote monitoring system.

For the control group, the PI demonstrated all exercises and asked the participants for a return demonstration of all learned exercises to ensure they understood all the exercises. The control group participants were instructed to mark the day’s check box after completing their daily exercises; this process helped the PI track their compliance. At the end of four weeks, the participants were asked to turn in the paper-based tracker to measure the HEP compliance rate.

Each participant from the experimental group received an eGripper and a 7-inch amazon fire tablet with the game app pre-loaded on it. The PI demonstrated how to

switch on the eGripper, open the tablet app, and play with it. All experimental group participants were asked to return-demonstrate on the operations of the eGripper and the app. Only the grip strength data were collected remotely via the android tablet in a secure online cloud database system (Google-Firebase). Each day the games could be played for up to 5 sessions with a max of 10-minute blocks. The participants were not required to play games for 10 minutes every session. After each session, the participant could not play the games for at least one hour to force a rest break to prevent fatigue.

At the end of 4 weeks, final grip strength was measured for all participants, and they were asked to complete two standardized surveys to measure the usability of the telerehabilitation system. Chapter six will describe the methodology of usability testing.

Data Analysis:

A pre and post-test measure of hand grip strength of the affected hand were taken. Grip strength is measured in pounds. The pretest measures of hand grip strength for the two groups were compared using t-tests for independent samples to determine that the groups were similar before starting the experiment. At the end of four weeks, a t-test for independent samples was used to compare the mean change scores for the two treatment groups. A box plot was plotted to show the visual difference between the groups. To compare compliance, a comparison of the number of days engaged in therapy was shown as a bar chart.

Findings

Descriptive Analysis

For this clinical experiment the participants age ranged from 39 to 67 years with mean (standard deviation) age of 58 (8.98). Of the 8 participants, 6 were right-handed and 2 left-handed, with equal male and female ratio. The participant had a variety of diagnoses from carpel tunnel syndrome, tennis elbow, multiple sclerosis, mild traumatic brain injury, stroke, and cervical radiculopathy.

After determining that the samples had been drawn from populations with equal variances, the two-sample t-test comparing the initial grip strength for both experimental and control groups was completed. No statistically significant differences were found on the pretest grip strength measures comparing the experimental and control groups prior to starting the intervention ($p > .09$; See Table 8). The posttest t-test results differed significantly ($p > .01$) between the experimental and control groups (See Table 9). These results provide support that grip strength increased significantly when participants used the eGripper.

Table 8

Pretest Two-Sample t-Test: Comparison of Grip Strength

	Control	Experimental
Mean	34.75	49.25
SD	12.37	6.95
Observations	4	4
Hypothesized Mean Difference	0	
df	6	
t Stat	-2.04	
P(T<=t) two-tail	.09	
t Critical two-tail	2.45	

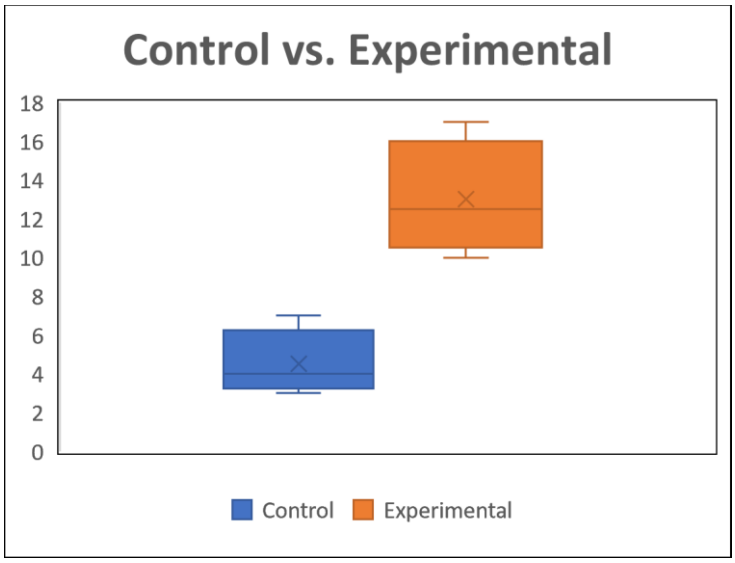
Table 9

Posttest Two-Sample t-Test: Comparison of Grip Strength

	Control	Experimental
Mean	39.25	62.25
SD	12.04	8.38
Observations	4	4
Hypothesized Mean Difference	5	
df	3	
t Stat	-2.82	
P(T<=t) two-tail	0.01	
t Critical two-tail	2.45	

Figure 24

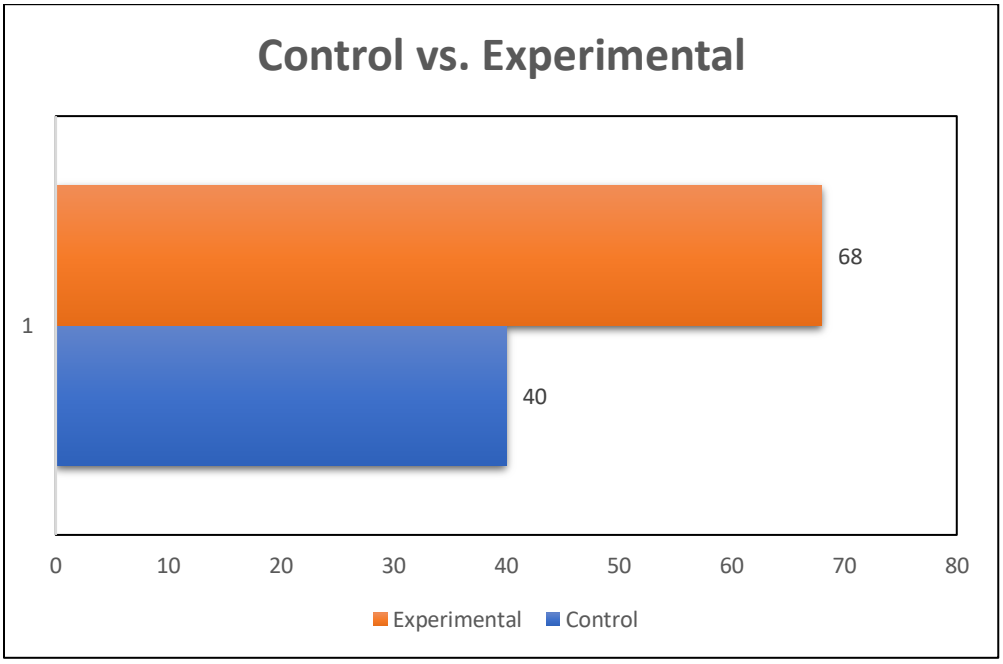
Boxplot for the difference in grip strength between control and experimental groups



Compliance was compared between the groups using the number of days HEP were performed by the experimental (eGripper) and control group (paper-based HEP). The results indicated that the eGripper group (n = 68) participated in exercises more days than the paper-based HEP group (n = 40). Figure 25 presents a graphical representation of this information.

Figure 25

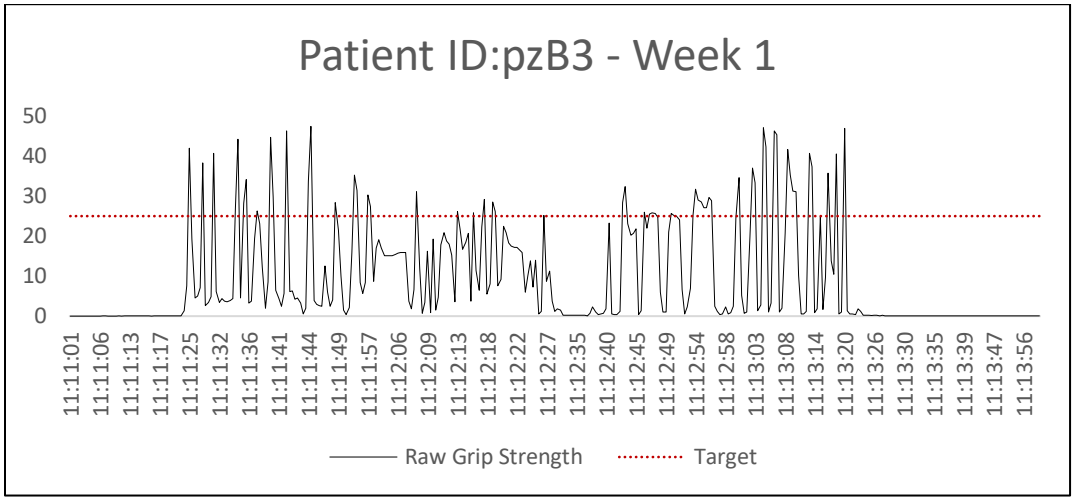
Horizontal bar plot comparing the total number of days of HEP compliance

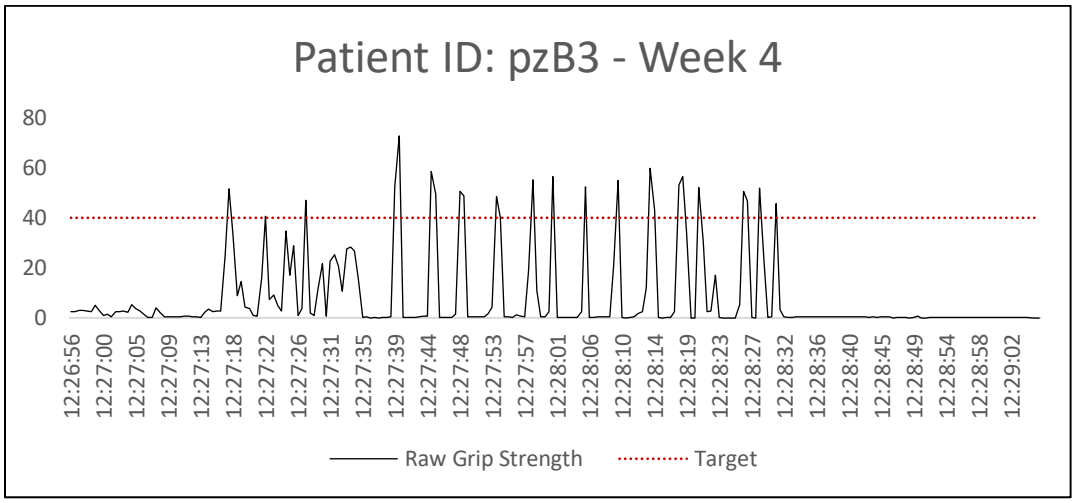


The eGripper raw data from one experimental participant was analyzed to examine changes in grip strength. During the initial week, the participant had an initial grip strength of 42 lbs. of force. The eGripper target was set to 25 lbs. The participant was able to play the game comfortably. The same participant was able to improve grip strength and the target was increased to 40 lbs. at the start of the fourth week. At the end of fourth week, the participant's final grip strength was 55 lbs. A sample session is presented in Figure 26.

Figure 26

Comparison of Raw Grip Strength Data and Target Levels for Week 1 and Week 4





During the four weeks of the experiment, all patients were able to perform an average of 1400 repetitions during their experimental phase. These repetitions form neuronal synapses that strengthen the brain's structure and function, enabling a person to perform specific tasks frequently and fluently. The neuroplastic principles predict that neurons can be remodeled and reorganized to achieve the required task.

CHAPTER SIX

USABILITY TESTING

Chapter 5 discusses the methodology of objective three, “to evaluate the usability of the telerehabilitation system.” Designers often think or imagine themselves as the targeted users to design a product, but an end-user group, for example, people with poor grip strength, uses a product or device like this telerehabilitation system. Usability testing is performed, so the design input should be obtained from the end users or the target audience to meet their needs better.

Usability Testing

Lange et al. (2009b) defined usability testing as a technique to evaluate how user-friendly an application or device is and to identify problems that need to be fixed to enhance the design and operation of the product. Lange et al. also mentioned that usability testing has five components: learnability, efficiency, memorability, errors, and satisfaction. Usability testing is done to find the ease of learning basic tasks of a device the first time they use it and, after initial learning, how quickly they can perform those same basic tasks without difficulties (Lange et al., 2009b). Usability testing is also done to determine if participants can remember basic tasks after a while and, if they make any errors, how quickly they can recover from them.

Usability testing is done either formally or informally. Some usability testing methods include focus groups, task analysis, user observation, and surveys. Formative usability testing is done in the early stages of product development, with summative

usability testing completed later. Usability testing is done in three phases. The first phase is to understand the end-user or target audience's needs and values about the product. In the second phase, a pilot testing of the prototype is performed to gain more insights into the product. The final phase was to evaluate the product after it has been released in the market for a while, and end-users can provide additional input for further development (Lange et al., 2009b).

Formative Usability Evaluation

Formative evaluation is qualitative-based research with potential users to understand a product using fact-finding and discovery-based processes. The product design stage is an iterative process involving focus groups and informal interviews to answer the "why" and "how" questions. The main objective of formative evaluation is to obtain design input from stakeholders, such as valuable product features and the complexity of basic tasks. Formative evaluation is performed during the prototype development stages to find errors and correct the design, influencing the product design (Bennett, n.d.).

Summative Usability Testing

Summative testing is done after the product is fully developed and available in the market. Summative usability testing uses quantitative methods to validate that a product meets its requirements to establish a benchmark (Barnum, 2020). Summative testing is mainly done to evaluate the functionality of the finished product by measuring task and time performance. Summative testing can be done in various locations (e.g., labs, conference rooms, and in-field) where the product is used. The disadvantage of

summative testing is that it is usually conducted after the product has been launched, and no actions can be taken with the findings, but it can help the next upgrade of that product.

Methodology

Participants

Five physical and occupational therapists at Select Specialty Hospital, Pontiac, MI, and Professional Physical Therapy, Warren, MI, participated in formative usability testing. The participants recruited for the clinical experiment also completed the summative usability testing.

Procedures

Chapter Three describes the initial prototype's design and development as an iterative process. During the design stages, informal interviews and focus group meetings were conducted as a part of formative usability testing

Informal interviews were conducted with the physical and occupational therapists to explore the essential design features of the game and the eGripper device. A few guiding questions that were used for the informal interview and focus groups include:

- What type of game will be best suited for this application?
- How long should a patient play this game?
- What steps should a patient take when entering the game app?
- How should the points or rewards be allocated?

After the prototype was completed, each person was instructed to set up the system. The game rules were displayed on the smartphone, and they played the game for 10 minutes. Following the gameplay, an informal interview was conducted regarding the

enjoyment of the game, game operations and ease of use, therapeutic effects of the game design and game mechanics, and any overall feedback regarding the telerehabilitation system. Since responses were more subjective and descriptive, their feedback was incorporated into the design of the telerehabilitation system to make appropriate and relevant changes to the final product.

For the summative usability testing, the four participants were asked to complete two quantitative usability surveys after completing the clinical experiment at the end of the four weeks. The two quantitative surveys used in this phase of the summative usability testing were System Usability Scale (SUS) (Brooke, 1996) and Suitability Evaluation Questionnaire (SEQ) for virtual rehabilitation systems (Gil-Gómez et al., 2013) (Appendix xx).

System Usability Scale

The SUS provides a global perspective of subjective assessment of a system's usability. The scale has 10 items rated using a 5-point from 0 ("STRONGLY DISAGREE") to 4 ("STRONGLY AGREE") Likert scale. Five items on the SUS are positive statements, such as "I think that I would like to use this system frequently" and "I thought the system was easy to use." The remaining five items are negative, for example, "I found the system unnecessarily complex" and "I think that I would need the support of a technical person to be able to use this system." All items must be rated on the survey; if the participant could not respond, they should mark the neutral (3) point. Scoring the SUS using the author's protocol provided scores ranging from 0 to 100. The

total score provides the participant's perceptions of the general usability of the eGripper and app for HEP. The interpretation of the SUS score was given by Bangor (2009).

Table 10

Adjective Rating of Corresponding SUS Scores

SUS Mean Scores	Adjective Rating
90.90	Best Imaginable
85.50	Excellent
71.40	Good
50.90	Okay
35.70	Poor
20.30	Awful
12.50	Worst Imaginable

Suitability Evaluation Questionnaire

SEQ is a novel survey designed to use explicitly for game-based rehabilitation. It has 14 items, including 13 easy-to-understand questions graded on a 5-point Likert scale and one open question. The first seven questions measure the game enjoyment, the sense of being in the system, feeling of success, and control, realism, understanding of instructions, and general discomfort. The following four questions ask specifically whether the gaming system causes any discomfort like dizziness, nausea, eye discomfort, disorientation or confusion, and a sense of progress in the game program. The first eleven questions were graded from “NOT AT ALL” to “VERY MUCH.” The 12th and 13th questions were graded from “VERY EASY” to “VERY DIFFICULT.” The total score ranges from 13 poor suitability to 65 excellent suitability. Gil-Gómez et al. reported

(2013) that SEQ has proven efficacy and an acceptable internal consistency of Cronbach's alpha = 0.7., which means how closely related a set of items are as a group.

Findings

The formative usability testing results were descriptive answers to the questions mentioned in the procedure. Some answers were "What type of game will be best suited for this application?" – many potential games like balloon burst, angry bird, flappy bird, and car race were discussed, and the flappy bird style game was selected. "How long should a patient play this game?" – about 10 to 15 minutes were chosen because patients can be fatigued with the eGripper. "What steps should a patient take when entering into the game app?" – after opening the app, the patient should directly play games; too many options can confuse patients. "How should the points or reward be allocated? – more points when a patient dodges an obstacle and negative points when they hit obstacles."

The summative usability testing has two survey results from four patients who participated in the clinical experiment. Both survey results were presented with overall mean and standard deviation scores in Table 11 and individual items for SUS in **Table 12 and SEQ.**

Table 13

Table 11

Means and Standard Deviation of the Surveys' Composite Scores

Survey	Mean	SD
SUS	76.25	10.31
SEQ	47.50	1.73

Table 12

Means and Standard Deviation of individual items of SUS

System Usability Scale (SUS)	Mean	SD
Q1. I think that I would like to use this system frequently	4.50	0.58
Q2. I found the system unnecessarily complex	1.50	0.58
Q3. I thought the system was easy to use	5.00	0.00
Q4. I think that I would need the support of a technical person to be able to use this system	3.25	0.96
Q5. I found the various functions in this system were well integrated	4.50	0.58
Q6. I thought there was too much inconsistency in this system	3.25	0.50
Q7. I would imagine that most people would learn to use this system very quickly	4.00	0.82
Q8. I found the system very cumbersome to use	1.75	0.96
Q9. I felt very confident using the system	4.75	0.50
Q10. I needed to learn many things before I could get going with this system	2.50	1.00

Table 13

Means and Standard Deviation of individual items of SEQ

Suitability Evaluation Questionnaire (SEQ)	Mean	SD
Q1. How much did you enjoy your experience with the system?	4.75	0.50
Q2. How much did you sense being in the environment of the system?	3.50	0.58
Q3. How successful were you in the system?	4.50	1.00
Q4. To what extent were you able to control the system?	3.75	0.50
Q5. How real is the virtual environment of the system?	1.50	0.58
Q6. Is the information provided by the system clear?	4.25	0.96
Q7. Did you feel discomfort during your experience with the system?	1.75	0.96
Q8. Did you experience dizziness or nausea during your practice with the system?	1.00	0.00
Q9. Did you experience eye discomfort during your practice with the system?	1.50	0.58
Q10. Did you feel confused or disoriented during your experience with the system?	1.25	0.50
Q11. Do you think that this system will be helpful for your rehabilitation?	4.25	0.96
Q12. Did you find the task difficult?	1.75	0.50
Q13. Did you find the devices of the system difficult to use?	1.75	0.96

CHAPTER SEVEN

DISCUSSION

This chapter discusses the research goals, questions, associated hypotheses and findings, outcomes, interpretation, limitations, and suggestions for future research. This research attempted to resolve an important problem of poor health status associated with impaired grip strength and noncompliance with HEP. The research problem was when people were prescribed HEP, they were up to 70% non-compliant and people with weak grip strength also are noncompliant with HEP, which leads them to depend on ADL tasks and functional mobility.

A smartphone-based telerehabilitation system (eGripper system) that includes an eGripper device and a smartphone application (app) was proposed to resolve the noncompliance with grip strength HEP. Video game-based rehabilitation can create a fun and entertaining environment that can motivate patients to engage in exercise (Lange et al., 2009). An eGripper system was developed to engage patients through video games using a specially designed sensor-based grip strength exerciser as a game controller. The system aims to resolve exercise compliance issues by engaging patients in playing games rather than focusing on relentless repetitive movements. This eGripper system challenges patients with impairments (i.e., poor hand grip strength) to play video games using the repurposed grip strength device (eGripper) as part of their home exercise programs. The game was designed to be customizable for each patient according to their level of

weakness, making it playable for all grip strength ranges and providing incentives for completing therapy.

Validation experiments are warranted as the eGripper system was built from repurposed hand dynamometers, and a new firmware was written. Hence, validity and reliability tests were performed to meet "gold" standards set by the Jamar dynamometer. Randomized clinical trials and usability testing were completed to measure the efficacy and usability of the eGripper system. Results from validity and reliability tests were consistent with previous studies (Flood-Joy & Mathiowetz, 1987; Hamilton et al., 1992; King & Berryhill, n.d.; Mathiowetz, 2002).

Pearson correlation coefficients for concurrent validity with known weights for all four eGrippers resulted in $r = .99$. Findings from the validity tests indicated that all the eGrippers demonstrate excellent validity and have a strong positive association with the known weights, meaning that all eGrippers measure what they were supposed to measure. Concurrent validity with the gold standard Jamar was supported with findings of no statistically significant differences between the groups of more than 2.5 pounds. In addition, 4.89% (3.24 lbs.) and 2.91% (2.02 lbs.) percentage (mean) differences between right and left eGripper and Jamar dynamometers were less than 5% (Mathiowetz, 2002).

Other hand grip devices (e.g., Rolyan, Dexter, Baltimore Therapy Equipment (BTE), and grip-ball), when compared to Jamar, reported similar inter-instrumental reliability (Beaton et al., 1995; Bellace et al., 1954; Chkeir et al., 2012; Hamilton et al., 1992; Mathiowetz, 2002; Myers et al., 2021). In the same way, findings from the present study also reported excellent inter-instrumental reliability between the gold standard

Jamar and eGripper (i.e., ICC ranges from 0.94 to 0.97). The eGripper showed an acceptable reliability score that signified the eGripper could be used instead of Jamar for measuring hand grip strength as a part of telerehabilitation.

The literature review addressed the first research question: "Is it feasible to design and develop a game-based telerehabilitation system to monitor and deliver home exercise programs on a smartphone along with repurposed electronic hand dynamometer to improve grip strength?" Table 3 and Table 4 provides a list of grip strength devices, with a few of those devices mentioned has wireless capabilities. A study by Espinoza et al. (2016) mentioned remote monitoring of grip strength, but those devices or systems presented in the literature review lacked an important feature of telerehabilitation, specifically the feedback or remote adjustments of game parameters. In the present research, that feedback loop was added to keep a patient engaged in the game by adjusting game parameters. The eGripper was able to bridge the gap for remote monitoring and remote gradation of game based HEPs. The eGripper could be used as a remote grip strength monitoring tool based on validity and reliability findings.

The HEP part of the system was tested using a clinical trial with patients with poor grip strength. Participants were divided into two groups, experimental and control. In the clinical trial, the grip strength was measured for all participants in both groups before the start of the experiment. A two-sample independent t-test with a hypothesized mean difference of zero was used to compare the experimental and control groups' pretest grip strength. The t-test indicated that both groups had similar strengths before starting the experiment. After four weeks, a post-test two-sample independent t-test with

a difference of means greater than 5 lbs. were statistically significant, providing evidence of a significant difference between the groups. The two-sample independent t-tests show that the experimental group using eGripper to perform HEP significantly improved their grip strength after four weeks of intervention. The results of this testing provided support for previous research on improvement in muscle strength using resistance training among different disease conditions (Aamann et al., 2020; Dalgas et al., 2009.; Eng, 2004; Hare et al., n.d.; Ouellette et al., 2004; Shang et al., 2021). As the purpose of the present study was to measure the efficacy of the telerehabilitation system, only pre, and post-test grip strength measures were studied.

The HEP compliance was measured using the paper-based tracker for the control groups and the administrator dashboard for the experimental group. The number of days from both the group's trackers was calculated, with the experimental group participating in HEP 70% more days than the control group. This result indicated that the experimental group that performed HEP using the eGripper system was more compliant. Based on these findings, we conclude that the eGripper system has supported its efficacy by improving grip strength and HEP compliance.

The final experiment of this study was a qualitative experiment to study the user experience with the eGripper system. During the initial stages of the design process, formative usability testing using focus groups and informal interviews yielded answers to some design questions. Design suggestions from the focus groups provided ideas to design the customized game for the eGripper system. Participants in the experimental group completed two final usability surveys, System Usability Scale (SUS) and

Suitability Evaluation Questionnaire (SEQ). The SUS provides information on general system usability and ease of use. Some high-scored responses were “I thought the system was easy to use,” “I felt very confident using the system,” “I found the system unnecessarily complex,” and “I like to use the system frequently.” These survey responses indicate that the eGripper system was easy to use, and participants were confident in using the system. The mean composite score was between “good” and “excellent” usability, with the lowest scores in the “okay” range.

The SEQ measured usability relating to the use of video game-based rehabilitation. High-scored responses showed that participants enjoyed the experience and successfully used the system. In contrast, low-scored responses were related to nausea and dizziness and feelings of confusion and disorientation experienced during the eGripper system usage. The overall SEQ composite score for the eGripper system provided good suitability for game-based telerehabilitation.

Limitations and Future Directions

This study has a few limitations, such as a small sample size to establish validity and reliability. The study measured the validity and reliability data from participants ranging from 27 to 62 years old. If research using participants with uniform age distribution were used, data could be more robust in providing validity and reliability of this eGripper system for HEP. A single eGripper was used to collect the validity and reliability data. In future studies, more eGrippers could be used to improve the inter-rater reliability of different systems.

The clinical experimental study was done with patients with considerable grip strength at baseline pretest mean (i.e., 34.75 and 49.25 lbs.). All these patients were recovering from minor physical illnesses. A lower grip strength sample could be studied to determine the efficacy of the eGripper system. This initial feasibility study indicated that the system effectively met its purpose. However, a larger sample size with random assignment to the experimental and control group could provide more efficacy. Compliance rates should be studied with a longer duration and greater sample size.

Conclusion

An eGripper telerehabilitation system to resolve the issues of HEP compliance has been developed for this study. The test results for eGripper's reliability and validity have supported the system's efficacy in improving grip strength among individuals with poor grip strength. The use of a game instead of repetitive exercises was found to motivate participants to be compliant in performing their HEP more regularly. The qualitative results indicated that the patients who used the eGripper system were generally happy with the equipment and willing to use it to complete their exercise regimens. Future research is needed to continue developing both the eGripper and the associated games to help patients with poor hand strength improve their ability to grip.

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APPENDIX

1. Permission Letters
    a. IRB Approval Letter
    b. Select Permission letter
    c. Professional PT Permission letter
    d. Complete care rehab Permission letter
2. Recruitment flyers – Experiments 1 and 2
3. Citi training certificates
4. Demographic sheets
5. SUS and SEQ
6. HEP – paper handout and tracker

Appendix A: Institutional Review Board (IRB) Approval Letter

OAKLAND UNIVERSITY

Institutional Review Board

July 9, 2020

Protocol #: IRB-FY2020-17

Research Team:
Sam James
Sankar Sengupta

Based on applicable federal regulations, the following study, "Efficacy of telerehabilitation to improve grip strength" has been determined to be Approved, with the following categories 1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

This letter along with the IRB date stamped consent documents can be found in Cayuse in the Submission Details page under Letters and Attachments, respectively.

Please note that Oakland University has mandated a temporary stoppage of all in-person human subjects research procedures.

Notes for Researcher(s):
This approved study includes the following documents:

- Flyer
- Oral Script
- Grip Strength Data Collection
- Surveys (2): System Usability Scale and Suitability Evaluation Questionnaire

This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved protocol.

Consent Document(s):
IRB date stamped consent documents must be used in consenting participants. Federal regulations require that

each participant receive a copy of the consent document unless a waiver is granted by the IRB. Signed consent form(s) must be retained for a minimum of three years after the completion of the project. Please remember that informed consent is a process that continues throughout the project, starting with recruitment and assurance of participant understanding of the project, and followed by a signed consent form when applicable.

Modifications:
Any changes to the approved project must be approved by the IRB prior to initiation by submitting a MODIFICATION request. Do not collect data while the changes are being reviewed. Data collected during this time cannot be used in research.

Incidents:
All unanticipated problems involving risks to participants or others, serious and unexpected adverse events, non-compliance issues and/or serious complaints regarding this project must be reported promptly to the IRB by submitting an INCIDENT report.

You are approved to start the research. Please retain a copy of this notification for your records.

If you have any questions, please contact the IRB office.

Thank you.

The Oakland University IRB

Appendix A: Select Medical Permission Letter

RESEARCH AND DATA USE AGREEMENT

THIS RESEARCH AND DATA USE AGREEMENT (the "Agreement") is made as of March _____, 2021 by and between Select Medical Corporation, a Delaware corporation, having its principal place of business at 4714 Gettysburg Road, Mechanicsburg, PA 17055 ("Select"), and Sam James, having his principal address at 301 Engineering Center, 115 Library Drive, Rochester, MI 48309 ("Investigator").

WHEREAS, Select is a private company engaged in, among other things, the management and operation of long term acute care and rehabilitation hospitals;

WHEREAS, Investigator wishes to obtain from Select certain data and information to be used in the Research Study (as defined herein);

WHEREAS, Select wishes to provide Investigator with a limited data set for use in the research study;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, Select and Investigator agree as follows:

1. DEFINITIONS

As used in this Agreement, capitalized terms have the meanings given them below or elsewhere in this Agreement:

1.1. "Confidential Information" shall mean the proprietary, confidential, or trade secret information or know-how belonging to the disclosing y or which the disclosing y is under an obligation to maintain as confidential, whether or not it is in written or permanent form. Confidential Information shall include, without limitation, technical and business information relating to the disclosing party's inventions or products, research and development, patient data, finances, customers, marketing, production, and future business plans. Confidential Information shall not include information which the receiving y can prove: (i) was in the public domain at the time of disclosure or has entered the public domain through no fault of the receiving y; (ii) was known to the receiving Party, without restriction, at the time of disclosure; (iii) was disclosed by the receiving Party with the prior written approval of the disclosing Party; (iv) was independently developed by the receiving Party without any use of the Confidential Information of the disclosing Party; (v) becomes known to the receiving Party, without restriction, from a source other than other than the disclosing Party and otherwise not in violation of the disclosing Party's rights; or (vi) is disclosed pursuant to the or requirement of a court, administrative agency or other governmental body; provided, however, that the receiving Party shall provide prompt notice of such court order or requirement to disclosing Party to enable disclosing Party to seek a protective order or otherwise prevent or restrict such disclosure.

1.2. "Limited Data Set" means clinical data that has been assembled by Select and by the Investigator that will be stored, secured and de-identified in accordance with the requirements of 45 C.F.R. 164.514. The components of the Limited Data Set are set forth in

Exhibit C of this Agreement. For clarity, the Limited Data Set shall include data from Select Specialty Hospital-Macomb County, Inc. dba Select Specialty Hospital- Pontiac ("Select Facility"), and no other Select owned or operated hospitals or facilities.

1.3 "Research Study" means the research study entitled "Efficacy of telerehabilitation to improve grip strength".

2. RESEARCH STUDY

2.1. Protocol. A description of the Research Study to be performed by Investigator is contained in the Protocol attached hereto as Exhibit A ("Protocol"). A copy of the approval of the applicable Institutional Review Board for the conduct of the Research Study is attached hereto as Exhibit B ("IRB Approval").

2.2. Investigator Standard of Care. Investigator agrees to conduct the Research Study: (a) in a competent and professional manner, (b) in accordance with the specifications, terms and conditions of the Protocol, as amended in writing from time to time with the written consent of Select, which consent shall not be unreasonably withheld or delayed, and (c) in accordance with all applicable laws and regulations. Except for the Limited Data Set, Investigator shall provide the necessary patient data personnel, equipment and supplies required to perform the Research Study.

2.3. Reporting. Investigator will keep Select informed of the results of the work performed in connection with the Research Study. Investigator will deliver to Select a written report describing the progress of the Research Study no later than fourteen (14) business days following the last day of each calendar quarter during the term of this Agreement, and confer with Select upon the request of Select. Investigator will provide Select with a final written report setting forth the complete data, results and findings of the Research Study no later than sixty (60) days following the completion of the Research Study.

2.4. No Guarantee of Results. Neither Party represents or warrants that the Research Study will be successful or that any specific results will be obtained.

2.5. Ownership and Use of Limited Data Set.

2.5.1. The Limited Data Set shall be assembled and de-identified pursuant to the requirements of 45 C.F.R. 164.514 by the Investigators and Select and shall contain the data components set forth in Exhibit C. The Limited Data Set is the sole property of Select, is deemed the Confidential Information of Select, and is subject to the protections stated in Article 3 of this Agreement. Investigator agrees to use the Limited Data Set solely for the purpose of performing the Research Study in accordance with applicable laws, and for no other purpose. The Limited Data Set shall not be used by Investigator in any other research projects, grant applications, commercial, paid, reimbursable or non-reimbursable clinical activities without the prior written consent of Select.

2.5.2. The Limited Data Set and all materials, documents and information of every kind supplied by Select to Investigator pursuant to this Agreement shall be the sole and

exclusive property of Select, and Select shall have the right to make whatever use it deems desirable of any such materials, documents and information.

2.5.3. Investigator shall not report, publish, share or disclose the Limited Data Set, and shall not report, publish, share or disclose the data or results arising from the Research Study without Select's prior written consent.

2.5.4. Select hereby grants Investigator a non-exclusive, royalty-free license for the term of this Agreement to use the Limited Data Set solely for the purpose of conducting the Research Study in accordance with the terms of this Agreement and the Protocol.

2.6. License to Select. Investigator hereby grants to Select a perpetual, non-exclusive, royalty free license to use the data and results arising from the Research Study, either alone or in aggregate, for any purpose

2.7. No Implied License. Except as specifically provided herein, no license is granted under this Agreement by either Party to the other Party, either expressly or by implication, under any trademarks, patent rights, information, know-how, or other intellectual property right owned or controlled by such Party.

2.8. Audit. On reasonable notice, and at reasonable intervals, Select shall have the right to inspect and copy all such records of Investigator regarding the use of the Limited Data Set in the performance of the Research Study.

3. CONFIDENTIAL INFORMATION

3.1. A Party's acceptance and use of any Confidential Information supplied by the other Party in the course of the Research Study will be subject to the following:

3.1.1. Each Party will use reasonable efforts to limit the exchange of Confidential Information.

3.1.2. Where a Party does accept Confidential Information, such Party agrees to use reasonable care to prevent the unauthorized use, dissemination, or publication of the Confidential Information (a) disclosed in tangible form clearly labeled as confidential or proprietary at the time of disclosure; or (b) disclosed in non-tangible form, identified as confidential or proprietary at the time of disclosure, briefly summarized in writing, designated as confidential or proprietary, and delivered to the other Party within thirty (30) days after disclosure; or (c) which the receiving Party should have known was confidential or proprietary information of the disclosing Party.

3.1.3. A Party's obligation to hold Confidential Information in confidence expires ten (10) years after the termination of the Research Study.

3.2. Investigator acknowledges and agree that Select's Confidential Information includes, among other things, the Limited Data Set.

4. FINANCIAL TERMS

Each Party shall be responsible for its own expenses in connection with their respective performance of this Agreement.

5. PUBLICITY

5.1. Neither Party will identify the other in any products, publicity, promotion, promotional advertising, or other promotional materials to be disseminated to the public, or use any trademark, service mark, trade name, logo, or symbol that is representative of a Party or its entities, whether registered or not, or use the name, title, likeness, or statement of the other Party's Personnel, without the other Party's prior written consent. Any use of a Party's name shall be limited to statements of fact and shall not imply endorsement of products or services.

5.2. Notwithstanding the foregoing, Investigator hereby authorizes Select to use Investigator's name and the name of the Research Study: (i) in any listing of research involving Select; or (ii) as may be required by applicable law, as determined by Select in its reasonable discretion.

6. PUBLICATION

6.1. Investigator may publish the validated results of the Research Study with the prior review and consent of Select.

6.2. Investigator will provide Select the option of receiving an acknowledgment in any such publication.

7. INDEMNIFICATION

7.1. As used herein, "Claim" includes but is not limited to every phase of any lawsuit, loss, claim, damage or liability for death, illness or personal injury of any person and/or for property damage. "Claim" includes claims brought by a third party.

7.2. Investigator agrees to indemnify, defend, and hold harmless Select, and its employees, agents, directors, and officers from any Claim arising out of or connected with this Agreement or the Research Study to the extent such Claim is due to Investigator negligence or willful misconduct, including the breach of a representation or warranty set forth in Section 8 of this Agreement. Select shall promptly notify Investigator of any such Claim and shall cooperate with Investigator and his insurance carrier in the defense of the Claim.

7.3. Investigator shall maintain during the performance of this Agreement a policy or polices of comprehensive general liability insurance at levels sufficient to support the indemnification obligations of this Agreement. Investigator will provide Select with a certificate of insurance evidence such coverage upon request.

8. REPRESENTATIONS, WARRANTIES, LIABILITY LIMITS

8.1. Due Authorization. Each Party hereby represents and warrants that such Party (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and to authorize the performance of its obligations hereunder and the grant of right extended by it hereunder.

8.2. Right to Perform Research Study. Investigator represents and warrants that he has the full legal right to conduct the Research Study under this Agreement, and that there is no claim, litigation or proceeding pending or threatened against Investigator with respect to such research or any of the results of the Research Study alleging infringement of any patent or copyright or violation of any trade secret or any other proprietary right of any person.

8.3. EXCEPT AS OTHERWISE SET FORTH HEREIN, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATERIALS, PROCESSES, LIMITED DATA SET OR REPORTS, OR THE PERFORMANCE OF THE RESEARCH STUDY HEREUNDER, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OR ANY WARRANTY ARISING FROM A COURSE OF DEALING, TRADE USAGE OR TRADE PRACTICE.

8.4. EXCEPT FOR THE OBLIGATIONS PURSUANT TO SECTION 8, IN NO EVENT SHALL ANY PARTY (OR THEIR RESPECTIVE AFFILIATES, SUBSIDIARIES, EMPLOYEES, OFFICERS, DIRECTORS, CONSULTANTS OR AGENTS) BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY CONSEQUENTIAL, INDIRECT OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS, LOSS OF OPPORTUNITY, LOSS OF USE OR LOSS OF REVENUE) OF THE OTHER PARTY OR OF ANY THIRD PARTY ARISING FROM OR RELATED TO THIS AGREEMENT.

9. TERM AND TERMINATION

9.1. Term. This Agreement will remain in effect for two years from the date first written above unless terminated sooner or extended in writing signed by the Parties in accordance with this Agreement

9.2. Termination. Either Party may terminate this Agreement for any reason upon thirty (30) days prior written notice.

9.3. Effect of Expiration/Termination. Each Party will provide for the timely and orderly wind-up of, and/or transfer of responsibility for Research Study activities in progress at the time of expiration or termination of this Agreement or Research Study.

9.4. Survival. The provisions of Sections 2.5.2, 2.5.4, 2.7, and Articles 3, 5, 6 and 8 through 10 will survive any expiration or termination of this Agreement.

10. GENERAL

10.1. Compliance with Laws. All information provided to Select pursuant to this Agreement shall be accurate in accordance with scientifically accepted standards. Investigator shall comply with all current government regulatory requirements as applicable to the Research Study and the Protocol, as well as all other applicable national, federal, state and local laws and regulations applicable to the Research Study and the Protocol.

10.2. Binding Effect; Assignment. Investigator may not assign or delegate the rights or obligations under this Agreement without the express written consent of Select.

10.3. Entire Agreement. This Agreement constitutes the entire agreement between the Parties relating to the Research Study, and any and all prior or contemporaneous negotiations, representations, agreements and understandings are superseded hereby. No amendment or change to this Agreement may be made except by means of a written document signed by duly authorized representatives of the Parties.

10.4. Notices. Any notice required or permitted by this Agreement shall be in writing and shall be deemed sufficient upon receipt, when delivered personally or by courier, overnight delivery service or confirmed facsimile, or three (3) business days after being deposited in the regular mail as certified or registered mail (airmail if sent internationally) with postage prepaid, if such notice is addressed to the Party to be notified at such Party's address or facsimile number as set forth below, or as subsequently modified by written notice.

10.5. Applicable Law. This Agreement will be construed and enforced in accordance with the laws of the Commonwealth of Pennsylvania, without regard to any choice or conflict of laws, rule or principle that would result in the application of the laws of any other jurisdiction. Any dispute arising from this Agreement shall be submitted to a court of competent jurisdiction residing in Harrisburg, Pennsylvania.

10.6. Headings. Headings included herein are for convenience only, and will not be used to construe this Agreement.

10.7. Relationship of Parties. For the purposes of this Agreement, each Party will be, and will be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party will have authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other Party, except as explicitly provided for herein or authorized in writing.

10.8. Severability. If any provision of this Agreement will be found by a court of competent jurisdiction to be void, invalid or unenforceable, the same will either be reformed to comply with applicable law or stricken if not so conformable, so as not to affect the validity or enforceability of this Agreement.

10.9. Force Majeure. Neither Party will be liable for any failure to perform as required by this Agreement, if the failure to perform is caused by circumstances reasonably beyond a Party's control, such as labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of

aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, pandemics, thefts, or other such occurrences.

10.10. Further Assurances. Each Party shall perform any and all further acts and execute and deliver any documents which are reasonably necessary to carry out the intent of this Agreement.

10.11. Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Select:	**Investigator:**
Select Medical Corporation	Sam James
By:	By:
Typed Name: Samuel I. Hammerman	Typed Name: Sam P. James
Title: Executive Vice President, Chief Medical Officer	Title: Rehabilitation Therapy Manager
Date: 3-19-2021	Date: 3/23/2021

Appendix A: Professional Physical Therapy Permission Letter

Professional Physical Therapy PC
31150 Hoover Road, Suite C Warren MI 48093
45634 Schoenherr Road Shelby Twp. MI 48315
Ph: 586 268 1929 Fax: 586 268 1933

December 10, 2020

Oakland University
The Research Office
Wilson Hall
371 Wilson Boulevard
Rochester, Michigan 48309-4486

Re: Efficacy of tele rehabilitation to improve grip strength

To Whom It May Concern:

The purpose of this letter is to grant Sam James, a graduate student in industrial and systems engineering at Oakland University, permission to collect study data from patients at Professional PT.

Sam's proposed project entails the evaluation of an instrumented dynamometer and a novel tele rehabilitation application designed to improve compliance with grip strength exercises. As a study venue, Professional PT. is suitable for answering questions regarding upper arm strength rehabilitation in an outpatient setting.

As the President of Research at Professional PT, I am aware of Sam's project proposal and agree that it is appropriate for our patient population. I support Sam's plan to submit an IRB application and protocol, and I approve his plan to conduct his PhD research at Professional PT.

Should you have additional questions or concerns, you may contact me at vik@painandyou.com or at 248 798 5514.

Sincerely,

Please feel free to contact me directly if you have any questions or concerns regarding this matter.

Thanks

Dr. Vik Ahluwalia

Appendix A: Complete Care Rehab Permission Letter

PHYSICAL THERAPY
COMPLETE CARE REHAB

February 4, 2021

Oakland University
The Research Office
Wilson Hall
371 Wilson Boulevard
Rochester, Michigan 48309-4486

Re: Whom it may Concern:

The purpose of this letter is to grant Sam James, a graduate student in Industrial and systems engineering at Oakland University, permission to collect study data from patients at Complete care rehab LLC. Sam's proposed project entrails the evaluation of an instrumented dynamometer and a novel tele- rehabilitation application designed to improve compliance with grip strength exercises. As a study venue, Complete care rehab is suitable for answering questions regarding upper arm strength rehabilitation in an out-patient setting.

As an Administrator of Complete Care Rehab I am aware of Sam's project and agree that it is appropriate for our out-patient population. I support Sam's plan to submit an IRB application and protocol, and I approve his plan to conduct his PhD research at Complete care rehab.

Should you have additional questions or concerns, you may contact me at Jay@completecarerehab.com or 586-675-1178.

Sincerely
Jay Umapathy

18200 E. 10 Mile Rd, suite 200
Eastpointe, MI 48021
Ph: 586-756-7570
Fax: 586-486-1700

26440 Hoover Rd #A
Warren, MI 48089
Ph: 586-756-7500
Fax: 586-486-1700

Appendix B: Recruitment Flyer

RESEARCH STUDY

Efficacy of Telerehabilitation for improving grip strength

CONDUCTED BY:

Sam James, PhD Candidate
Department of Industrial and Systems Engineering
Oakland University

Faculty Advisor:
Dr. Sankar Sengupta, Professor
Department of Industrial and Systems Engineering
Oakland University

STUDY LOCATION:

If you are a patient from Select Specialty Hospital your study location will be	**7th Floor Therapy Gym Select Specialty Hospital Pontiac, MI**
If you are a patient from Professional Physical Therapy and Complete Care Rehab your study location will be	**Initial visit at your respective clinic and afterwards your home**

PURPOSE:

To evaluate the validity and reliability of the newly designed telerehabilitation system.

YOU MAY BE ELIGIBLE FOR THIS STUDY IF:

You are a healthy adult aged above 18 years and with no hand impairments - no arthritis, no pain, etc.

Your willingness to spend at least 10 to 15 min for the research study.

IF INTERESTED:

Please Contact Sam James at (248) 452-5204 or spjames@oakland.edu

Appendix B: Reliability and Validity Experiment Consent Form

Consent Form for Expedited Research

Experiment 1: Validity and Reliability of the Telerehabilitation System

Introduction
You are asked to participate in a research study that is done by Sam James, Ph.D. Candidate, Industrial and Systems Engineering at Oakland University, under the direction of Dr. Sankar Sengupta, Professor of Industrial and Systems Engineering at Oakland University.
Your decision to participate in this study is voluntary. You can choose to stop your participation at any time or skip any part of the research if you are not comfortable. Your decision will not affect your present or future relationship with Oakland University, the researcher, the Industrial and Systems Engineering, Select Specialty Hospitals, Pontiac, MI, Professional Physical Therapy, Warren MI or Complete Care Rehab, Eastpointe MI

What is the purpose of this study?
The purpose of this research study is to quantify whether the device is measuring what it is supposed to measure and to see whether the measure of the newly designed device is reliable against the current equipment.

Who can participate in this study?
Any healthy adults aged above 18 years with no hand impairments - no arthritis, no pain can participate in this study.

How long will I be in the study?
You will be spending 10-15 min in this study.

Where will this study take place?
This study will take place in the Rehab Gym on the 7th-floor, Select Specialty Hospital, Pontiac, MI.

What do I have to do?
If you agree to participate in this research study, you will be asked to come to the Rehab Gym on the 7th floor. We will measure your maximal grip strength for both hands using two different devices. We will measure three trials of each handgrip with a 1-minute rest break between the devices and the hands.

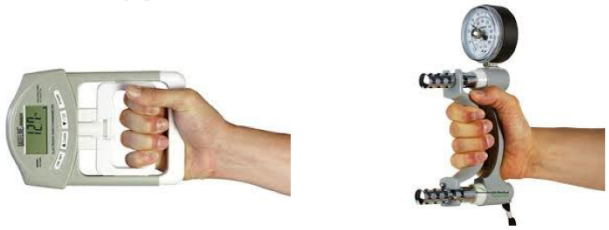

Figure 1: Devices to measure grip strength

Are there any risks to me?
You may feel anxious or have mental fatigue during the experiment. If you do feel any anxiety or mental exhaustion due to participation in the research, you can express your concerns to the researcher. You can ask that the experiment be stopped or paused at any time.

IRB #2020-17
Approved Consent Form V 2/22/2021

With many research studies, there is a risk of someone who is not part of this research, accidentally seeing your personal information. Safeguards will be in place to minimize this risk by keeping your research records as confidential as possible. When the results of this research are published or presented at conferences, no information will be included that personally identifies you.

Are there any benefits for me?
There may be no direct benefits to you, although the results of this study may benefit others in the future.

What are the alternatives to participation in this study?
You may choose not to participate in this study.

Will I receive anything for participating?
You will not receive anything to participate in this study.

Who could see my information?
Your research records may be shared and reviewed by the following groups:

- Representatives of the Oakland University, Institutional Review Board, or other regulatory compliance staff, whose job is to protect people who are in research studies.
- Regulatory authorities who oversee research (Office for Human Research Protections, or other federal, state, or international regulatory agencies)

De-identified data (measures of grip strength, age, gender) may be used or distributed to another investigator for future research use without additional informed consent from you.

What if I want to stop participating in this study?
Your decision to participate in this study is voluntary. You may choose to leave the research at any point in time, or refuse to answer any questions that may be asked during the experiment. If you would like to stop participating in this study due to discomfort, fatigue, anxiety, or any other issue, you can let the experimenter know at any time.

Whom do I contact if I have questions about this study?

Principal Investigator:
Sam James, Ph.D. Candidate,
Dept of Industrial and Systems Engineering,
Oakland University.
spjames@oakland.edu
248-877-4624

Faculty Advisor:
Dr. Sankar Sengupta, Professor,
Dept of Industrial and Systems Engineering,
Oakland University.
sengupta@oakland.edu
248-370-2218

For questions regarding your rights as a participant in human subject research, you may contact the Oakland University Institutional Review Board, 248-370-2762.

Signing the consent form
Your signature below means that you have read this form, or someone has read it to you, and you agree to participate in this study. You are not giving up any legal rights by signing this consent form. You will be given a copy of this form.

_____ _____
Print name of participant **Signature of participant**

_____
Date

IRB #2020-17
Approved Consent Form V 2/22/2021

Appendix B: Clinical Experiment Consent Form

Consent Form for Expedited Research

Experiment 2: Efficacy of Telerehabilitation for improving grip strength

Introduction
You are asked to participate in a research study that is done by Sam James, Ph.D. Candidate, Industrial and Systems Engineering at Oakland University, under the direction of Dr. Sankar Sengupta, Professor of Industrial and Systems Engineering at Oakland University.
Your decision to participate in this study is voluntary. You can choose to stop your participation at any time or skip any part of the research if you are not comfortable. Your decision will not affect your present or future relationship with Oakland University, the researcher, the Industrial and Systems Engineering, Select Specialty Hospitals, Pontiac, MI, Professional Physical Therapy, Warren MI or Complete Care Rehab, Eastpointe MI

What is the purpose of this study?
The purpose of this research study is to measure the effects and compliance (adherence) to a home exercise program to improve grip strength among individuals with brain injury, delivered via telerehabilitation technology (providing rehabilitation using smartphone and internet).

Who can participate in this study?
You are being asked to participate in the study because you are a person with low or reduced grip strength measured with JAMAR dynamometer (a device to measure hand squeeze strength) with at least 10 pounds force in either hand, aged 18 years and above, and no mental impairments.

How long will I be in the study?
You will be spending four weeks at least 10- 20 min x 3-5 times a day based on your interest in playing games while working on hand exercises as prescribed by the researcher.

Where will this study take place?
If you are a patient at Select Specialty Hospital, Pontiac, MI, this study will take place in your room, otherwise if you are patient from Professional Physical Therapy, Warren MI or Complete Care Rehab, Eastpointe MI, the study will take place at your home.

What do I have to do?
If you agree to participate in this research study, the researcher will come to your room and will measure three trials of your highest grip (hand squeeze) strength for both hands using two different devices with a rest break of 2-5 min between hands and trials. After the measurement, you will be assigned to either a paper-based home exercise group or a telerehabilitation group (Wireless hand squeeze device to play games).

IRB # 2020-17
Approved consent form V 2/22/2021

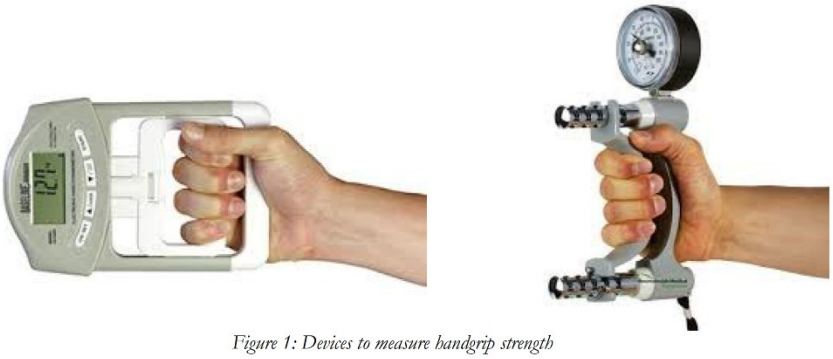

Figure 1: Devices to measure handgrip strength

The researcher will instruct and demonstrate exercises for the paper-based hand exercises group. You will be required to, in return, show the learned exercises if you have any questions regarding the exercises the researcher will continue to explain until you learn and understand them. After learning these exercises, you will be asked to do every day at least 10-15 min 2-3 times a day for four weeks based on your exercise tolerance. You will be required to track the progress using the paper-based exercise log. At the end of the experiment, you are required to return the paper-based exercise log to the researcher.

For the telerehabilitation group, the researcher will provide you with a smart telerehabilitation (wireless hand squeeze device to play games with) device and a 7" amazon fire tablet. The researcher will instruct and demonstrate to open the app and play the games using the smart telerehabilitation device. You will be instructed to play at least 10-15 min 2-3 times a day for four weeks, based on your interest and exercise tolerance. Your progress will be tracked remotely using a therapist computer dashboard. The data that will be collected will include your average grip strength, maximal grip strength, and how often you played on the game app; no further information will be collected. At the end of the experiment, you are required to return the newly designed device and the 7" tablet to the researcher.

Are there any risks to me?
For this study, the potential risks and discomforts that are known include feelings of anxiety or mental fatigue during the experiment. If you do feel any anxiety or mental fatigue due to participation in the experiment, you can express your concerns to the researcher. You can ask that the experiment be stopped or paused at any time. With every research study, there is a risk that someone who is not part of this research may accidentally see your personal information. Safeguards will be in place to minimize this risk by keeping your research records as confidential as possible when the results of this research are published or presented at conferences, no information that personally identifies you will be included.

Are there any benefits for me?
There may be no direct benefits to you, although the results of this study may benefit others in the future.

What are the alternatives to participation in this study?
You may choose not to participate in this study.

Appendix C: Citi Training Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sam James (ID: 4151362)
- **Institution Affiliation:** Oakland University (ID: 1563)
- **Institution Email:** spjames@oakland.edu
- **Institution Unit:** ISE

- **Curriculum Group:** CITI Health Information Privacy and Security (HIPS)
- **Course Learner Group:** CITI Health Information Privacy and Security (HIPS) for Clinical Investigators
- **Stage:** Stage 1 - Basic Course
- **Description:** This course for **Clinical Investigators** will satisfy the mandate for basic training in the HIPAA. In addition other modules on keeping your computers, passwords and electronic media safe and secure are included.

- **Record ID:** 12950817
- **Completion Date:** 03-Mar-2020
- **Expiration Date:** N/A
- **Minimum Passing:** 85
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Basics of Health Privacy (ID: 1417)	03-Mar-2020	5/5 (100%)
Health Privacy Issues for Clinicians (ID: 1418)	03-Mar-2020	5/5 (100%)
Basics of Information Security, Part 1 (ID: 1423)	03-Mar-2020	5/5 (100%)
Basics of Information Security, Part 2 (ID: 1424)	03-Mar-2020	5/5 (100%)
Oakland University (ID: 13470)	12-May-2014	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k17a5c2be-935c-4bda-bb91-4cf6e557359f-12950817

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sam James (ID: 4151362)
- **Institution Affiliation:** Oakland University (ID: 1563)
- **Institution Email:** spjames@oakland.edu
- **Institution Unit:** ISE

- **Curriculum Group:** CITI Health Information Privacy and Security (HIPS)
- **Course Learner Group:** CITI Health Information Privacy and Security (HIPS) for Clinical Investigators
- **Stage:** Stage 1 - Basic Course
- **Description:** This course for **Clinical Investigators** will satisfy the mandate for basic training in the HIPAA. In addition other modules on keeping your computers, passwords and electronic media safe and secure are included.

- **Record ID:** 12950817
- **Report Date:** 24-Mar-2020
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Oakland University (ID: 13470)	03-Mar-2020	No Quiz
Basics of Health Privacy (ID: 1417)	03-Mar-2020	5/5 (100%)
Health Privacy Issues for Clinicians (ID: 1418)	03-Mar-2020	5/5 (100%)
Basics of Information Security, Part 1 (ID: 1423)	03-Mar-2020	5/5 (100%)
Basics of Information Security, Part 2 (ID: 1424)	03-Mar-2020	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sam James (ID: 4151362)
- **Institution Affiliation:** Oakland University (ID: 1563)
- **Institution Email:** spjames@oakland.edu
- **Institution Unit:** ISE

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Student and Faculty Advisor Basic/Refresher
- **Stage:** Stage 2 - Refresher Course

- **Record ID:** 22291653
- **Completion Date:** 04-Mar-2020
- **Expiration Date:** 04-Mar-2023
- **Minimum Passing:** 85
- **Reported Score*:** 95

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Oakland University (ID: 13470)	03-Mar-2020	No Quiz
Students in Research (ID: 1321)	03-Mar-2020	5/5 (100%)
Assessing Risk - SBE (ID: 503)	03-Mar-2020	5/5 (100%)
Informed Consent - SBE (ID: 504)	04-Mar-2020	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	04-Mar-2020	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sam James (ID: 4151362)
- **Institution Affiliation:** Oakland University (ID: 1563)
- **Institution Email:** spjames@oakland.edu
- **Institution Unit:** ISE

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Student and Faculty Advisor Basic/Refresher
- **Stage:** Stage 2 - Refresher Course

- **Record ID:** 22291653
- **Report Date:** 24-Mar-2020
- **Current Score**:** 96

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	03-Mar-2020	5/5 (100%)
Oakland University (ID: 13470)	03-Mar-2020	No Quiz
Assessing Risk - SBE (ID: 503)	03-Mar-2020	5/5 (100%)
Informed Consent - SBE (ID: 504)	04-Mar-2020	5/5 (100%)
Research with Children - SBE (ID: 507)	12-May-2014	4/4 (100%)
Internet-Based Research - SBE (ID: 510)	04-Mar-2020	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k93f2005c-fd97-45b7-88c1-d6e2c932ff7c-22291653

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

CITI PROGRAM

Completion Date 04-Mar-2020
Expiration Date 04-Mar-2023
Record ID 22291653

This is to certify that:

Sam James

Has completed the following CITI Program course:

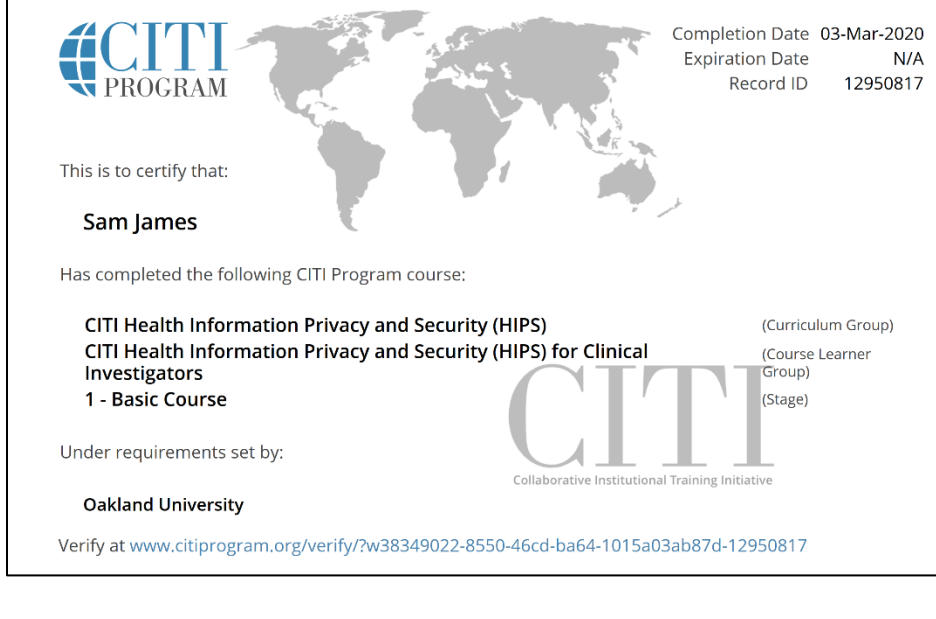
Human Subjects Research	(Curriculum Group)
Student and Faculty Advisor Basic/Refresher	(Course Learner Group)
2 - Refresher Course	(Stage)

Under requirements set by:

Oakland University

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wd3c45eb5-f894-41ef-a719-7058c3b37309-22291653



CITI PROGRAM

Completion Date 03-Mar-2020
Expiration Date N/A
Record ID 12950817

This is to certify that:

Sam James

Has completed the following CITI Program course:

CITI Health Information Privacy and Security (HIPS)	(Curriculum Group)
CITI Health Information Privacy and Security (HIPS) for Clinical Investigators	(Course Learner Group)
1 - Basic Course	(Stage)

Under requirements set by:

Oakland University

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w38349022-8550-46cd-ba64-1015a03ab87d-12950817

Appendix D: Experiment 1 Data Collection

Data Collection Log for Grip Strength

Name: _____

Age: _____

Gender: _____

Date: _____

Jamar	Right Hand	Left Hand
Trial 1		
Trial 2		
Trial 3		
Mean		
New Device	Right Hand	Left Hand
Trial 1		
Trial 2		
Trial 3		
Mean		

Appendix D: System Usability Scale

Participant ID: _____ Site: _____ Date: ___/___/___

System Usability Scale

Instructions: For each of the following statements, mark one box that best describes your reactions to the system *today*.

		Strongly Disagree				Strongly Agree
1.	I think that I would like to use this system frequently.	☐	☐	☐	☐	☐
2.	I found this system unnecessarily complex.	☐	☐	☐	☐	☐
3.	I thought this system was easy to use.	☐	☐	☐	☐	☐
4.	I think that I would need assistance to be able to use this system.	☐	☐	☐	☐	☐
5.	I found the various functions in this system were well integrated.	☐	☐	☐	☐	☐
6.	I thought there was too much inconsistency in this system.	☐	☐	☐	☐	☐
7.	I would imagine that most people would learn to use this system very quickly.	☐	☐	☐	☐	☐
8.	I found this system very cumbersome/awkward to use.	☐	☐	☐	☐	☐
9.	I felt very confident using this system.	☐	☐	☐	☐	☐
10.	I needed to learn a lot of things before I could get going with this system.	☐	☐	☐	☐	☐

Brooke describes (1996) how to calculate the SUS scores. Each item contributes a score from zero to four; for each of the positive odd-numbered statements, one was subtracted from their response, and for the even-numbered items, the score contribution was five minus the response. All the contributed scores were summed and multiplied by 2.5 to obtain the overall SUS score.

Appendix D: Suitability Evaluation Scale

Question	Response				
	Not at all				*Very much*
Q1. How much did you enjoy your experience with the system?	1	2	3	4	5
Q2. How much did you sense to be in the environment of the system?	1	2	3	4	5
Q3. How successful were you in the system?	1	2	3	4	5
Q4. To what extent were you able to control the system?	1	2	3	4	5
Q5. How real is the virtual environment of the system?	1	2	3	4	5
Q6. Is the information provided by the system clear?	1	2	3	4	5
Q7. Did you feel discomfort during your experience with the system?	1	2	3	4	5
Q8. Did you experience dizziness or nausea during your practice with the system?	1	2	3	4	5
Q9. Did you experience eye discomfort during your practice with the system?	1	2	3	4	5
Q10. Did you feel confused or disoriented during your experience with the system?	1	2	3	4	5
Q11. Do you think that this system will be helpful for your rehabilitation?	1	2	3	4	5
	Very easy				*Very difficult*
Q12. Did you find the task difficult?	1	2	3	4	5
Q13. Did you find the devices of the system difficult to use?	1	2	3	4	5
Q14. If you felt uncomfortable during the task, please indicate the reasons.	Open response: (No) or (Yes + reasons)				

Appendix E: Home Exercise Program

Routine For: Sam James
Created By: Sam James, OTR

Oct 03, 2019

FINGER - 48 Flexion (Resistive Putty)

Keeping fingertips straight, press putty towards base of palm.

Repeat 10 times.
Do 2-4 sessions per day.

FINGER - 51 IP Fisting (Resistive Putty)

Keeping knuckles straight, bend fingertips to squeeze putty.
Repeat 10 times. Do 2-4 sessions per day.

FINGER - 54 Grip Strengthening (Resistive Putty)

Squeeze putty using thumb and all fingers.

Repeat 10 times.
Do 2-4 sessions per day.

FINGER - 55 Grip Strengthening (Isometric)

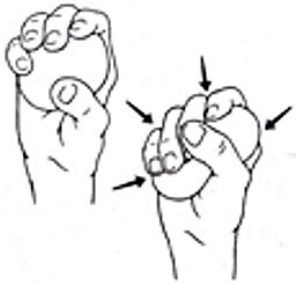
Squeeze washcloth roll.

Hold 5 seconds.

Relax 2 seconds.

Repeat 10 times.
Do 2 sessions per day.

STRENGTH BUILDING - 4 Putty-in-Your-Hand



Slowly squeeze putty or a soft rubber ball while breathing normally. Repeat with other hand.

Repeat 10 times. Do 2 sessions per day.

HAND - 47 Towel Roll Squeeze

With right forearm resting on surface, gently squeeze towel.

Repeat 10 times per set. Do 2 sets per session.
Do 3-4 sessions per day.