Designing The Armadillo Orthosis
User experience design for a wearable upper limb stroke therapy device.

By

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1.0 Abstract
Stroke is a medical condition causing disability worldwide (Feigin et al., 2014; Murray et al., 2012; National Heart Lung and Blood institute, 2016). It can leave people with physical and cognitive deficits. The individual’s function in everyday activities following a stroke depends on the severity of the stroke and the amount of therapy available to them. Rehabilitation for the physical impairments, such as upper limb deficits, can promote recovery and is delivered by physiotherapists and occupational therapists. Therapy takes place predominantly in the clinical environment. It is manual, task based, delivered one on one, and can be time intensive. Self-management methods for patients’ stroke rehabilitation are gaining attention from healthcare professionals (Taylor, Monsanto, Kilgour, Smith, & Hale, 2019). Rehabilitation that can be done at home has benefits for the individual, the family or caregiver, the therapist and the healthcare system. Independent rehabilitation at home reduces pressure on healthcare resources and can be beneficial for stroke patients recovery. So, medical interventions and products are shifting from clinical to community and home environments.

The use of robotics for rehabilitation has the potential to support recovery of function and assist with everyday tasks in a variety of ways. This paper explores the design of a robotic device for the hand. By involving stroke patients, clinicians and carers in the design process, this research aims to improve the user experiences of a robotic device for hand rehabilitation. Designing for the user experience has the potential to improve the engagement and acceptance of the robotic device for independent home therapy.

A combination of methods have been used to include users in the design process and gather qualitative data to inform the design. The methodologies include research through design and human-centred design. Research through design includes methods such as a literature review, using and adapting design criteria, prototyping, iteration, user-testing, and thematic analysis. Human-centred design is about involving users in the development process and include methods such as surveys, semi-structured interviews, observations, and user testing. There were four clinicians and seven stroke patients that met inclusion criteria and participated in the testing. Three patients and three clinician participants were involved in the interviews. Personas were used to understand user wants and needs, and to inform criteria for the design process.

By using these methods we gain a better understanding of the users' needs in order to improve the design of the pre-existing robotic upper limb stroke rehabilitation device. The purpose of the design is to meet the needs of the stroke patient in his or her own home. This design study focuses on developing the user experience by addressing usability. Interactions considered during the iterative design process are putting on and taking off the device. It is found through testing and iterations that comfort, cleaning and safety were necessary for this wearable robotic upper limb stroke therapy device to be easily worn and used in the home.
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2.0 Introduction
Stroke is one of the leading causes of long-term disability worldwide, with approximately 15 million new cases every year (Feigin et al., 2014; Murray et al., 2012; National Heart Lung and Blood Institute, 2016). Stroke patients can experience long-term effects, including motor and cognitive impairments (Pinter & Brainin, 2012; Stroke Foundation NZ, 2019). Motor impairments require therapy for recovery; however, therapy delivery is well below the recommended levels (Kimberley, Samargia, Moore, Shakya, & Lang, 2010; Lang, MacDonald, & Gnip, 2007; Stroke Foundation NZ & New Zealand Guidelines Group, 2010; Australian Stroke Foundation, 2017). In short, many stroke patients are not receiving the level of therapy that would be most beneficial for their rehabilitation.

Robotics such as orthoses are artificial external devices with the purpose to assist movement of the upper limb. They have the potential to deliver therapy at comparable levels to conventional manual therapy (Kutner, Zhang, Butler, Wolf, & Alberts, 2010). However, there are still gaps in the knowledge regarding robotic systems; specifically, more research is needed on the design of robotic devices and involvement of users in the design process since user experience and independent use contexts are not often addressed (Blackman, 2013; Wu et al., 2014).

This research aims to re-design a pre-existing robotic device using the theoretical framework of constructivism, undertaking human-centred design and research through design methodologies. Specifically, this research investigates the experience of initiation and conclusion of use. The scope of this research is limited to the interactions and experience of stroke patients with putting on and taking off of the device and subsequently the interactions during actual use of the device in therapy or tasks are not examined in this thesis. The research findings suggest design needs to consider functionality, ease of use, and wearability. These factors are considered in the context of user experience in the home environment.

The researcher was motivated to undertake this research because a family member was affected by stroke. The researcher is an industrial designer with experience in designing medical product and an understanding of how stroke can affect a person. However the researcher, had no experience in undertaking academic research, designing for stroke affected people, or knowledge of what motor impaired stroke patients need and want from therapy. This was gained throughout the research process.
3.0 Literature review
3.1 Stroke

In order to understand and design devices suitable for stroke rehabilitation we first need to understand stroke, its variable effects, and therapy practices.

Stroke can affect people at every stage of life, although it is most prevalent among adults aged 65 years and older, with around 75% of all strokes occurring in this age group (Blackman, 2013; Feigin et al., 2014; Murray et al., 2012; National Heart Lung and Blood institute, 2016; Stroke Foundation NZ, 2019; Feigin, Lawes, Bennett, Barker-Collo, & Parag, 2009; Patten, Lexell, & Brown, 2004). In New Zealand, about 9,000 people have a stroke each year with an estimated 60,000 people living with the effects of stroke (Stroke Foundation NZ, 2019).

As the population ages, older adults are becoming an increasing percentage of the global population (World Health Organization, 2019). This group, specifically those over 65 years, are most at risk of experiencing a stroke, meaning that clinical time and resources will be put under increasing pressure as their numbers increase (Stroke Foundation NZ, 2019).

A stroke is also referred to as a cerebrovascular accident (CVA). A CVA occurs when the brain has reduced blood flow in an area of the brain, resulting in cell death. There are two main types of stroke. The most common type is ischaemic stroke, which occurs when a blood clot blocks an artery in the brain, the second type is haemorrhagic stroke, occurring when blood leaks into the brain tissue from an artery rupture (Donnan, Fisher, Macleod, & Davis, 2008; National Heart Lung and Blood institute, 2016; Stroke Foundation NZ, 2017). Both cause damage by starving the brain tissue of oxygen and nutrients, thus causing loss of function. It is possible to suffer from multiple strokes; however, this study will focus on patients recovering from a singular stroke event that affects one side of the brain. In upper limb stroke rehabilitation devices, there is an assumption that there is one unaffected hand and arm which may not be the case if the patient has multiple stroke events. As part of this, the unaffected side takes up the dexterous tasks, even when it is not the dominant side.

The effects of a stroke depend on the location and severity of damage to the brain tissue. Disabilities range from mild to severe and can include motor, sensory and cognitive impairments (Pinter & Brainin, 2012; Stroke Foundation NZ, 2019). Motor impairments affect up to 83% of stroke patients, with the majority having an impairment in upper limb function (Pinter & Brainin, 2012; Stroke Foundation NZ, 2019; Weiss, 2010). Motor impairments can include weakness or paralysis of the affected side. Other impairments can include reduced sensation, balance and vision, and difficulty forming and understanding speech (Pinter & Brainin, 2012; Stroke Foundation NZ, 2019). Cognition can also be impaired, affecting attention span, concentration, ability to learn, judgment, memory and executive functions (Pinter & Brainin, 2012; Stroke Foundation NZ, 2019). These impairments have an impact on patients’ ability to participate and engage in activities of daily living (ADLs) and rehabilitation exercises, thus a device that is complex to use would be impractical.

Stroke is a disruption to life, and an individual’s adjustment to life and identity afterward is dynamic and requires a process of rebuilding and adaptation (Lou, Carstensen, Jørgensen, & Nielsen, 2017). Many stroke patients have some level of impairment involving the upper limb. This is a large contributor to the burden that stroke patients experience, as impaired
function of the arm and hand causes difficulty with ADLs (Prange et al., 2015). These difficulties are often ongoing, with fewer than 20% of stroke patients having full upper limb recovery six months after the stroke (Prange et al., 2015). Difficulties with ADLs may include tasks of self-management such as dressing, eating, personal care such as toileting and require arm function to enable task completion (Smarr et al., 2012).

The arm and hand are essential for our interaction with the world around us. The hand is the region of the body that allows us to manipulate our surroundings. The most common effects on the hand post-stroke are reduced opening and/or closing, and reduced control; devices could assist. In order to regain motion and/or control a patient may require intensive training. Patients may also require assistance with everyday tasks. In the area of robotics, the most requested and preferred areas for aid were assistance with independent task completion of ADLs such as personal hygiene, dressing/grooming, eating and preparing food (Prange et al., 2015). Therefore a design aiding in daily tasks must not block the grip or become a hindrance to task completion.

3.2 Promoting recovery

Upper limb rehabilitation can be affected by the phenomenon of learned non-use: where the brain suppresses the affected extremity from being used (Ballester et al., 2016). This study covers the use of therapy to counteract this effect. High-intensity, repetitive and task-based practice is a remedy for cognitive impairments that helps to restore motor function (Pinter & Brainin, 2012). Types of motor functions to be regained include gripping, gross or large movement in the upper limb. This research focuses on delivering clydrial grip because it is identified in the literature as important for stroke devices patients, and their achievement of daily tasks (Prange et al., 2015).

Therapy options for motor recovery are typically manual and require repetitive movement with clinician guidance and tools such as braces and apparatus (Langhorne, Bernhardt, & Kwakkel, 2011; Pinter & Brainin, 2012). Other rehabilitation practices, include constraint-induced movement therapy and electro biofeedback (Pinter, 2012). Another option is the use of robotics in therapy (Langhorne et al., 2011; Pinter & Brainin, 2012). It is important at this stage to differentiate between maintaining independence with aids that enable non-use, compared with therapies and devices that aid in actual motor recovery. The challenge is in delivering hospital quality therapy within the home. This is because in the home, there is less access to medical professionals and greater need for the facilitation of independent therapy. In stroke therapy, a patient may require intensive training to regain motion and/or control of the upper limb (Pinter & Brainin, 2012).
3.3 The problem with therapy doses

Therapy is a crucial part of recovery and regaining functionality after a stroke. However, evidence shows that patients are not receiving the recommended amount of therapy for recovery. The clinical guidelines for motor recovery state that for stroke recovery five or more hours of therapy a day, with 400-600 repetitions of each exercise, are required (Australian Stroke Foundation, 2017; Kimberley, Samargia, Moore, Shakya, & Lang, 2010). However, studies show that the actual amount of therapy patients receive is much lower, averaging at two hours, 15 minutes per day, with 23-32 repetitions per exercise being delivered (Stroke Foundation of New Zealand, 2010; Lang, et al., 2007). This includes inpatient care, where a patient has the highest access to intensive rehabilitation (Lowry, 2010).

There appears to be a disconnect between the recommended therapeutic time and the actual time each patient spends doing therapy. Suggested barriers leading to this discrepancy include pressure on clinical time and resources, patients’ ability to participate outside the clinical environment and their ability to engage also influences outcomes, so the design must engage the user.

From health professionals perspectives, national clinical guidelines by themselves are insufficient in enabling therapy delivery (Donnellan, Sweetman, & Shelley, 2013). Conventional stroke rehabilitation, such as constraint-induced movement therapy, is also one on one, time intensive and exhausting for both patient and clinician (Langhorne, Coupas, & Pollock, 2009). As the guidelines state, the time spent doing therapeutic exercises is extremely important, but if all work is done one-on-one, it puts pressure on health provider’s resources and limits the number of patients a clinician can work with in a day. There appears to be increasing pressures on resources, as numbers of patients are increasing worldwide as well as numbers of those more likely to have a stroke (older adults)(World Health Organization, 2019; Stroke Foundation NZ, 2019). Due to the demands on healthcare some patients wait up to six months to start receiving therapy. As the brain’s ability to re-learn reduces overtime, delaying therapy can render it ineffective (Lowry, 2010). Independant therapy options need to be available early and be intuitive for patients to do.

Additionally, advancements in therapy can have delayed implementation in inpatient and clinic-based stroke therapy, as they need to be proven with a strong evidence base, which reduces the ability of clinicians to deliver up to date care to individuals in rehabilitation (Baatiema et al., 2017). This can be a burden on health providers to allow for holistic care, therapy and funding. Home and community care can be more flexible and may be able to test and adopt new technologies as they are developed. By creating advancements for home based therapy we can deliver independent therapy to patients and aid in daily tasks.

With pressures on time and resources in the clinical setting, implementing independent therapy in a home-based environment is becoming increasingly important. If effective therapy can occur in communities and homes, it will reduce impact on clinician resources and difference between recommended rehabilitation time and actual time spent doing exercises. However, the barriers to home-based therapy are not to be ignored. Accessibility to funding, appropriate equipment and support are a barrier to home therapy (Lowry, 2010; Lequerica et al., 2009; Lequerica and Kortte, 2010; Medley and Powell, 2010). Patients level of compliance with, participation in, or engagement with independent therapy can also be a barrier (Lowry,
Research shows that when independent exercises are implemented in stroke therapy, only 31% of stroke survivors do their exercises correctly and with enough repetitions (Alankus, Lazar, May, & Kelleher, 2010; Shaughnessy, Resnick, & Macko, 2006). So, potential robotic therapy devices must be capable of delivering the correct movement and delivering enough repetitions in independent use.

The literature suggests that increasing pressures on time and resources of clinicians are occurring and independent home therapy options are becoming more important. Robotic therapy options are a potential solution to aid and enable independent therapy. Designing with stroke patients needs in mind could help improve the design of therapy robotics, and furthermore, enable stroke patients to use them independently at home and in their community.

### 3.4 Robotics in therapy

Robotic devices are being increasingly proposed to address many tasks and situations across a range of contexts. A robot can be defined as a device or machine that uses electronic components to undertake a physical task. There is a current trend towards self-management and independent stroke rehabilitation practices (Taylor, Monsanto, Kilgour, Smith, & Hale, 2019). Therapy robotics are being proposed and developed for the clinical context because robotic devices can deliver therapy at the same level as conventional therapy. When comparing 60 hours of manual therapy with a combined 30 of manual and 30 of robotic therapy, stroke patients had comparable improvement in their chosen task; this shows that robotics can provide meaningful therapy (Kutner et al., 2010). Robotics can be designed to make measurements, assess, support recovery as well as aiding in everyday tasks to help maintain the independence of older adults (Blackman, 2013; Wu et al., 2014). Stroke robotics for the upper limb, focus on delivering large reaching movements (gross) and grip, rather than promoting dexterity, as it is assumed the user has one affected upper limb.

The use of robotic training both in therapy and a home programme can deliver a similar perceived improvement of hand function to the patient as traditional therapy (Kutner et al., 2010). Patient focus and intensity during a hand movement in robotic guided task therapy are beneficial for motor learning outcomes (Kim, Hinojosa, Rao, Batavia, & O’Dell, 2017). Home device functions can include monitoring, documentation, diagnosis, prevention, treatment and rehabilitation. Rehabilitation devices at home can enable patients to receive convenient personalised therapy every day (Bitterman, 2011). Devices delivering home exercises make therapy more accessible to patients. This makes it easier to participate and engage in rehabilitation, as it can deliver clinic-level repetitions and task based therapy independently. This can increase potential therapy time and enable patients to receive therapy early and assist recovery.

Robotics are used occasionally in clinical therapy; however, there is a need to involve users in development to address their experience when using the device, as it may impact their independent home therapy. Previously, requirements for users of robotic upper limb therapy devices include: usability, interaction, comfort, size and weight; safety, reduction of skin pressure, chafing, sharp edges; also function, support cylinder grasp, enable flexion and extension, varying flex ability and independent finger function (Prange et al., 2015).
Case study 1: the Gentle G system

The Gentle G system is used in upper limb stroke therapy in clinical environments. It uses robotics in virtual exercise to retrain reaching and grasping and utilises biofeedback to positively affect recovery (Loureiro, Lamperd, Collin, & Harwin, 2009). This system enables therapy by engaging the fingers and supporting a natural grip. It utilises training games that mimic everyday actions and could increase engagement in therapy. The Gentle G delivers therapy with little consideration of aesthetics or user perception (Loureiro et al., 2009). This system has many parts, including a frame, chair, orthosis, table, screen, speakers, keypad, gravity mechanism and grasp assistive robot attached to the hand and arm (Loureiro et al., 2009). It takes up a large amount of space, is costly and is run by trained personnel. Its use is limited to clinical environments with space, funds and personnel to support the use of the Gentle G. This robotic delivers an upper limb therapy motion that is similar to the position from the pre-existing robotic device in this thesis. However, it is not suitable for independent therapy in a home environment, and there is no indication that aesthetics or other features to design for acceptance have been implemented in the design.

Case study 2: The Able X

The Able X system includes several devices combined with rehabilitation games for upper limb stroke rehabilitation and other similar conditions (AbleX Healthcare Ltd, 2019). It is part of the ImAble system, which had positive outcomes from pilot testing, where arm movement and patient motivation were positively affected by using the game system (Jordan, Sampson, Hijmans, King, & Hale, 2011). The Able X is compact and designed for independent rehabilitation in clinical, home and community environments, such as stroke clubs. The games developed require specific motions for therapeutic exercises. This device requires a level technology ability for home users. The games, as stated by Able X, enhance engagement with therapy exercises and give the movements meaning (AbleX Healthcare LTD, 2019). This system is focused on designing for the engagement of users. It can make therapy more enjoyable, and the cost per device is more accessible for individuals at a range of $920-$2,000 in addition to a rental option (AbleX Healthcare Ltd, 2019). This is important for getting therapy into homes and communities however, the Able X does not facilitate passive rehabilitation or the movements of individual fingers.

Case study 3: Astro stroke orthosis

The Astro stroke orthosis system is under development by Victoria University of Wellington’s School of Engineering and Computer Science. This robotic system works by manipulating the hand between open and closed grip positions using electronics to pull a system of artificial tendons (strings) (Rajendran, Browne, & Hollitt, 2011). The electronics of the system include two motors, a motherboard, sensors, cogs, and strings. The coding explored by the engineering team involves delivering repetitions of a movement, aiding movement compilation (haptic feedback), connection with computer game software and transmitting data to graph software.
This device delivers a cylindrical grip to hold up to 1kg. It can deliver this grip with passive repetition of motion designed for therapy and/or assistive motion which finishes a movement aiding in hand function for aid in and achievement of daily tasks (Rajendran, Hollitt, & Browne 2011). The passive delivery of repetitions also occurs in manual therapy for a person with little or no control of their hand. The aim of this mode is to maintain muscle tone, joint mobility and potential for brain recovery. The assistive function of the robotic device uses sensors to detect movement, then integrate actuators to help finish an open or closed hand grip. This gives more functionality to a person's hand. There is potential in game therapy and resistive forces for strengthening or virtual reality use. There has also been some exploration of combining the system with digital games using haptic feedback.

In this device’s development, both functions have the potential to be implemented in independent patient therapy. However, the assistive potential of the device could be implemented in activities of daily living, thus improving a patient’s post-stroke lifestyle. Additionally, there has been some consideration of cost, size and weight. However, the design of the device has not been considered, leaving it bulky, components exposed, and difficult to apply.

Figure 1: Astro stroke orthosis. The pre-existing system for this research.
3.5 Problems with developing robotics

This section addresses the wider issues, context, experience, acceptance, design and design process problems with robotic development.

Rehabilitation practices appear to be slow to implement robotics, even when they have a strong evidence base (Baatiema et al., 2017). Robotics are complex products that can have many features. In general, products can have issues such as cost, safety and usability (Lee et al., 2005). Clinicians indicate that there are important factors to consider when developing upper-limb stroke robotics. This includes addressing diverse hand movements, use, user feedback, activities of daily living, home use, adjustable difficulty levels and cost (Lu et al., 2011; Pei, Chen, Wong, & Tseng, 2017).

Therapy appears to be moving from hospitals to homes (Bitterman, 2011). When designing for home-use in general it is important to consider usability, safety, aid in daily tasks, and variable levels of difficulty. Wearable upper limb stroke therapy aids may have further user requirements such as user independence, usability for interactions, comfort, size and weight, safety, function in support of a cylindrical grasp, and independent finger motion (Prange et al., 2015). Although robotics can deliver recommended levels of therapy and can provide many benefits to users, they may not be adopted by the user, or clinically accepted (Kutner et al., 2010). In particular, there is a gap in robotics for addressing the interactions between humans and robots, that needs to be considered (Pei et al., 2017).

There is a difference in devices that work well in the hospital and those that work in homes and the community. In the clinical environment of a hospital, devices are operated by trained, able-bodied professionals (Bitterman, 2011) and robotics need meaningful feedback on exercise compliance and labour savings (Kutner et al., 2010). This differs from users in the home, who are operating devices on themselves or with the support of family and/or caregivers (Bitterman, 2011). Home users have variable ability and experience, which affects how they may use devices. On top of this, patients affected by stroke have potentially limited motor and cognitive function which can affect their ability to use a device (Bitterman, 2011).

Understanding and addressing the usability issues for patients is important in enabling home therapy delivery, however, the usability of devices and involvement of users is not always addressed or incentivised (Grant, 2014). Therefore, many of these devices are not getting commercialised or used in therapy (Pei et al., 2017). Usability is a key user requirement for designing upper limb therapy robotics (Prange et al., 2015). Designing home medical robotics that address usability issues for the home environment is important for independent use. Enabling home users to comply with home therapy is crucial for designing medical devices for the home. When a device has issues with usability or does not properly consider the user, it can cause frustration and may lead to rejection of a product. Therefore, designing for usability is an important part of enabling stroke patients to comply with rehabilitation at home (Bitterman, 2011). Usability and interactions with a device need to be addressed in order to allow engagement and acceptance to occur (Wu et al., 2014).
3.6 User experience

*User experience* is a term that describes the perceptions of people and their responses that result from their actual or expected use of a product, system or service (Bevan, 2009). Both stroke patients and their clinicians/carers can have perceptions and experiences of a device. Clinicians, as medical professionals can prescribe and recommend therapy products for their patients for both hospital and home use. Stroke patients have varied experiences in the journey through therapy. Lowry (2010) states that stroke patients highly value their rehabilitation experience. Which can be categorised into engagement, autonomy, uncertainty, hope and social relations (Lou et al., & Nielsen, 2017). Research with stroke patients suggests that engagement is a key part of a positive rehabilitation experience (Lou et al., 2017). Engagement can be defined as the act of participation and involvement (Dictionary.com, 2019). An individual’s engagement in therapy can impact the rehabilitation outcomes either positively or negatively (Lequerica & Kortte, 2010; Medley & Powell, 2010). When a patient is not engaged in their rehabilitation, it can be a barrier to the functional recovery of both motor and cognitive functions and even extend hospital stays (Lequerica & Kortte, 2010). Also, an individual’s stroke impairments can be barriers to therapy participation and engagement. Thus the device to be designed for therapy of ADLs must consider the barriers and user experience of patients, such that a patient is able to engage in therapy or ADLs that require aid or support. In this research this will be done by addressing usability.

According to Norman (2013), positive user experience involves designed interactions and relationships between object and use. From a user perspective, there are two key aspects to consider: the first is discovery, finding which interactions are possible and how to do them, and the second is understanding what something is and how to use it. Affordances are object-person relationships, including object properties, while signifiers, such as marks or sounds, can communicate how to use an object. Signifiers need to be visible and illustrate the correct signal; for example, a flat panel on a door illustrates the need to push to open it, and can also be aesthetically pleasing. These features help individuals to have an intrinsic understanding of possible interactions (Norman, 2013). These can be implemented in a physical design to easily communicate how to interact with the device to the user.

In addition to understanding how to use a device, patients must have an adequate level of acceptance for the device in order to initiate use. Perceptions of a robotic device are representations of acceptance. Medical devices can be difficult to accept and user perceptions can be negative (Wu et al., 2014). Product stigma which can be considered the opposite of acceptance, is a negative response to a product. Medical products required for ADLs that are visible to others can create stigma for patients (Vaes, 2014). Low acceptance is also linked to issues with accessibility, cost, safety issues, and poor usability (Lee et al., 2005; Pei et al., 2017). Acceptance can be difficult to measure, and researchers such as Wu et al. (2014) use perceptions as an indicator.

In robotic development, design is identified as important, but in reality it is not focused on (Kutner et al., 2010; Smarr et al., 2012). There are several common themes that need to be addressed in the development of a device including involvement of users in the design process, and addressing usability in designing human-robot interaction (Bitterman, 2011; Grant, 2014; Lee et al., 2005; Lu et al., 2011; Pei et al., 2017; Prange et al., 2015; Wu et al., 2014). It is important in this context that design considers more than just mechanical functions...
or components. To include users in the design process and understand their experiences, needs and wants, human-centred design (HCD) will be used. Research through design (RTD) methods include interviews, observations and user testing. Involving users in the design process has the potential to improve the design of the pre-existing device.

3.7 Evaluation of the literature

Stroke is a significant issue affecting many people globally. It requires therapy which is predominantly in clinical environments and is often not at recommended levels, resulting in stroke patients not getting enough therapy. Robotics have potential to deliver comparable ongoing therapy in the home. However, robotic development has its own set of issues, particularly for independent use.

Implementing user involvement in development has the potential to address usability, engagement and acceptance. The avenues for solving these issues in the pre-existing system include exploring robotic actuator options, evaluating the system, testing with participants for the development of the system and designing for user experience of usability, which can influence engagement and acceptance. Usability of the device in the home context can be explored and initial features and interactions for design development established. It also establishes the importance of user involvement in device development to best meet their needs.

In order to understand how to design for the user, an understanding of their perceptions is necessary. This could be achieved by using Human centered design to inform an iterative process. Exploring user experience of usability and interactions with a wearable robotic therapy device to build upon the existing robotics, that can deliver the repetitions and movement needed for recovery and aid. The creation of an accessible device that delivers both independence and recovery, would be ideal for home users (Section 7.4).

Evaluation of the literature identified a number of themes and gaps in robotic devices used in stroke therapy. The main gaps cited in literature is a lack of, or low user involvement in development and that usability is not always addressed (Grant, 2014; Kutner et al., 2010; Smarr et al., 2012). Other gaps include therapy delivery, design for acceptance, addressing human robot interactions, and meeting user and therapy needs in the shifting environment in which therapy is delivered.

By understanding the patients’ needs and perceptions, in response we can create/provide a design that addresses these needs, and could better communicate how to use it we could improve the user experience. As a result, improve the engagement and acceptance with a device and with therapy. Patients’ user experience should be considered and explored in the design process. This research investigates the user experience and usability of a designed robotic device with particular focus on initiation and conclusion of use.
4.0 Aims and objectives
The aim of this study is to improve the experience of using a wearable upper limb robotic device. This study will explore the use of a device in the home. Specifically, the ease of putting on and taking off for people who have had a stroke. Information from user’s perceptions of the pre-existing robotic system will be gathered. This information will be analysed and considered in the design process, iterations and testing. Qualitative research will be analysed and made into design criteria and personas. This will be implemented in the design process, alongside testing and iterations. The final design will then be developed based on this process.
5.0 The team
This research is one stage of a MedTech CoRE research group project. It involved input from team members with engineering, occupational therapy, and industrial design specialties. The project has been developed by numerous team members over many years. It started as an engineering project in 2010 (Rajendran, Browne, & Hollitt, 2011). Team members changed throughout this timeline and more recently in 2017 occupational therapy and industrial design inputs were introduced.

The engineering group developed the mechanisms, electronics and frame of the pre-existing robotics project. They are continuing with size reduction of electronics, coding for therapy and information display, the engineering advances are outlined in the evaluation of the pre-existing device (Section 7.4).

The occupational therapy input focused on a systematic review of current upper-limb stroke therapy robotics, to gain an understanding of the literature and available types of robotics and robotic therapy. This may identify and advise on features and effectiveness of current robotic therapy devices.

This is the first stage of the project to which industrial design input has been applied. The industrial design input is the subject of this thesis. Industrial design expertise was sought to address human-robotic interactions for specific contexts in order to explore product development and user experience with the device.
6.0 Methodology
This research will focus on the user experience design of the pre-existing wearable robotic device for upper limb stroke therapy. The primary aim will be to investigate and improve the interactions between the user and the device in an environment by involving users’ feedback in the design process. Therefore, a combination of research through design and human-centred design methodologies will be used to achieve this aim.

6.1 Theoretical framework

The theoretical framework approach for this study is constructivism as it recognises that people construct meaning based on their subjective experience. This provides a framework for methods, to gather feedback from participants, to assess and evaluate feedback, and develop the design process (Rodríguez Ramírez, 2017).

6.2 Design methodology

6.2.1 Research through design

This research will utilise a research through design (RTD) approach which is an overarching framework for ideation, iteration, and evaluating testing to build upon pre-existing robotics. This methodology involves the development of a design criteria to inform an iterative design process (Rodriguez Ramirez, 2017, pp. 14; Krogh et al., 2015).

The components of RTD used in this study are: literature review, thematic analysis, create design criteria based on the analysis to inform the design process, surveys, rapid prototyping, user testing, and observations.

6.2.2 Human-centered design

This research will also use a human centered design (HCD) approach which is a framework for involving users in the design process. It requires iteration and modification to meet users’ needs, and has steps that enable in depth consideration of human needs within the design process for any product (Norman, 2013; Grant, 2014).

When designing for people, understanding human psychology and technology are crucial (Norman, 2013). HCD needs to be conducted with both patient and clinician users to enhance the user experience of the pre-existing device, leading to potential increased therapy.

The participants in this study are stroke patients, clinicians and/or carers. They play a key role in device development, where devices are built for them and their needs. A stakeholder in this study could be a stroke patient, who is the key beneficiary of a device, a clinician applying and operating a device on others, and/or a carer (often a family member).
6.3 Methods

The methods implemented in this study include literature review, surveys, semi-structured interviews, user-testing, and thematic analysis.

Figure 2: Project components that work together resulting in a final prototype.
6.3.1 Literature review

A literature review enables the key aspects and connections from the pre-existing research and studies to be explored, evaluated and ordered (Cresswell, 2013; Martin & Hanington, 2012).

The literature was to gain insight of the relevant aspects for the design of robotic devices for upper limb therapy. The review has been used to evaluate current practices, research case studies and devices to enable the knowledge base to be built on. Critical evaluation was applied to find and include appropriate source material. This includes consideration of relevance, studies inclusion and exclusion criteria, participant sample size, study limitations/gaps and citation number. The search engines used in this research include Google Scholar, and the Victoria University of Wellington library.

The search terms included, stroke, therapy, robotics, products, user experience and their sub-categories in various combinations and or synonyms of these search terms. The discovered literature was analysed using a matrix to distill themes in literature and assist in thesis preparation.

6.3.2 Surveys

To discover users’ perceptions and responses to the pre-existing robotic device, this research utilised a robotic acceptance survey by Wu et al. (2014) and adapted it for the audience. Two surveys were created (for clinicians and patients) with similar questions, to assess current levels of robotic acceptance, as well as some additional questions to identify user needs (Price, 2017). The clinician survey was created to gain an understanding of current therapy practices and clinician acceptance and the perceived patient acceptance of the pre-existing device. It seeks to shed light on the understanding of devices use, and the needs of clinicians and their patients in upper-limb therapy. A survey for participants was created to understand the needs of people who are affected by stroke, the devices they use, their levels of robotic acceptance and their requirements for an upper limb therapy device. The surveys can be found in the appendix (Appendix 3 surveys).

Clinician survey

Recruitment was undertaken at a stroke research conference. During this event, a demonstration of the pre-existing robotics manipulating a hand through functional grip movements was undertaken. The anonymous digital survey included an information sheet, and by choosing to carry out the survey they were giving their consent. The survey included a range of questions around their own and patient use of devices, and what they would want and need from a robotic device.

The participant number was much lower than expected meaning no trends could be observed, and could be due to the steps involved in undertaking the survey. With one participant, a clinical researcher, who does not use robotics or medical devices in delivering therapy. The participant has been included due to a high level of knowledge as a researcher of clinical practice in stroke therapy.
Patient survey

Participants were recruited from a stroke club after attending a presentation regarding the research and a demonstration of the pre-existing robotics. Consent was gained prior to the surveys being filled out. The inclusion criteria were stroke-impacted individuals who had attended the session, and were motor impaired. A printed survey, information sheet and consent form and pen were provided for each participant. The information sheet and consent form were also verbally explained. The participant group was given 30 minutes to answer 26 questions, in which four questions involved ticking or marking a yes/no box, one marking all applied, and 15 involving Likert scales from ‘agree’ to ‘disagree’ for specific statements, the remaining questions were asking short answer for qualitative feedback. Help was given to participants who needed questions explained to them. At the end, the consent forms and surveys were collected and participants could take home the information sheets.

<table>
<thead>
<tr>
<th>Survey participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, 3 1/2 months post-stroke, motor function impairment.</td>
</tr>
<tr>
<td>Male, 1 1/2 years post-stroke, motor, cognitive and psychological impairment.</td>
</tr>
<tr>
<td>Female, 17 years post-stroke, single sided weakness.</td>
</tr>
<tr>
<td>Female, 3 months post stroke, motor function impairment.</td>
</tr>
</tbody>
</table>

6.3.3 User testing

Semi-structured interviews

This method enables the gathering of qualitative data with critical topics that enable asking questions in differing ways in a conversational format (Martin et al., 2012, pp. 102). This method was chosen to gather insight into therapy practices, devices and personal experiences, to understand the needs of the participants, and allow participant questions and comments that expand critical topics for future testing. Likert scales were used to indicate perceived ease of use or usability when compared with other prototypes in clinician and patient sessions based on System Usability Scale (SUS). The interview guide was based on the survey.

In this testing stage, semi-structured interviews and observations were used to explore the user experience of both patients and clinicians. The testing guide sheet was based on the surveys, and can be found in the appendix. The prototypes were introduced to participants in chronological order, and they could choose to touch and try on prototypes. Semi-structured questions were asked, giving space for feedback on which features were successful or unsuccessful.
Patient testing had initial questions that were asked about the participant’s stroke, impairments, and device use. First, the pre-existing device was discussed with the participant, then they were introduced to the phase 1 prototypes. One patient was also introduced to the phase 2 prototypes at a later date. Interactions with the prototypes were observed or recorded. Open questions on what the participant thought about the prototypes were asked, and their thoughts on a set list of topics including aesthetics and functional aspects, perceptions, ease of use and intention to use were requested. Time was given for the participant to ask questions and for discussion on robotic devices in general to occur. The participant was thanked and the equipment packed up.

The testing included participants that were clinicians, with experience in upper-limb therapy and wearable devices in delivering stroke rehabilitation. Current therapy practices, the needs of devices, thoughts, insights and recommendations are to be gathered through semi structured interviews. Each Clinician had two sessions spaced several months apart. In the first session, they were exposed to the pre-existing device and first phase prototypes. In the second they were exposed to all of the prototypes including the new prototypes. Clinicians were recruited through conferences or word of mouth.

Participants:

There were 3 groups of participants: industry professional, clinician and patient. An Industry professional was interviewed about their experience with developing stroke rehabilitation products. Insights into acceptance and initiation of use with these types of devices were gained. Recommendations for future product features were also included. With patients there were two phases of this user testing. The first part took place with two participants, the second test repeated the first and added additional prototypes with a new participant at a later date. These participants are different to the survey participants except for participant 3 whom participated in both.

### Patient participants

| Participant 1, male, 11 years post-stroke, left side affected, flaccid upper limb with no control. Uses wheelchair, medical bed and electro-muscle stimulators. Requires assistance to apply devices to the affected upper limb. |
| Participant 2, male, 9 months post-stroke, right side affected, seized-up fingers, some index and thumb motion. Made his own cardboard splint. |
| Participant 3, male, 6 months post-stroke, left side affected, can control open and close, but motion is delayed, stiffness in thumb motion. Does not use a wheelchair due to feelings of being judged. Was involved in survey stage. |
Three clinicians were interviewed: one physiotherapist, and two hand therapists. Two had face-to-face Interviews, and one was completed via video.

**Clinician participants**

**Clinician 1, Physiotherapist.** Treats patients from three months to several years post-stroke. Uses Able X gaming device as part of patient therapy and resistance band devices like the Saebo glove.

**Clinician 2, Hand therapist.** Typically engages with stroke patients many years post-stroke with learned non-use. Uses splints and other devices to maintain hand tone and hand hygiene.

**Clinician 3, Hand therapist.** Engages with stroke patients 2-10 years post-stroke. Uses splints and other devices to maintain hand tone and improve hand hygiene.
6.3.4 Observations

Observations were used alongside the semi-structured interviews. Observations are a useful way of gathering data about interactions that may not be able to be described by the participant (Boyatzis, 1998). Prototypes were introduced in the user testing. It was made clear that the participants could choose whether or not they would like to interact with any prototypes. This included the ways in which interactions occurred and descriptions from participants about which parts they liked/disliked, or found easy or more difficult to use, and suggestions to aid the design process.

6.3.5 Thematic analysis of testing

Thematic analysis is used to classify pre-existing or found themes from a range of qualitative data, and enables data classification and frequency of theme used to be tracked. It uses multiple phases of data reduction to find the themes and critical factors (Alhojailan, 2012). Thematic analysis is necessary to deduce key themes from qualitative data. The data was collected from testing sessions and semi-structured interviews with patients and clinicians. The data included audio recording, video or photo plus observers notes. This method enabled validation of essential factors and themes, which would need to be addressed through design.

6.3.6 Personas

Personas are described by Maguire (2001) as representing the needs of key user groups to the design team. Personas are used as a subjective tool to understand the human aspects (Pruitt & Grudin, 2003). Personas are typically affiliated with a scenario of use and portray some personality features. User requirements can be created from personas, which give an avenue for prototype evaluation. Within innovation, personas are also used to inspire rather than create specific solutions. This study uses personas to give insight into user needs in an easy to assess format to add to and validate criteria and inspire device development.

6.4 Ethics

Ethics approval was granted by Victoria University of Wellington Human Ethics Committee (0000023011). Ethical approval was granted from the Health and Disabilities Ethics Committee (HDEC 16CEN5). The consent forms and information sheets can be found in the Appendix.
7.0 Design process
In this section we first explore the hand, then undertake early exploration of possible project directions, explore and analyse the pre-existing system. Then the personas and criteria are applied to the design process and further developed through testing. The design process adopted addresses the key criteria in phase 1 and phase 2 of the design process with the development of the final prototype in the results (section 8.2). Developing usability of the device for the home environment is the aim. In this research usability will be broken into three key categories for users: function (see astro orthosis and team), wearability, and ease of use. They contain exploration of into the interactions with putting on and taking off the device (don/doff) and assembly and disassembly, safety, comfort, cleanability, fit and customisation.

7.1 The hand

In order to create design criteria, we first need to understand the motion of the hand, wrist and fingers. The joints in the hand allow the muscles to move the bones in various directions. These movements include finger bending and straightening and an opposable thumb. Wrist movements for turning upwards and downwards as well as forwards and backwards and combinations for grip and dexterity.

Grip function includes finger bending (flexion) and straightening (extension), wrist flexion, extension (wrist and fingers in line with the arm) or hyperextension. Hyperextension is when the back of the hand moves further towards the arm. Movements in the hand are caused by muscle groupings attached to both sides of the bone via tendons: messages are received from the brain for one group to tense the other to relax to create a flex. Muscle control and range of joint motion is required to create a normal grip function (Tortora & Grabowski, 2003).

The hand wrist and finger control can be impaired as a result of a stroke. The hand can become tightly closed and stiff (spasticity), loose and floppy (flaccidity) and/or have reduced or delayed control. The hand motion required for grip is explored in this design study (Figure 3). The thumb has not been included, as the engineering team excluded the thumb prior to the commencement of this study. Reasons for prior exclusion being complexity of the thumb and cost (see 7.4).

In affected grip function, therapy and aiding devices are used to help with a range of motion and/or control. Hands come in many shapes and sizes where it is common for designers to develop three sizes of products (small, medium and large) to fit most people.
7.2 Products worn on the hand

Products commonly worn on the hand are used to inspire aesthetics, interaction and physical interface with the hand. Relating to features of everyday universal products that are designed for everyone to use, boosting acceptance. These include gloves, sports protective wear, wrist and hand braces and jewellery (Vaes, 2014). The prototypes developed in this research explored aesthetics and function through drawings, 3D printing, and prototyping with fabrics.

Gloves or mittens come in different sizes, and can be mass produced. The most common colours are black or a light-mid grey, and are typically knit/fabric texture or leather. The way gloves are interacted with is that they are pulled on, which is simple in concept but may pose difficulty to a person with limited hand motion to get individual fingers into the correct places in the glove.

Jewellery can be worn on the hands and/or wrists, including rings, watches and bracelets. Jewellery is typically silver/grey, or gold/yellow and uses luxury aesthetics. They are commonly slid on, buckled or clipped using one hand.
Medical braces are less common. Braces typically have thick, technical fabrics with Velcro-strapping or buckle fastening, and some have metal or plastic reinforcing. Braces can be used in therapy practices and are most commonly black, bandaid pink or grey. They can come in several sizes or be size adjustable. Medical brace aesthetics are often associated with the hospital, being unwell, having an injury and/or support recovery. Aesthetically the person would have an idea of the purpose, and the materials could support the limb and maybe robotic components.

The final common product is sports protective wear braces for the hand and wrist. These often use a mixture of hard and soft parts to protect and support the hand and/or wrist. Sports braces often use a wrapping method with Velcro for closure. These braces come in different colours and are typically black with a bright edging or a pop of colour. Sports protective wear gives an active, healthy, safe or sporty aesthetic.

7.3 Early ideation

To start exploring how to improve the design of the pre-existing robotic device, other robotic and technology options were considered. One possible alternative system is soft robotics that use inflation. How an inflatable robotic might work was sketched (Figure 4). Existing robotic test prototypes exist; however, the process in creating them is complex. They require much engineering to get right and creating them would involve multi-material moulding or 3D printing. The recommendation from the engineering team is that the pneumatic system for inflation would need many tethered cables and would be bulky. This would negate the ability of the device to support daily tasks.
3D knitting and 3D printed chainmail were possibilities. The knitting process is soft, even studies that explore knitting with solid materials such as wire (Yun, 2014). 3D printed chainmail has the potential to have a solid and flexible sections. However, it would be complex to design and difficult to manufacture.

This led to exploration into 3D printing on fabrics which has both hard and flexible sections. 3D printing, enables the device to be fully solid, moderately solid, or flexible sections based on the material (Hashemi Sanatgar et al., 2017). Textiles are associated with wearable products and it has potential.

3D scanning (Figure 5) was considered as a way to create bespoke devices within hospitals. Early tests were undertaken in a parametric software called Grasshopper (Figure 6). This option would require time, expense and space for machinery in hospitals. It has barriers, such as difficulty of implementation, required machinery and trained people available on location.

The project aims to work with developing the pre-existing system. The way the finger section and robotic unit is attached was initially explored, then other test prototypes were created (see 7.6.2 wearability). The scope of this design project does not include the coding and development of the technology and electronics inside of the robotic unit.

This study uses the pre-existing device technology, coding and hardware. This enables the focus on the interface between the arm and robotic is being considered and attachment is an action that makes the interface occur.

Figure 4: Sketches exploring how inflation might bend the hand open and closed.
Figure 5: 3D arm scan.

Figure 6: Scan with grasshopper test, for bespoke device creation.
Figure 7: Journey map of the pre-existing device.

**Don**
1. Lay on side
2. Peel & pull through velcro
   2a. Peel & fold out velcro
3. Position arm in line with device
4. Finger straps position, fold in part 1, fold in part 2.
   Repeat
5. Wrap strap, pass through slot, pull tight, fold down.
   Repeat

**Doff**
1. Place on side on a surface
2. Peel and pull through velcro straps.
   Repeat
3. Peel & fold out finger strap 1, fold out fingerstrap 2.
   Repeat
4. Remove arm
5a. Feed strap through slot, fold down strap.
   Repeat
5b. Fold in strap 1, fold in strap 2.
   Repeat for other fingers
7.4 Exploration of the pre-existing system

The pre-existing device (Case study Astro stroke orthosis) has both positive and challenging features, which have been used to guide the development process. The evaluation of this device included, visual and physical features, the interaction with the device, various engineering reports including Rajendran, Hollitt, and Browne (2011), and conversations with the engineering team on this project.

There are several positive aspects to the system. The first is that it uses electronics and sensors to move or aid the fingers in and out of a cylindrical grip and can hold up to 1kg. This allows the delivery of movements required in therapy, daily task completion, and in gripping everyday objects. The device can deliver a large volume of repetitions of movement crucial to therapy.

Testing has been done to link the device to therapy games. The device needs to deliver the promised functions of independent therapy and aid. Cost has also been considered. Each unit has commonly available electronics, sensors and motors, and battery technology to enable untethered use. The intention was to keep the cost of each unit under $1,000 NZD. The thumb was excluded to reduce costs, and design complexity. Including the thumb would require double the amount of actuators and the thumb path would block the ability to grip onto everyday objects.

From an engineering perspective it is not yet set up to provide therapy achievement and monitoring data to users, however, the potential of Bluetooth technology has been identified to connect to an application graphing the information. There has been some development for an application to record the number of repetitions, range of motion, and grip strength, to provide clinical evidence of therapy achievement and improvement to patients.

The pre-existing system address accessibility and delivery including cost, therapy, changeable difficulty levels, movement assistance and passive motion. The existing technology delivers passive therapy and can be used as an aid utilizing haptic feedback to increase hand functionality. However, there was no consideration to aesthetics or the perceptions of the users in the development.

Wearability issues consist of device features that impact or get in the way of therapy or daily tasks and user comfort. The device is intended for use by motor functionally impaired people who can have issues with weakness in the upper limb, where lifting and manipulating the weight of a device and gripped object can be difficult. The device profile can appear bulky, and takes up both physical and visual space, bumping into objects in the environment. The device has prominent arms that stick out on the palm side and above the back of the hand by more than 6.5 cms, as well as robotics that extend along the forearm. The skin surface is directly interfacing or in contact with solid plastic or Velcro. This could create pressure points, rubbing, and sweat build up that have the potential to become uncomfortable over a therapy session.
Safety and cleaning are issues in the existing robotics. The current system has many exposed parts, including cogs, electronics and strings, which could pose safety and cleaning challenges. Exposed skin, clothing, food and dust could easily become trapped or tangled in the machinery, could injure, be crushed or tear, leaving the device and electronics damaged. Once dirt or food has become stuck in the device it requires dusting off or a wipe down. It is difficult to remove all of the material, and cleaning fluids could damage exposed electronics.

The main area of interest is in addressing usability, particularly for the initiation and conclusion of use (putting on and taking off) of this device. The existing device has not yet been designed for an independent use context. The attachment method and interactions have not been fully explored. An able-bodied designer had difficulty self-attaching the device, this is in part due to the complexities in the strapping system. This system has four sets of straps: two are at the fingers where two hands are needed to get the correct placement and fit, the other two straps require a high level of dexterity to be passed through a slit, then tightened and pressed down (Figure 7). This process is perfectly acceptable for a trained person to apply to someone else, but not for self-application. Improved usability, safety, comfort, weight and profile reduction need to be undertaken.

These key factors could be improved by involving users in the design process, to develop features that combat the issues with the pre-existing robotic device, and to improve the initiation and conclusion of use.

To understand the process and interactions of how the pre-device is applied and removed, the interactions with the initiation and conclusion of use were broken down into component parts (Figure 7). This process has multiple steps, which have the potential to be reduced. Reducing the number of straps, and the complexity of interactions was identified as important to increasing ease of use. This is especially important for stroke patients who could have limited to no control over their upper limb, and would need to don a device with a single arm.
7.5 Criteria for prototype development

7.5.1 Persona analysis

Each person is affected differently by stroke, and has different needs and viewpoints. Based on talking with clinicians, some people will never want to use or try a device, others would try anything that could help them, and others are in between. Patients can be split into several groups based on where they are in their recovery and therapy, including acute stage with hospital therapy (initial hospital admission), sub-acute under 1 year post stroke and receiving outpatient care (home and community therapy), and chronic stroke requiring long-term management. Hands are also affected in three main ways including spasticity (stiffness), facticity (floppiness) and loss of control. To apply these insights to the design process, while maintaining consideration of the uses, the categories will be created into personas, insights from this will be used to guide the device development. Testing will be undertaken with people at different stages post-stroke, with differing impairments.

The literature review, interviews and surveys with patients and clinicians were used to develop three patient persons (Table 1). These were used on a theoretical interview basis to explore other criteria that may influence the criteria of the design. The persona development provided further insight on how the device would fit in a daily routine of a patient at home.
Table 1: Developed personas for enquiry from user-testing.
7.5.2 Identification of criteria for Design Progression

The criteria for this study has been developed based on the literature review, results from the survey, interviews, evaluation of the pre-existing device, and testing. The participants included patients, clinicians, health-tech industry practitioner, and a clinical researcher. Recommendations for similar devices to the pre-existing robotic have been considered when developing criteria for design.

User requirements of wearable devices were; usability, safety, and cylindrical grip function to support daily tasks (Prang et al., 2015). Additionally, factors of interaction with don/ doff (putting on and taking off), comfort, size and weight were also found important (see testing results). A surprising factor was the importance placed on hand hygiene by the clinicians and ability to clean the device by patients (see interview results section 8.1.2 & 8.1.3 ).

<table>
<thead>
<tr>
<th>Criteria For Design progression</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Functionality:</strong></td>
</tr>
<tr>
<td>Safe delivery of the therapeutic motion</td>
</tr>
<tr>
<td>In the context of independent home use.</td>
</tr>
</tbody>
</table>

| **Ease of use:** |
| Don/doff and assembly/disassembly |
| Cleanability |

| **Wearability:** |
| Low profile, size and weight |
| Comfort |
| Customisation |

Table 2: Design criteria.
7.6 Key criteria

Users of home-use medical products can have conditions that affect their ability to use a device (Bitterman, 2011). When a device has usability issues, or does not properly consider the user, it may cause frustrations and eventually lead to rejection of a product that may help them recover. Usability is essential, as the reduced motor function may impact a person’s ability to use devices. If a person cannot use a device, there will be little ability to engage with or accept it.

Usability can be linked with interactions and product features that enable people to have a positive experience of a product (Norman, 2013). However, usability and the interaction between user and robot are often overlooked in design development (Pei et al., 2017), despite being part of suggested criteria for robotic devices that also includes safety and function (Prange et al., 2015). Usability is the base that enables participation, leading to engagement, and a positive experience as well as enabling device functions to be delivered at home.

In this study the usability criteria will be addressed separately as function, wearability and ease of use, while the applicability of safety, comfort, aesthetics and customisation will also be addressed.

7.6.1 Functionality

The functionality of the device is the principle criteria in the development of any product. In this study the device needs to be able to provide the prescribed therapeutic forces and actions, in a form that is safe and easy to use repeatedly at home.

Factors influencing functional improvement in the device were explored by considering:

- The mechanics required to deliver the required forces for hand opening and closing
- The device hand interface and the natural hand motion in terms of ergonomics and freedom of movement.
- Ability of the device to be set up and used daily by users at home. The function of the pre-existing device has been an engineering consideration.

The function of the device was a main consideration of other members of the research team. However, the industrial designer had to ensure that development addressed device function. Safety is considered to be a key user requirement of therapeutic upper limb devices (Prange et al., 2015). Three areas for safety consideration were identified from the evaluation of the pre-existing device: achieving the therapeutic forces without harming the patient, make the device safer to use in the home environment and allow fingers to grip objects.
7.6.2 Wearability

Wearability was identified as a key criteria through testing, evaluation and persona creation. Designing for wearability of the device in the home environment for stroke affected people. Wearability concerns and themes identified from research and testing (see literature review and testing) are:

Comfort

Comfort is a key theme from testing and literature. Prange et al., (2015) identifies comfort as a key user requirement for designing upper limb stroke robotics. Comfort can be addressed in the design process through the materials chosen for the textile and robotic components, and in the design of the shape and form of the components themselves.

For comfort the following are developed:

Ergonomics: facilitate the natural movement of the hand during therapy.

Fit: device and attachments need to fit different arm and hands without excessive constraint and not restricting blood flow or causing pain.

Breathability: minimise enclosure and perspiration.

Tactile: use materials which are pleasant on the skin e.g warm, soft, plient and avoid materials that are itchy, sticky or hard edged.

Customisation

The prototypes also addressed aesthetics and personalisation. Exploration of this included familiarity of form through the adoption of aesthetic attributes from everyday items, potential personalisation with colour or materials, and design adaption were explored.
7.6.3 Ease of use

One of the main factors identified by users and clinicians was the ease of implementing the device for independent therapy.

The primary factors for ease of use were considered to be:

Assembly and fitting.
The ease and simplicity of assembly/disassembly, Don, fitting and off of the device.

Cleanability.
Hygiene management and ability to clean the device were found to be important to users in both home and clinical settings. Patients wanted to be able to clean their device. Criteria to consider are, assess for cleaning and simple cleaning process, e.g. laundering.

7.7 Design process adopted

The design process is outlined chronologically in this section. Where relevant the key criteria are identified.

7.7.1 Functionality of the device

The functionality of the device includes consideration to the device hand interface and the creation of natural hand motion.

Interfacing with the hand - ergonomics/movement

In this section, the direct interface of parts with the hand and robotics were explored. Modelling tests were conducted to establish a direction with how to attach and move the fingers. The moulded models explored using splint shaping technology to create an ergonomic fit each time (Figure 8). This is not ideal but it could create a more jewellery like fit on the fingers, e.g. a ring.
Enabling the hand to open and close without the upper arms was explored to reduce the height of the device (profile) (see Case Study 3: Astro stroke orthosis).

1. First test was undertaken; positioning the artificial tendons to enable the hand to open using a glove, and beads to control placement on the hand. This worked well to open the hand. However, putting it on individual fingers may be difficult for someone with reduced hand movement or control. This led to tests with combinations of fabrics and 3D printing materials.

2. Second round of tests were undertaken, which involved the application of material to fabric. The fabrics included polyester, lycra, acrylic and mesh as well as blends of these materials. The 3D printing materials included ABS plastic, PLA plastic, and PLA flexi plastic. The most successful prints were a polyester mesh with ABS plastic and a Lycra-polyester blend also with ABS.
3. The successful glove test to see if upper tendons would open the hand (Figure 9), and 3D print tests were combined with another paper test (Figure 16), paper was used to test early prototypes before 3D printing.

The glove layer is based on a fingerless glove. However, early tests covering the palm, with prints attached proved difficult to put on and take off (Figure 10 & Figure 25). The decision to open the glove at the wrist stemmed from cycling gloves opening with velcro at the wrist. This change along with removing finger separations was in order to make the prototypes easier to apply. This also enabled the fabric to be removed from the palm as well as the fingertips, which could give stroke patients a clearer line of sight to their hand, give them a chance to feel objects they are interacting with, and utilise the natural grip within skin. This included two parts: the underglove and the 3D printed armadillo plates that cover the fingers and wrist (Figure 11).

4. The 3D printed finger sections were initially shaped for left-hand use. This was during the exploration for the artificial tendons' positioning and development of the closure features. The opening was the first to be explored, as the pre-existing device had a very prominent arm extending over the back of the hand which could easily get in the way (see evaluating the pre-existing device). In initial prototypes the strings were made of clear fishing line the same as used in the pre-existing device as it functioned with the robotics.

Figure 10: Plate and wrist feature test.

Figure 11: 3D printed armadillo tests with tendons.
5. The robotic unit was measured at 6.5cm high above the arm. After discussions with the engineering team, it was decided that by using more compact components, the unit could be reduced in profile to 4cm in height off the arm. With consideration to maintain function from the artificial tendons (strings), this was reduced by removing the upper arm and moving the pulling forces to the wrist. String positioning was considered earlier with completely internal channels (Figure 12). However, this did not print well on the fabric as the internal channels would not be able to be cleared and the way the strings pulled was not very effective. The shift to external tendons was made with the functioning open and close prototype (Figure 12). The artificial tendon guides started as beads, then moved to sloped housings; however, the strings did not flow very well over the edge of the hand segments and there was a lot of friction that could damage the strings. Features that guide the strings over the segment edges were prototyped to address this problem.

The closing of the unit was developed to not block the grip with the artificial tendons. Segments the same shape as the fingers in a closed position were developed (figure 12 C), for the index and pinky finger side of the hand component, with a string path that is shortest in that position. By the robotics pulling on the artificial tendons the components move becoming flush with each other with the shortest string length being the closed position.

Figure 12: Armadillo with finger separations for hand closure.

Figure 13: String guides and friction reducing features.
7.7.2 Wearability

This section addresses designing for stroke affected people wearing a device in the home environment. Wearability themes from research and testing include comfort, safety and cleaning (see section 3.0 and 8.0-8.1.3). Aesthetics that fit the home context will also be addressed.

Comfort

Comfort is a key theme from testing and literature. Prange et al., (2015) identifies comfort as a key user requirement for designing upper limb stroke robotics. Comfort is addressed in the design process through: the materials chosen for the textile, robotic components, and the design of the components.

Split models

1. The prototypes did not fit the hand perfectly. The hand is not flat and has curvature that needs to be considered, so splits were created as a way to curve and fit over many hand shapes (Figure 14a). The option of using flexible 3D printing material was also tested as a different way of conforming to varied ergonomics (Figure 14b). However, the level of flexibility made the safety features nonfunctional.

Materials for comfort

Gloves, medical braces, and sports protective wear were determined to provide the most scope for applying robotic components to the upper limb. This was partially due to the componentry and materials that are already used in these products, the interactions, and the factors their materials address.

Light breathable and slightly stretchy fabrics were initially used as gloves and to 3D print on. Then heavier structural, padded, velcro attachable material, similar to medical braces and sports protective wear.

Figure 14a: Designing for ergonomics and comfort of the hand by exploring splits that allow flex over the hand.
2. The glove was extended into a full sleeve prototype with a detachable upper glove layer that incorporates the armadillo plates and support. The need to structurally support the robotic unit, upper glove layer and address comfort, a heavier padded fabric that cushions from potential pressure points was chosen. A high tech foam filled dual velcro attachment sided material was sourced from a New Zealand supplier, sleeve options were prototyped, and patterns made and manufactured. It required the attachment of velcro on both sides, this made it more complicated to quickly try and test prototypes.

3. Using mesh to 3D print the armadillo plates on, worked well and would be very breathable. However, the stress of the robotics damages the mesh, and a number of prototypes were ripped with only light interaction. So, the later prototypes used adhesion (glue), to a stronger base fabric, which would be more easily implemented in mass manufacturing, this base then attached to an undersleeve (see Figure 15).

Covering the unit
1. The robotic unit was exposed in the pre-existing device, which presented a risk for food or fingers to get caught in there. This posed both a safety and a cleaning issue. It creates a barrier between the person and moving parts by physically covering the unit, can help prevent these issues. A smooth covering surface would also enable the device to be wiped clean. See aesthetic form for images of the cover (Figure 20).

Armadillo plates
1. The paper model was prepared with hinged joints (Figure 16), this model was loosely based on the pads and plated used to protect the upperhand in some military and safety gloves and similar to the shell of an armadillo. This demonstrated that relatively thin separate plates may be effective in allowing natural movement. It also indicated that potential forces pulling the hand open and closed could be stopped without painful pressure to the user. Stronger material is needed to limit the over extension of the fingers and wrist.

2. This led on to some initial 3D prints that had hinging aspects and internal strings. The plastic hinges did not work well and broke easily (Figure 17) static joints were also not able to be adjusted to individual hand ergonomics.
Figure 15: Sleeve base with upper layer including armadillo plates, support, and robotic unit attached.

Figure 16: Paper model of potential movement with hand and safety feature.

Safety

3. A safety feature that stops the hand and fingers from being pulled into unnatural over extended position was identified as necessary. This was developed with overlapping plates that clash at the fabric hinge stopping hyperextension. This is developed at the wrist and knuckles, preventing excessive upwards wrist movement and finger extension while opening but allowing for flexibility while the fingers are closing. Safety also means reducing pressure points, and as discussed in the section about comfort, padding could aid in reducing pressure points.
Crackability

Cleanability

Hand hygiene management and ability to clean the device are important to users in both home and clinical settings. Patients wanted to be able to clean their device. Two features for cleaning were developed; the first covered wipeable robotic unit as discussed in the safety section, and a removable sleeve.

Removable sleeve

1. A removable undersleeve was developed. By having the full interface with the skin removable and washable, we were able to increase hygiene and make cleaning easier.

Aesthetics from braces and sports protective wear were utilised with the exploration into comfort, cleaning and attachments. Involving the development of a removable undersleeve, using more technical fabrics, and considering a wider range of attachment methods to the arm and also of the robotic unit and finger components to the sleeve.

Undersleeve development was spurred on by the importance of comfort for patient participant 1 and 2 of the clinicians and also the importance of the ability to promote hygiene and cleaning. The sleeve initially used thicker materials due to comfort concerns with multi layers of velcro and support. However, this made it more difficult to close the hand, testing found this was too warm, and interactions shows that interactions were not yet intuitive (see user testing).

The designs thus far have been modelled on a medium to large female hand. For testing, hand size and hand affected is not yet known. Therefore, an adjustable finger section, with a universal left or right fit and larger fit was created. Universal fit is about being switchable from right hand to left hand rehabilitation. This enables testing with patients with either hand affected.
Figure 18: Aesthetic sketch explorations.

Figure 19: Armadillo plate aesthetic exploration.

Figure 20: Robotic unit aesthetic exploration.
Customisation

Aesthetic development
Vaes (2014) indicates that the aesthetic features of a product should be universally designed for everyone, this includes familiar product aesthetics, which could increase product acceptance. The development of aesthetics was inspired by commonly used products for wearing on the hand. This section includes exploration of visual qualities, colour, size, and personalisation through sketches, form, material and colour, and experiments. Aesthetic exploration involved quick explorative sketches into various avenues for what the device could be like. These explorations were based on everyday products including, jewellery, gloves, sports protective wear, and clinical aesthetics and products (Figure 18).

Colour
The colours were inspired by everyday products. Light grey was chosen as it was not visually intrusive, and is a warm tone for the softer home environment. The colour of the edging was explored (Figure 21).

Personalisation
By having a removable undersleeve, customisation could potentially be low-cost and easy to implement as a part of mass production, just by switching the sleeve. This is because fabric edgings and threads could be different colours or patterns. Clinicians indicated that choice of colour could make patients more likely to use a prescribed wearable device (see testing results). Size is also an aspect that may need to be personalised to get a good fit (Figure 24a & 25).

Figure 21: Exploring edging colour and material options.
7.7.3 Ease of use

This section describes the development of interactions with the device. The main interaction of users would be with putting on and taking off the device (don/doff). There are also secondary interactions, that allow the sleeve to be removed for cleaning and sleeves to be switched, these interactions will be addressed as assembly and disassembly.

There are many ways a person can interact with an object. Konkar (2015) states that there are 10 key stages of product use interactions that need to be considered to ensure a device is not missing key usability features. These interactions need to be designed to fit the needs of the user. For a home user, the relevant interaction phases are in the setup, adjustment, use and docking.

The discovery or possible interactions and understanding of how to use a device are key to enabling positive user experiences (Norman, 2013). The engagement of users with these interactions can lead to the user having a positive experience with the product.

Don and doff

Putting on and taking off the device is essential because if someone cannot put the device on, they cannot use it. Ease of attachment of the robotic unit onto the hand and forearm needs to be addressed. Being able to attach or detach the device in under one minute was considered reasonable (see testing). Many strategies were explored and considered, including familiarity with attachment action, number of actions, time needed to don and doff, and the attachment motion.

Figure 22: Exploratory sketches into application techniques.
Exploring familiar attachment techniques for worn items should enable increased understanding, making the device easy to interact with and promote ease of use. Attachments that were explored include straps, velcro, clips, sleeves, buttons, domes, hooks, and zips. Also other fastening options included buckles, ties, and stretch materials. Familiar motions of wrap, pull, slide, and strap were explored (Figure 22).

The term Velcro is used in this thesis as a ‘generic’ name for the type of hook and loop fastener patented by Velcro BVBA.

Domes were found to be the most difficult to use, followed by hooks and buttons. The easiest to use and understand were sleeves and velcro and it is commonly used in wearable product (see products worn on the hand).

The pre-existing system had four Velcro attachment locations: two at the fingers getting one Velcro strap to meet another, and two on the forearm involving feeding the Velcro through a hole and back on itself (Figure 7). Reducing the difficulty or number of these actions would influence the time it takes to attaching the robotics and enable increased actual and/or perceived ease of use. Clinicians indicated that simplifying the actions needed to interact with the design is important for the use of the device.

Figure 23: Early exploration of fastening methods.
Figure 24a: Phase 1 prototypes fit fully covered palm, non adjustable and adjustable fits.

Figure 24b: Phase 1 prototypes two different unit heights, solid and split armadillo plates.

Figure 25: Phase 1 prototypes for don/doff and size adjustable finger strap.
Figure 26: Phase 2 developing the brace prototype.
Assembly and disassembly

This development began with the detachable sleeve. The removable interface could be beneficial for cleaning/hygiene (see cleanability), and could increase comfort. The use of an undersleeve also meant a different don/doff interaction and the necessity to design the assembly and disassembly.

In early glove prototypes, it was not possible to detach some of the parts from the fabric, increasing the difficulty of cleaning the fabric, and the artificial tendons would need to be detached during cleaning and reattached afterwards. The development of features that enable the device to be cleaned including a sleeve that will be removed, needs consideration to the interactions involved in assembling and disassembling the device for the removal to occur. The way the robotic components could be attached to and removed from the brace are numerous. The strategy for this was explored through buttons, Velcro, and straps (Figure 28). The easiest and most secure method was adhering to the components with Velcro. However, the shape and number of the robotic straps, particularly the six straps near the fingers, cause the Velcro to be difficult to remove and reattach (Figure 29 & 30). Moreover, there is no guarantee the components will be reattached in the optimum location to deliver the hand motion.

The design of one of the phase 2 prototypes brace and spider prototype enabled assembly and disassembly, as well as allowing the fingers to bend where they need to, with an additional velcro closure for easy adjustment. However, this does make the device more bulky on the palm side of the fingers, as there are multiple layers, and dealing with three straps is very fiddly.
Figure 28: Interaction board to understand robotic unit attachment.

Figure 29: The upper glove layer development of the spider prototype to allow finger flex.
Figure 30: Phase 2 assembly/disassembly of the brace/spider prototype.
7.7.4 Design process conclusions

The design process was centred on usability that may influence engagement and acceptance, specifically initiation of use, which is addressed in the functional aspects as well as the aesthetics. This has been explored through iterative design focusing on found factors that patients and clinicians want and need (see testing results). These key factors are ease of use, wearability, comfort, safety, cleanability and natural hand motion.
8.0 Results
8.1 Testing results

The results from surveys, interviews and user testing are outlined in this section. One industry professional and 3 clinicians were interviewed, one clinician and 4 patients were surveyed and three patients were interviewed as part part of the study; the results are summarised and broken into themes in the appendix Table 4.

8.1.2 Industry professional: Phone interview

Early in the study an industry professional involved in developing the Able X stroke therapy device was consulted (Appendix Table 4). The professional stated that the Able X “50-page booklet … load software … dongle … connection … login … calibration, before you can even start to play the game”, and “often sympathise with users who do not get past the set up stage.” The Able X is Giving “100 movements an hour and automotive type systems, that’s a motion that I would expect, compared with conventional therapy that is roughly 30 movements in a session. ... people engage with their hands more than any other part of the body.”

A positive user experience was required for clinician and patient engagement with the robotic device, and for ongoing use. Also, there could be a varied level of device acceptance amongst clinicians. It is clinicians who recommend and prescribe a robotic device for use and/or therapy.

They provide valuable early insights into the benefits and potential of robotics in this context. This outlines the importance of addressing the needs of all user groups and consideration to engagement, ease of use and active meaningful task therapy.

8.1.2 Clinician testing

Clinician survey results

The clinician survey identified that, current therapy is delivered manually in 45-minute sessions, five times per week. These sessions do not contain the amount of therapy needed in the period until the next session. Patients are likely to complete independent therapy. Patients are somewhat likely to try to accept new devices and equipment and the most essential thing for them is recovery.

The participant indicated that assistive devices and equipment can take up to one minute to put on and take off. Also, product features that fit within the themes of ease of use, cost, comfort, appearance, recovery, effectiveness and evidence were considered necessary in a device.
Clinician interview results

Three Clinicians were interviewed on two occasions see Table 4 in the appendix for important quotes. The first occasion introduces the pre-existing and phase 1 prototypes shown in (Figure 1, 24a, 24b & 25). The second was the Phase 2 ‘brace and spider’ prototype and the interaction board (Figure 27, 28 & 30).

There were clinician insights into therapy, patients, ease of use, aesthetics, cleaning, outcome measures and cost. Clinicians indicated that therapy by robotics needed to deliver something that manual therapy by clinicians can not deliver or do not have time to deliver.

Therapy needed to “tap into the old muscle memory patterns”. One clinician said “the hardest part is to get them engaging with a home exercise programme”. It was reported that robotic devices needed to be part of an individual’s exercise programme and “if it can only do one type of grip you will be limited to those functional tasks that need that type of grip”.

Patients are also more receptive to new ideas early in therapy. Clinicians stated that patients want to feel normal, but what is normal and how they are affected is different for every individual. The design needs to consider patients impairment “if they have an upper limb impairment they will have a grip impairment”. It is also noted that addressing grip without addressing issues like shoulder strength in some patients may not provide an adequate function for everyday tasks.

Clinicians reported that the ability for patients to use the device independently was important, and “being able to don it independently would be a big plus”. Two of the three clinicians thought the reality would be a carer applying the device for the majority of home users. Clinicians indicated that neutral colour tones or patient choice in colour was desirable. One clinician suggested that male patients might be more accepting of a robotic device as a “terminator arm” and “for guys... some of them really like to expose the inner workings and wiring of it, where as, potentially some ladies might not like the robotic nature of it”.

The ability to clean the device for hand hygiene was reported by clinicians as essential for stroke patients. Having a separate sleeve that was easy to detach was considered useful. Feedback from clinicians on the Phase 2 ‘Brace and Spider’ prototype indicated re-assembly of the device and sleeve was thought to be complicated due to the many velcro straps. Also the brace material was found to be too stiff for effective hand closure.

Clinicians reported that they needed to be able to justify the prescription of a robotic device for funding, e.g. “justifying it to ACC (NZ Accident Compensation), or core funding, if I can show that they have used your device an hour a day for the past month, that would be amazing”. Measuring upper limb function or movements is a selling point, as outcome measures like this can be difficult to obtain. Video is a current method used to record, track and observe tasks to compare against future progress, but makes exact measurements difficult to obtain. For justifying prescribing a device a clinician stated “It’s got to be easy to use, it’s got to have a purpose and it’s got to do something either we can’t do as therapists or don’t have time to do as therapists”. Preferred features included splits in the plates to enable higher comfort, lower profile unit, grey tones, reduced strap number, detachable parts for cleaning, reduced strap number and forming a natural grip.
8.1.3 Patient testing

Patient survey

Seven participants answered questions in the survey provided at a stroke club, where all attendees were provided with a survey and their stroke affects were not known prior (Appendix 3 surveys). Four people met the inclusion criteria of which only three completed more than 50%. The inclusion criteria were: having motor impairment from a stroke and the ability to answer some of the questions in the survey.

All four participants included in the survey measured high in robotic acceptance when introduced to the pre existing device. The statement “if the robot was available, I would use it” was answered with agreement by all four participants and all disagreed with the statement “I find the robot scary”. All participants had been prescribed or used devices to aid in therapy or compensate for lost function.

Questions in the survey were assessing anxiety and attitude toward robotics, intention to use, perceived usefulness, perceived ease of use and perceived enjoyment, all participants indicated elevated robotic acceptance. Reduced size, cost, and increased availability were identified as features needing to change with the pre-existing robotics.
Patient interviews and user testing

The pre-existing and Phase 1 prototypes were tested on all three patient users and the Phase 2 prototype and an interaction board were tested on one participant. The results are outlined below.

All three patient participants had demonstrated high robotic acceptance, and were found to associate robotics with mechanical features. Their feedback indicated the prototypes were moderately to extremely difficult for participants to apply independently, particularly when dealing with two independent straps. One participant reported the “straps are a nuisance”, and Velcro was considered easy to understand.

Two of the participants said the robotic therapy would be useful to them. Comfort was very important to one participant and neutral to the other two. Cost was reported as an important consideration by all participants. All participants thought cleaning was important and one said “I would wash it every few weeks”. Two of the 3 participants preferred the reduced profile of the robotic unit of the prototypes and one reported that “reducing the profile was needed for daily activities”. The split feature on the armadillo plates enabled the greatest comfort. The brace prototype foam material was considered more comfortable than the thin, stretchy Lycra, but it was too warm, and breathable material was recommended by participant 3. Patients interviewed reported that aesthetics (colour and form) were unimportant. However that does not mean that aesthetics should be ignored.

The Phase 2 ‘Brace and Spider’ prototype foam material was considered comfortable but too warm by one participant. This participant considered the stretchy Lycra as breathable.

This information was evaluated and criteria for prototype improvement were adjusted and captured in developing the Phase 2 & 3 Prototypes. Observations made by the designer during early user testing indicated the sizing of some of the prototypes was too tight to fit over the participants’ fingers. Two of the three participants had a visibly larger stroke-affected hand than their unaffected side. The wrap don/doff interaction was awkward for patients, and unexpected interaction methods were undertaken by participant 3 to don/doff the prototype.

This information was evaluated and criteria for prototype improvement were developed for subsequent design progression. Preferable features include splits in the plates for comfort, lower profile unit, reduced strap number, detachable parts for cleaning. Usability, functionality, ease of use, cleaning, comfort were considered important.
8.2 Findings from design process

This section discusses the prototype progressions. Prototypes from the first and second phases of development were user tested, and the findings were critically evaluated and used to develop the subsequent phase of prototypes. The resulting final physical design output of this project is the armadillo orthosis prototype is introduced in this chapter and is described along with the improvements made (Table 3) throughout the design process (section 7.0).

8.2.1 Findings from each phase of progression

First round of user testing and interview prototypes (Pre-existing and Phase 1 prototypes)

The Phase 1 prototypes (Figure 24a, 24b & 25) were created from literature indicated criteria, pre-existing device evaluation and design intuition. They were taken to interviews with clinicians and user testing sessions in patients’ homes. Features assessed include: palm covered or open, two different unit heights off the arm, different finger tighteners, separate or connected unit and hand component and splits or not split prototypes.

Having an open palm on the device made it easier to put on. The reduced profile of the robotic unit was said to be preferable. The ability to adjust the finger section made it easier to fit to different hands. A separate unit and hand component was only preferable if a carer with two functioning hands was applying them. Manipulating two separate parts was difficult for patient participants. The connected robotic unit was challenging to manipulate, due to the multitude of Velcro straps. Clinicians liked the ability to separate the unit and hand component for sizing in clinic. The split feature on the upper glove layer was considered more comfortable than the not split one by one participant.
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Developments incorporated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don/DDoff</td>
<td>Affordance- familiar sleeve and glove form and materials. Ease of fitting-opening sleeve fastened with velcro and glove to allow one handed fitting. Adaptable fitting- the device fits to either right or left arm.</td>
</tr>
<tr>
<td>Assembly/ Disassembly</td>
<td>Robotic Unit Connection -velcro simplest from interaction board trial. Ease – reduced to 2 straps. Fasteners – straps direct Velcro or pass through keepers and back onto themselves easing adjustment. Indicators – stitching provided to indicate fastening points easing assembly.</td>
</tr>
<tr>
<td>Comfort</td>
<td>Padding-sections were adopted to avoid pressure points. Shaping – sections shaped and curved to provide snug fit. Breathability-thinner fabrics and uncovered fingers to minimise perspiration. Ergonomics-splits (armadillo plates) in the upper hand cover. Tactile- soft material (PLA flexi) used in 3D printed tests. Fit-fastenings allow for firm but comfortable fit for extended use.</td>
</tr>
<tr>
<td>Interface with the hand</td>
<td>Fitted- Molded and 3D printed plastic tests. Tactile- soft fabrics against the skin rather than hard plastic.</td>
</tr>
<tr>
<td>Safety</td>
<td>Mechanism protection- electronics covered. Bulkiness- lower and smooth profile of the robotic unit reducing the potential for the device to be bumped or snagged at home. Weight- Reduced size of the robotic unit meaning reduced actuator size. Hyper-extension prevention- armadillo plates only bent in one direction.</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Easy cleaning materials- wipeable unit and washable quick dry fabrics. Easy care of device- Velcro eases detachment and reattachment of components, access for cleaning and fabrics to be laundered separately.</td>
</tr>
<tr>
<td>Aesthetics</td>
<td>Familiar Form – achieved through a clothing product look Personalisation – colour, materials and graphic design is easily incorporated and adaptable.</td>
</tr>
<tr>
<td>Universality</td>
<td>Left or Right Hand Use - Device includes features allow it to be used for either hand.</td>
</tr>
</tbody>
</table>

Table 3: Key criteria addressed and improvements from the design process.
Second round of testing with Phase 2 Prototype and interaction board

The ‘Brace and Spider’ prototype (Figure 27 & 30) was created with information from the first testing sessions. Also an interaction board (Figure 28) was developed to test assembly and disassembly of the robotic unit. These were taken to interviews with three clinicians and user testing sessions with one patient.

In response to Phase 1 testing feedback, the Phase 2 prototype included an undersleeve that was developed for cleaning and hand hygiene. The undersleeve was found to be more comfortable to wear and easier to put on and take off. The prototype included a heavier padded fabric on the forearm of the undersleeve to support the robotic unit. The undersleeve was a flat layer that is wrapped around the forearm and the opening fastened with Velcro. The upper glove ‘spider’ was secured with six straps around both the forearm, palm of the hand and fingers.

Also an interaction board was developed with a range of fastener types to explore the best means of connecting the robotic unit to the detachable undersleeve. The padded fabric was considered too thick, where the participant was concerned about getting too warm. Breathability, cleanability and ease of use were considered important. The wrap don/doff interaction did not do as well as expected, the technique observed in user testing where the forearm portion (sleeve) was just pulled on before tightening, and was the most intuitive to apply.

After each round of user testing and clinician interviews, the results were critically analysed against the previously assessed criteria for design. Potential modifications were considered and incorporated where possible. A summary of the clinician and user feedback is provided.
Figure 31: The armadillo orthosis.
8.2.2 The final prototype Armadillo Orthosis

The development of the final prototype includes considerations of the product features’ interaction and contexts that were not addressed by the pre-existing device (Section 7.4), and were brought up in testing and/or as a part of iterative design.

The integrated design approach resulted in development of the final prototype. Two phases of prototype, testing, interviews and observations were carried out to reach the final design. The improvements made that were incorporated into the final prototype is summarised in Table 3.

The final design receives its armadillo orthosis name from the plates that make up the safety feature, which resemble an armadillo. This device addresses design features, does not hinder completion of tasks and can be cleaned. A final prototype was created that was sleek and very easy to interact with when compared with the pre-existing device. The final device aesthetics, function and usability are designed for home therapy, as well as aiding in daily task completion.

The Under Sleeve

The need for a separate undersleeve was established from the importance participants placed on the ability to clean a wearable device, comfort, and the potential to decrease the number of interactions needed to put on and take off the device. The ability to remove the layer interfacing directly with the skin means all padding can be removed and washed like a typical clothing item. The undersleeve can be separated from the rest of the components. There was a need for strategically placed material quantities, for comfort, padded and breathable regions were created and machine washable fabrics were chosen. The sleeve was shaped for a snug fit, tapered at the forearm. The palm section was left open and the upper was curved to follow the crease of the knuckles around the back of the thumb and side of the palm. This was better ergonomically, did not restrict movement and increased comfort. A breathable, flexible, dual layer Lycra and a stiffer padded, single-sided Velcro attachable material were sourced.

The Lycra sleeve has a padded panel under the robotic unit, and is reinforced to provide support for the attached components on the forearm and the fingers, and it is similar to the loop component of Velcro. The Velcro straps were backed with a velcro adheasable fabric allowing velcro to wrap and stick to itself as well as the sleeve panels. Top stitching was provided on the forearm of the sleeve to guide placement of the robotic unit. Once adjusted the sleeve enabled a slide on/off action which improved usability.

A universal Left/Right hand fitting was developed. The final device is shown in a right hand fitting, but Velcro adjustment of the attachments has been addressed to allow fitting to either hand.
Figure 32: Diagram of the split finger tab to flex at the finger joints.

Figure 33: The armadillo orthosis naming the components.
Upper glove layer

An upper glove layer was developed using separate stiff plates resembling an Armadillo’s shell. It was unknown which side of a person would be affected, so universal left or right fit was designed. The armadillo plates were 3D printed PLA plastic, and are separated in two directions, with shaped joints located at the knuckles and finger joints and ergonomic splits to allow flex over different hand shapes. The plates were adhered to continuous flexible fabric which provides hinging and some give at the joints, as well as the wrist component being a tooth on the robotic unit. This combination allows ergonomic finger bending, ergonomic fit, and a natural grip.

The separations across each knuckle and joint of the wrist and fingers follow the opening and closing hinging of the joints. The separations along the back of the hand and over the fingers allows for ergonomic fit and allows a more natural grip of the long bones of the wrist hand and fingers as the hand is pulled closed.

Raised guides on the back (upper) side of the plates were introduced to control the position of the artificial tendons that run through holes from the robotic unit to the end of the upper glove layer. This allows tension in the artificial tendons to be transferred directly to the finger attachments. This mimics the natural tendons of the hand.

The overlapping armadillo plates form a safety feature that prevents the fingers and wrist from being pulled into an unnatural position should the electronics fail to stop. The plates overlap at the knuckle blocking hyper-extension (i.e. excessive upward bending) of the fingers. Also an upward angle was incorporated to the bottom of the plate closest to the wrist so it would clash with the robotic unit tooth, preventing upward over-extension of the wrist.

The upwards curve in the upper most plate edge allowed visual flow to the unit the curve viewed from above was to allow freedom for sideways (left and right) movement of the wrist joint. The plates can be wiped for cleaning.

Robotic Unit

A 3D printed PLA plastic was used to form a smooth thin but strong cover for the electronic and robotic mechanism and included an extruded ‘tooth’ at the wrist. The dimensions were agreed with the engineering member of the team, as the minimum size allowing robotics to be installed, and provide the tension required on the cords. The profile was able to be reduced from 6.5cm in the pre-existing device to 4cm in the final prototype and the upper and lower string guiding arms are removed. The lower smoother profile was less likely to catch on household items and is easier to wipe clean, providing wearability, cleaning and safety benefits. The base of the unit was formed into a rounded shape matching the forearm, for comfort. Covering the robotics component provided protection for the mechanism and reduced the risk of it being knocked or bumped. Less material was required for the final mechanism than the pre-existing reducing size and weight of the robotic unit. This improved usability as the reduced size and streamlined shape was designed to be less likely to get caught on household objects and is lighter and therefore easier to move around the home.
Figure 33: The armadillo orthosis physical interaction diagram.
Artificial Tendons

The artificial tendons were changed from the original fishing line to braided fishing line. This braided cord is thinner, strong (12kg loading) and is also more flexible, meaning that it can bend through smaller design features. Guides and features to reduce cord friction were included on the armadillo plates.

The hand opening is done with three cords mimicking natural hand tendons running through raised guide holes on the armadillo plates, the robotic unit will shorten the cords pulling on the end of the fingers enabling the hand to open.

Two cords run along either side of the hand and along the fore finger and little finger. These side parts correspond with the shape of the finger joints when in a closed position. These components have an internal string guides where the shortest travel distance for the string is the closed hand position. When the cords are pulled the hand is tugged into a closed grip.

This mechanism will provide the therapeutic forces required for patients with locked or weak fists and loss of muscle memory. The function of the robotic device is simplified to tensioning 3 cords while releasing 2 others to open the fist and vice versa for closing. This retained functionality of the device with reduced profile.

Attachments

The final device was specifically designed for single hand use by stroke affected people. Velcro hook and loop fastenings were found to be the easiest to use and were adopted universally. This enables the components to be separated while making assembly and disassembly easy to do and understand.

The number of attachments was reduced through development progression. The types or interactions were refined to slide and wrap. Two strap locations were used to attach the upper glove layer one at the wrist and the other on the palm side of the fingers. Once assembled only the finger strap would be adjusted for fit.

The finger strap is split into three segments that correspond with three finger joints allowing finger movement but simplifying the attachment process (Figure 32). This leaves the ends of the fingers uncovered facilitating skin sensation and friction for gripping objects. Two straps were used to attach the upper glove layer at the fingers.

The sleeve was attached by wrapping the material around the arm and closed with a Velcro fastening. This eased Don and doff of the device.

The wrap motion of velcro was also used to enable easy removal of the components. The reassembly was developed, as through iteration a need for guide marking was found. Stitched markings and material change on the device guided optimum device placement.
8.0 Discussion
There is a need for ongoing independent therapy in the home environment. Patients need to receive 400-600 repetitions and more than five hours of therapy per day to recover; however, in reality, patients typically receive less than half of the required time and barely 10% of the required repetitions (Australian Stroke Foundation, 2017; Kimberley et al., 2010; Stroke Foundation NZ, 2010; Lang et al., 2007). Robotics could deliver this therapy through both passive motion and aiding in daily tasks. However, current robotics are not meeting key user needs.

The people affected by stroke would be using the designed robotic device at home for therapy and aid. It is very important to acknowledge that the device developed is not suitable for all stroke patients. People are affected in many ways due to their stroke and up to 83% will have issues with motor function (Pinter & Brainin, 2012; Stroke Foundation NZ, 2019; Weiss, 2010). In upper limb motor function there are types of impacts including flaccidity, loss of control and spasticity. In this project creating personas helped to identify user needs and inform criteria. People with spasticity would be unlikely to be able to use the device, as their hand may be too stiff to be manipulated with robotics, as observed in testing. It is also of note that there are different patient views on aids and devices, with some people who would never use a device, use it if it was recommended, and others that would try anything that could help them.

This study focuses on stroke patients who are prepared to adopt a recommendation from their therapist to independently use a robot to gain their independence and increase therapy. A device that focuses on regaining function, aids in tasks, that addresses user experience through design, could increase use and therefore have therapeutic benefit. The design and development of the armadillo orthosis addresses user experience in the home, where the function of the robotic (delivered by engineering) and the usability (addressed through design) are key aspects.

The literature suggests that the user involvement in development is low, usability is not always addressed or incentivised when developing devices (Grant, 2014; Kutner et al., 2010; Smarr et al., 2012), and robot-human interactions need to be better understood (Pei et al., 2017). Therefore, it is important to involve users in the design process to better meet usability needs and design for their interactions.

Requirements for a wearable stroke rehabilitation device include usability, safety, and cylindrical grip function to support daily tasks (Prange et al., 2015) and were important to participants. However, cost, delivering the promised function and ability to measure recovery were also important. Additionally, factors of interaction with don/ doff, comfort, size and weight were also found important (Section 8.1).

Usability was broken into functionality (safety, home context), ease of use (interactions and cleaning), and wearability (comfort, customisation, profile, size, weight). Changes were made to the pre-existing device (Case study 3) to address the usability and user experience. The armadillo orthosis had changes to the interactions, aesthetics, profile/weight, artificial tendons, hand components and the addition of a removable sleeve.
Functionality

Supporting a natural grip was addressed through an in-depth analysis of hand and lower-arm movement in forming a grip, enabling the artificial tendon placement to promote this natural grip. Safety is important for a home-use product and to avoid hurting the user. There were two features that were developed for safety. The robotic unit was enclosed to create a barrier between potentially hazardous moving parts and the user. Another safety development was to protect the hand and wrist from unnatural movement. This was done with the development of armadillo plates that stop motion when pressed against each other. Finger and wrist segments were designed to prevent hyperextension into an unnatural position that could harm a person’s hand, instead the robotics would take the strain.

Ease of use

Ease of use was addressed for the specific interactions for don/doff, and assembly/disassembly. These interactions were addressed by simplifying the interactions needed. Velcro was the most straight-forward attachment style. For initiation and conclusion of use, initially the Velcro had two pieces that folded over each other which was difficult to apply with one hand at the correct tightness. A reduced number of straps or interactions was preferable. “Straps are a nuisance,” said one participant. For example, one prototype (Figure 29 & 30) had eight Velcro tabs for flexibility for the fingers, but was far too complex. The final device combined this into a flexible attached tab (Figure 32) that had slices to provide the flexibility that enables hand closure as well as simple attachment and fitting. The biggest usability change was as a result of an observation of a participant putting on and taking off an already fastened prototype (Section 8.1). The slide on/off action simplified the number of interactions required for single-hand application. This informed the types of interactions implemented in the final device. These were wrap/strap and pull/slide interactions to pull on the sleeve and wrap the Velcro straps to tighten and stabilise it. This caused an elevated ease of don and doff when compared to the pre-existing device (Figure 7 & 36) and changes to the system did make it easier to put on.

Cleanability

The importance of cleaning and hygiene was not mentioned in robotic literature (Grant, 2014; Kutner et al., 2010; Smarr et al., 2012; Pei et al., 2017). Patient participants 2 and 3 wanted to be able to independently clean the device, and clinicians needed to promote hand hygiene. To address this, a cover for the robotics was developed to prevent the need to clean delicate parts. It also enabled the exterior parts to be wiped clean. The other aspect was that parts directly contacting the skin needed to be easy to clean. The development of a removable undersleeve was in part due to the need to increase comfort with padded components, but equally the need for these to be washed. The sleeve creates a barrier between the skin and the device, and is fully machine washable to maintain hand hygiene. There are also potential benefits for clinical setting. Each patient could have their own sleeve and the robotic unit could be shared. This would prevent skin contact with the device and a higher-level of cleanliness.
Wearability

The wearable device needs to be designed for being worn by the user in the context of independent home use. The design development focused on streamlining wearability for ease of use in daily tasks, rather than on actual delivery of the therapy. Throughout the design developments, wearable features of the device were encouraged.

This included consideration of profile/weight. One aspect was reducing the device profile from 6.5cm in the original to 4cm, which reduced the material needed, required smaller electronics, which reduced the weight. Decreasing the profile and bulk means the device is less likely to get in the way of daily task completion.

The use of design materials and features reminiscent of commonly worn products also gives visual and texture cues that this is a device to be worn. The device has features and aesthetics similar to gloves, sports protective wear and medical braces. It also has a slide on/off interaction, use of fabric materials, and fit that is similar to a fingerless glove/sleeve.

A universal left/right fit was developed to enable testing with those affected on either side. Costs and assembly would also add pressure to develop a universal fit product.

Comfort

There was development of prototypes with a thicker padded fabric, that was more supportive but also was warm and potentially sweaty. Participant 3 suggested a more breathable material. Thinner material was more breathable but could not support the robotic function. There were issues with fabrics stretching.

The final device made a compromise between these by creating sections with differing qualities on the sleeve. This included using two different materials to create stretchy, breathable sections and stiffer padded sections.

The creation of splits into the upper glove layer was to better shape to different individuals’ hand ergonomics, creating a better fit and comfort for a range of hand sizes and shapes. Comfort was also influenced by fit. This included adjustment straps, and tailoring the undersleeve (Section 8.2.2).
User testing

The results indicate that by involving users in iterative design process, factors can be addressed to improve usability, and therefore user experience. The user experience particularly with usability, can be improved as indicated by literature (Grant, 2014; Kutner et al., 2010; Smarr et al., 2012; Pei et al., 2017). Patient participants self-selected into the study, which meant they were already interested in robotics or alternative therapy options. However, they are also likely to be part of the core market for the developed device and similar systems. People affected by stroke have different impairments and personalities. There was a need to understand different types of users. The use of personas helped to understand user wants and needs throughout the device development. This enabled the final prototype to better fit the patients’ needs than the pre-existing device.

The use of a survey was found inappropriate for this study, as participants struggled to fill out the survey. Semi-structured interviews and observations allowed flexibility in question wording and response. It is important in stroke research that participants’ individual stroke impairments, both motor and cognitive, are considered and the testing is designed to enable their participation.

Reduced cost and independent finger motion were considered important features for the wider system by some participants. However, these were outside of the scope of this study or already addressed by the engineering team.

Implications

Robotics have real potential but need buy in from patients, whānau/carers and clinicians. Robotic devices for independent therapy are not suitable for all people affected by stroke. Consideration needs to be given to the type of motor impairments that the device is being designed for, and the patient’s individual stance on using devices at home. This research indicated that rehabilitation could be improved when devices focus on usability and user involvement.

Manufacturing of the device needs to be considered. 3D printing takes time, it is likely that the preferable method will be moulding and then adhering the parts to fabric.

Designing with users for users will likely reduce the need for carers and family to apply devices at home. This would give stroke patients more independence in undertaking their therapy and/or daily tasks.

There is potential for future exploration and development of robotic devices in the use of therapy and rehabilitation. This study has found that a light device with a reduced profile, that is easy to put on and take off, has the greatest potential for use by both the subject and the clinician.
Limitations

This research could not cover everything to do with developing upper limb stroke therapy robotics, as it was limited by the scope of the pre-existing device functions.

Firstly, it is limited by the time and scope of a design masters research project. This meant that longitudinal studies with the device could not be conducted. Human ethics approval also limited the recruiting of patient participants to Stroke Clubs. A larger participant pool is needed for future testing.

The actual delivery of therapy was not measured, as the function of the robotics was in the domain of the engineering team. The human ethics approval also did not include activating robotic prototypes while participants were wearing them.

Acceptance and usability should be measured over time. This study used participant involvement to indicate potential improvements and whether the changes made were in the right direction rather than specifically measuring usability, acceptance or engagement.

Future research

Increasingly, the attitudes of healthcare professionals are changing towards promoting home-care programmes (Taylor et al., 2019), making research into home devices delivering therapy an option. Links between acceptance, adoption and engagement of this and other robotic home therapy, and how usability affects them, need to be researched. An in-depth testing and measuring with a larger participant pool over time is needed. This would also help to establish an evidence base for the device, meeting a need for clinicians who prescribe devices and therapies.

This study created a prototype, not a commercial device. This means that there is still development required before the device can be implemented, particularly in design for manufacture. Testing of the final prototype, development and research is needed. Also, solving issues with sizing, handedness and potential customisation is needed. With universal left/right fit the closure design is not as effective, especially on the smaller ‘pinky’ finger side of the hand. This needs to be further developed and tested, potentially continuing development for specific left or right handed devices.

There is also the potential for the design of the robotic system to influence the amount and effectiveness of therapy that is prescribed and delivered. A future clinical trial could measure this over an extended therapy experience.

Gender was mentioned by clinicians as a differentiation point, with groups having different requirements in devices. Studying the differences in gender acceptance and adoption of wearable devices could be investigated.

There is potential to conduct research in the application of resistive features to applying the robotics to other medical conditions, including musculoskeletal and could be combined with other technologies such as VR systems that was an aspect of the astro stroke orthosis research.
10.0 Conclusions
This research is focused on the user experience design of a pre-existing wearable robotic device for upper limb stroke therapy. The primary aim was to investigate and improve the interactions between the user and the device in the home environment by involving users’ feedback in the design process. The device was specifically developed to encourage initiation of use, rather than pure functionality. Which had been the focus of previous approaches including the Astro stroke orthosis that had not been widely adopted.

A combination of research through design and human-centred design methodologies was used to achieve this aim. The human centred design approach was found to be essential. Involving users in the development of the orthosis allowed the device to be user-friendly when considering activities of daily living. Especially as the device is for independent home use by people who have reduced hand functionality as a result of a stroke. User testing and interviews indicated the design feature changes that could increase engagement, acceptance and the potential for improved user experience.

This project has created the Armadillo Orthosis which has the potential to improve independent home therapy delivery for upper limb stroke patients. The device has been developed to be lightweight with a reduced profile that is easy to put on and take off, incorporating features designed to address safety and cleaning concerns to improve the potential for use by both the subject and the clinician.

Literature review indicated that ongoing rehabilitation is vital for maximizing recovery for upper limb stroke patients, and manual therapy is not optimal for rehabilitation. Robotics, which can be independently used, are one method to enhance rehabilitation. However, there are features that need to be addressed to allow this to occur. The design of an upper limb stroke therapy robotic device was approached by using iterative design processes and involving users to address the user experience.

The user group includes stroke patients and clinicians and were selected due to their familiarity and experience with stroke and stroke rehabilitation. The users informed design through prototype testing iterations and their feedback was critically analysed, along with persona development. Their experience and feedback from testing formed an integral part of this design study. This study involved 4 clinicians and 6 people affected by stroke using the methods of survey, semi-structured interviews and user testing. It identified the design factors that needed to be addressed. These included; function, wearability, ease of use, comfort, safety and cleaning for a positive interaction with the device.

Criteria was developed to guide the design process to improve the user experience. Usability was the key concern with both patients and clinicians. Where people cannot even consider wearing or using the orthotic if they cannot get the device on or off easily. A patient needs to be able to put on and take off the device independently if it is to be used in the home. Cleaning was also found to be an important consideration for both the patient and the clinician.
The pre-existing device was developed in three phases addressing the key design criteria of function, wearability, ease of use, comfort, safety and cleaning. The final device has a glove-like form with stiff but separated plates that enable hand opening and closing, which is actuated by tendon-like cords from the robotic unit in a low profile casing on the wrist. Possible interactions were explored and simplified by reducing strap numbers and simplifying the difficulty of each action. A sleeve was developed to allow the device to be more wearable by incorporating padding, affording breathability, allowing the device to be simpler to clean and to apply. Two components were developed for safety: covering the robotic unit with a thin wipeable shell and protecting the hand and wrist with overlapping plates that prevent hyperextension.

Designing a device that can open and close the hand of a person affected by strokes is functionally possible, but this does not mean that either clinicians or people affected by stroke want to use the device for their rehabilitation. Human centered design process aided in identifying the key criteria for developing the new orthotic. These criteria can be used in future development of the Armadillo orthosis, or other similar devices.

In conclusion, a device must be easy to apply and use if it is going to be included in patient home therapy following a stroke. Human centered design (HCD) has assisted the design process and device development implemented as part of this study. This research both identifies the design criteria and presents the development of an upper limb robotic device. This research demonstrates the potential that human-centred industrial design input can improve ease to use, affecting the experience and acceptance of users of an upper limb stroke rehabilitation device.


Bevan, N. (2009). What is the difference between the purpose of usability and user experience evaluation methods? Proceedings of the Workshop UXEM.


Appendix
Appendix 1 Information sheets

Designing a System for Stroke Rehabilitation
INFORMATION SHEET FOR PARTICIPANTS

Thank you for your interest in this project. Please read this information before deciding whether or not to take part. If you decide to participate, thank you. If you decide not to take part, thank you for considering my request.

Who am I?
My name is Jessica Saul and I am a Masters student in the School of Design at Victoria University of Wellington. This research project is work towards my thesis.

What is the aim of the project?
This project aims to design a system of physical devices and videogames that help stroke patients carry out their physical rehabilitation. This research has been approved by the Victoria University of Wellington Human Ethics Committee (2021/2).

How can you help?
If you agree to take part I will interview you in your office, in a meeting room in the School of Design’s campus, in a public place, such as a cafe, or anywhere you wish. I will ask you questions about stroke rehabilitation. I will audio record the interview and write it up later. We will construct a set of criteria and a design that facilitate stroke rehabilitation based on the findings from the research. In a second interview, we will seek your feedback about the new designs. Each interview will last 60 minutes. You can stop the interview at any time, without giving a reason. You can withdraw from the study up to four weeks after the first interview. After that time, we will use the information you provide to design new objects. You can also withdraw your information for the second interview up to four weeks after it occurs. If you withdraw, any information you provided will be destroyed or returned to you.

What will happen to the information you give?
This research is confidential. I will not name you in any reports, and I will not include any information that would identify you. Only my supervisors and some on the research team will have access to your information. The interview transcripts will be destroyed 2 years after the research ends.

What will the project produce?
This information from my research will be used in my Masters thesis. You will not be identified in my report. I may also use the results of my research for conference presentations, and academic reports. I will take care not to identify you in any presentation or report.

Participant Information Sheet

<table>
<thead>
<tr>
<th>Study title:</th>
<th>Initiation of use of upper limb devices for stroke rehabilitation</th>
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</thead>
<tbody>
<tr>
<td>Locality:</td>
<td>Wellington</td>
</tr>
<tr>
<td>Lead Investigator:</td>
<td>Brian Robinson</td>
</tr>
</tbody>
</table>

You are invited to take part in a study on the initiation of use of upper limb stroke rehabilitation devices. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

The Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, friends, or healthcare providers.

Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

This study is to develop a device that facilitates therapy of the therapy system that can be used by people who are recovering from stroke. This is for rehabilitation that they can carry out by themselves at home.

We want to know how you use devices and therapy. Our aim is to use the information you provide to create a device that will be easy to use and facilitate the initiation of use of the device in all therapy. It is also important that the movements made while using the device will help with stroke rehabilitation.

These devices and games will be developed by students as a requirement for a Masters degree. This research is funded by the School of Design at Victoria University of Wellington. Any other questions you have can be answered by Dr. Brian Robinson (043 61155).

This research has been approved by the Health and Disability Ethics Committee.

If you accept this invitation, what are your rights as a research participant?
You do not have to accept this invitation if you don’t want to. If you decide to participate, you have the right to:

- choose not to answer any questions;
- ask for the recorder to be turned off at any time during the interview;
- withdraw from the study up to four weeks after the interview;
- ask any questions about the study at any time;
- receive a copy of your interview recording if it is recorded;
- read over and comment on a written summary of your interview;
- agree on another name for me to use rather than your real name;
- be able to read any reports of this research by emailing the researcher to request a copy.

If you have any questions or problems, who can you contact?
If you have any questions, either now or in the future, please feel free to contact either:

Title: Student
Name: Jessica Saul
Student Supervisor: Dr Edgar Rodriguez

Human Ethics Committee information
If you have any concerns about the ethical conduct of the research you may contact the Victoria University of Wellington Human Ethics Committee – General Correspondence, Associate Professor Susan Corbett, Email: sec@vuw.ac.nz or Telephone: 04 463 5477.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We asked you to take part in this research because you have experience as a clinician and have aided in therapy for stroke patients. The research study will take place either in your home or in a public place. We will ask some questions about you such as how well you are, what your profession is, what types of stroke patients you have encountered, devices you use to deliver therapy, and your knowledge around therapy practices.

You will be asked to participate in a survey or an interview. You will be asked a series of questions about your experiences with devices and therapy for stroke patients.

Your involvement in the study will only be known by the researchers. We will record what you say. If you tell us something useful that we quote, we will not use your name with what you say.

Your participation requires your concentration in filling out a survey. You may be invited to take part again if you would like to help us test the created devices and changes.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefits are that the information that you provide will be used in creating a device that can aid in your therapy practices and deliver therapy to patients. We know that rehabilitation is more effective when it is carried out for several hours throughout the day, every day and the device is to support you and your patients achieve the optimum dosage of therapy. This study is to support people who have had a stroke to provide early interventions with stroke rehabilitation therapy through a device in their home. This can help themselves or with the help of care support or family members.

We are eager to find out whether a device would be useful in initiation therapy for stroke rehabilitation.

WHAT WILL I BE EXPECTED TO DO?

This study is funded by Victoria University of Wellington and the School of Design through medical technology research grants from the Ministry of Business, Innovation and Employment.

You will not incur any costs by taking part and we will travel to you.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would if you were injured in an accident at work or at home. You will have to report a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.
WHAT ARE MY RIGHTS?
You are volunteering to take part. You do not have to take part in this study and you can withdraw at any time. We can show you the video recording and photographs of you we have collected. We can also give you a copy of what we have recorded you saying to us about using the computer and data games. It is unlikely that participating will affect your health but if it does, we will contact you immediately. We will not identify you in any of the students work or presentations of the work.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?
After you have taken part and change your mind about being involved, please contact the researcher (design student) or the lead investigator (Brian Robinson, in the first instance, or Edgar Rodriguez) and any data, information and images associated with your participation will be destroyed. We will securely store the information and data you have provided for five (5) years and it will then be destroyed. We can present the findings of this study at stroke clubs within a year of conducting the study. We can also send you a summary of the students thesis describing the outcome of the study. We may also present this study with other similar studies we are conducting at conferences or in books or journals.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?
If you have any questions, concerns or complaints about the study at any stage, you can contact:
Dr Brian Robinson, Senior Lecturer, Graduate School of Nursing, Midwifery & Health, Victoria University of Wellington.

If you have other questions, concerns or complaints and wish to contact a Masit support person, you can contact:

Consent Form

If you need an INTERPRETER, please tell us. If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet.

Please tick to indicate you consent to the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. [Yes/No]

I have been given sufficient time to consider whether or not to participate in this study. [Yes/No]

I have had the opportunity to see a legal representative, welfare/ family support or a friend to help me ask questions and understand the study. [Yes/No]

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. [Yes/No]

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. [Yes/No]

I consent to the research staff collecting and processing my information, including information about my health. [Yes/No]

If I decide to withdraw from the study, I agree that the information recorded about me up to the point when I withdraw may continue to be processed. [Yes/No]

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any way beyond the scope of this study. [Yes/No]

I understand the compensation provisions in cases of injury during the study. [Yes/No]

I know who to contact if I have any questions about the study in general. [Yes/No]

I understand my responsibilities as a study participant. [Yes/No]

I wish to receive a summary of the results from the study. [Yes/No]

Declaration by participant:
I hereby consent to take part in this study.

Participant’s name:
Signature: Date:

Declaration by member of research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.
I believe that the participant understands the study and has given informed consent to participate.

Researcher’s name: Jessica Saul
Signature: Date:

If you want to talk to someone who hasn’t been involved with the study, you can contact an independent health and disability advocate on:

Phone:

For Masit health support please contact your health provider and they will refer you to the representative Masit health support group.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:

Email:
Appendix 2 Consent forms

Designing a System for Stroke Rehabilitation
CONSENT TO INTERVIEW

Researcher: Jessica Sack, School of Design, Victoria University of Wellington.

- I have read the Information Sheet and the project has been explained to me. My questions have been answered to my satisfaction. I understand that I can ask further questions at any time.
- I agree to take part in an audio-recorded interview.

I understand that:

- I may withdraw from this study up to four weeks after the first interview or up to four weeks after the second interview reviewing the designs, and any information that I have provided will be returned to me or destroyed.
- The information I have provided will be destroyed 5 years after the research is finished.
- Any information I provide will be kept confidential to the researcher and the supervisor. I understand that the results will be used for a Masters/PhD report and a summary of the results may be used in academic reports and/or presented at conferences.
- My name will not be used in reports, nor will any information that would identify me.
- I would like a summary of my interview: Yes ☐ No ☐
- I would like to receive a copy of the final report and have added my email address below: Yes ☐ No ☐

Signature of participant: ________________________________
Name of participant: ________________________________
Date: ________________________________
Contact details: ________________________________

Designing a Device for upper limb Stroke Rehabilitation
CONSENT TO PHOTOGRAPH

Researcher: Jessica Sack, School of Design, Victoria University of Wellington.

- I have read the Information Sheet and the project has been explained to me. My questions have been answered to my satisfaction. I understand that I can ask further questions at any time.
- I agree to take part in a photography and/or video session.

I understand that:

- My image or video will be used within both physical and digital publications.
- I understand that the resulting images and/or video will be used for a Masters/PhD report and may also be used in academic reports and/or presented at conferences.
- My name will not be used in reports, and images/picturing me may show features that would identify me.
- I agree not to disclose to any third parties any description of the designs that may be shown to me during the session: Yes ☐ No ☐
- I would like to receive a copy of the final report and have added my email address below: Yes ☐ No ☐

Signature of participant: ________________________________
Name of participant: ________________________________
Date: ________________________________
Contact details: ________________________________
Appendix 3 Surveys

Clinician

Which best describes your profession?
- Physiotherapy (1)
- Occupational therapy (2)
- Nursing (3)
- Other (4)

Do you work directly with the rehabilitation of stroke patients?
- Yes (5)
- No (2)

Do you work with upper limb rehabilitation for stroke patients?
- Yes (1)
- No (2)

At which stage post-stroke does your rehabilitation work with stroke patients typically begin? Click all that apply.
- 24-48 hours post stroke (1)
- 1 week post stroke (2)
- 1 month post stroke (3)
- 3 months post stroke (4)
- 4 months post stroke (5)
- 1 year post stroke (6)
- More than 1 year post stroke (7)
- Other (8)

Do you feel that time allocated with a patient is sufficient to deliver all the therapy needed until the next session?
- Yes (7)
- No (2)

On average how much time do you spend per session with a patient? In minutes and hours

On average how many sessions would you have with a single patient in a given week?

Consider "How likely your patients are to complete independent therapy activities?"

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<th>Rate (1)</th>
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<th>Somewhat likely (2)</th>
<th>Neither likely nor unlikely (3)</th>
<th>Somewhat unlikely (4)</th>
<th>Extremely unlikely (5)</th>
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Consider "How likely your patients are to try new devices and pieces of equipment?"

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<th>Rate (1)</th>
<th>Extremely likely (1)</th>
<th>Somewhat likely (2)</th>
<th>Neither likely nor unlikely (3)</th>
<th>Somewhat unlikely (4)</th>
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Consider "How likely your patient are to accept new devices and pieces of equipment?"

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<th>Rate (1)</th>
<th>Extremely likely (1)</th>
<th>Somewhat likely (2)</th>
<th>Neither likely nor unlikely (3)</th>
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</table>

How likely are you to try out new devices and pieces of equipment?

<table>
<thead>
<tr>
<th>Rate (1)</th>
<th>Extremely likely (1)</th>
<th>Somewhat likely (2)</th>
<th>Neither likely nor unlikely (3)</th>
<th>Somewhat unlikely (4)</th>
<th>Extremely unlikely (5)</th>
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As a clinician what are the most important things for you?

What in your opinion are the most important things for your stroke patients?

Page 2 of 7
Are you open to trying new systems and making changes to your therapy practices?
- Yes (1)
- Maybe (2)
- No (3)

If yes how many hours would you be able to dedicate to learning a new system or therapy:
- Less than 1 hour (1)
- 1-2 hours (2)
- 1/2 day (3)
- Full day (4)
- 2-3 days (5)
- 1 week (6)
- More than 1 week (7)

Have you used mechanical or robotic devices in your therapy delivery? For example, the sweatro glove:
- Yes (1)
- No (2)

Could you see a benefit in including a robotic device in therapy?
- Yes (1)
- Maybe (2)
- No (3)

How long do you think it should take to put on or take off an assistive device:
- Less than 10 seconds (1)
- 10-20 seconds (2)
- 20-40 seconds (3)
- Up to one minute (4)
- 2-5 minutes (5)
- 5-10 minutes (6)
- More than 10 minutes (7)

What would you need from a device that rehabilitates hand functionality?

Do you have any additional comments?

Thank you for taking part in this survey.
If you would like to be more directly involved in this research please leave your name and contact details below.
Robotic acceptance Questionnaire

How long have you been recovering from stroke? In years and months

What types of impairments have you been left with as a result? Mark all that apply

- Motor function impairment
- Cognitive impairment
- Psychological impairment
- Other

Have you been prescribed or use any therapy devices or daily aids? Mark all that apply

- Yes
- No

If yes to the above, what are the devices you use?

In your experience have there been any devices you have been offered and been reluctant or against using? Mark all that apply

- No
- Yes

If yes to the above, give a brief description of the device or tool and your experience.

Moving on to questions about today’s session

Mark the circles in which best describe your perspective on the wearable robotic device introduced to you.

If the robot... Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

- If I should use the robot, I would be afraid to make a mistake with it
- I find the robot scary
- I find the robot interesting
- It is a good idea to use the robot to help me with everyday tasks in the future
- The robot would make my life more interesting and stimulating in the future
- It would be good to make use of the robot to help me with everyday tasks today
- The robot would make my life more interesting and stimulating today
- If the robot was available, I would use it
- I think society will encourage stroke patients to use the robot to assist people in everyday tasks

In the coming years, my family (husband, wife, children) and health professionals would appreciate that I use a robot to help me with everyday tasks in the future, it will be a trend for stroke patients to use robots to help them manage everyday tasks

- I think the robot would be useful for me today
- I think the robot would be useful to me in the future
- I think that I will learn quickly how to use the robot
- I find the robot fascinating
- I find the robot boring
- I think the robot is nice
- I think the robot would be easy to use
- I think I would be able to use the robot by myself
- I think I would be able to use the robot if there was someone around to help me
Appendix 4 Interview guide

Testing procedure

- Arrive at participants house with one support person
- Introductions
- Set up video and audio equipment at dining table or similar
- Go over info sheet and get consent
- Turn on audio
- First non-prototype questions 10-20 mins
- Turn on video equipment with positioning that shows users hands / arms / upper body not face
- Bring out robotic device 1 and describe / demonstrate 5-10 mins
- Ask questions / discuss prototype one
- Prototype 2/3/4 do not describe give 2-5 mins to look at and go into question set
- Give space for more questions and discussion
- Thank
- Pack up
### Appendix 5 Interview quotes analysis table

<table>
<thead>
<tr>
<th>Patients Survey &amp; User testing</th>
<th>Quotes</th>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“I would wash it every few weeks.”</td>
<td>Cleanability</td>
</tr>
<tr>
<td></td>
<td>“Straps are a nuisance.”</td>
<td>Useability</td>
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<td></td>
<td>“If the robot was available I would use it”</td>
<td>Acceptance</td>
</tr>
<tr>
<td>Clinicians</td>
<td>Therapy includes everyday items to &quot;tap into the old muscle memory patterns&quot;</td>
<td>Functionality, Acceptance</td>
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<td></td>
<td>Roboticists need to deliver something the clinician cannot, such as &quot;using it as a home exercise programme&quot;</td>
<td>Functionality</td>
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<td></td>
<td>Patients want to feel normal, but what is normal and how they are affected is different for every individual: &quot;if they have an upper limb impairment they will have a grip impairment&quot;</td>
<td>Function and Context (understanding background)</td>
</tr>
<tr>
<td></td>
<td>Patients are receptive to new ideas early in therapy, but &quot;the hardest part is to get them engaging with a home exercise programme&quot;</td>
<td>Engagement, acceptance</td>
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<td></td>
<td>Patients paying privately for treatment are much more independent with therapy.</td>
<td>Functionality Effectiveness of device</td>
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<td>“If it can do only one type of grip, you will be limited to those functional tasks that need that type of grip”.</td>
<td>Functionality</td>
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<td></td>
<td>“It’s got to be easy to use, it’s got to have a purpose and it’s got to do something either we can’t do as therapists or don’t have time to do as therapists”</td>
<td>Ease of Use</td>
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<td>“being able to do it independently would be a big plus”, as one clinician stated.</td>
<td>Ease of Use</td>
</tr>
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<td>“For guys… some of them really like to expose the inner workings and wiring of it. Whereas, potentially some ladies might not like the bulky robotic nature of it”</td>
<td>Aesthetics</td>
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<tr>
<td></td>
<td>male patients could be accepting of robotics, seeing the robotics as a “terminator arm”.</td>
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<td>“justifying it to ACC, or core funding, if I can show that they have used your device an hour a day for the past month, that would be amazing.”</td>
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<tr>
<td></td>
<td>products ‘under $500 per patient’, would be more likely to be prescribed, and ‘under $250 per unit’, would reduce funding barriers.</td>
<td>Aesthetics, Personalisation, Acceptability</td>
</tr>
<tr>
<td>Clinical researcher</td>
<td>device needs to include: “Ease of use, cost-effectiveness, enhances recovery of normal patterns of functional movement, comfort, cosmetic appearance, effectiveness and evidence to support.”</td>
<td>Benefits of Device</td>
</tr>
<tr>
<td>Industry Professional</td>
<td>Product features</td>
<td>Assessability</td>
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<tr>
<td>------------------------</td>
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<td>device needs to include: “Ease of use, cost-effectiveness, enhances recovery of normal patterns of functional movement, comfort, cosmetic appearance, effectiveness and evidence to support.”</td>
<td>product features</td>
<td>assessability</td>
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<tr>
<td>“Needs to be something that they can relate to, some other product like a glove.”</td>
<td>Affordance, acceptance</td>
<td></td>
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<td>The Able X, has a “50-page booklet … load software … dongle … connection … login … calibration, before you can even start to play the game”</td>
<td>Ease of use</td>
<td></td>
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<td>The industry professional “often highly sympathise[s] with users who do not get past the setup stage”</td>
<td>adoption/rejection</td>
<td></td>
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<td>“if you are not engaged you are not going to use it”</td>
<td>engagement</td>
<td></td>
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<td>“People engage with their hands more than any other part of the body”</td>
<td>engagement interaction</td>
<td></td>
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<tr>
<td>“With the Able X you are getting 100 movements an hour and automotive type systems, that’s a motion that I would expect, compared with conventional therapy that is roughly 30 movements in a session.”</td>
<td>therapy</td>
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<tr>
<td>“The stroke survivor can generally get on their daily living without it with one good side.”</td>
<td>therapy</td>
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</table>
Hand devices used by clinician 2 & 3.

Splint used by a participant; described as bulky and difficult to put on, help is required.

Tools used by a participant in therapy activities.
Simple cardboard splint made by the participant, reduced bulk, weight and was ‘more comfortable’.

2 of the patient participants favorite prototype from phase 1. with splits and reduced height unit.
Phase 1 prototype solid plates, full finger coverage, left hand fit. Connects to either unit.

Phase 1 prototype solid plates adjustable finger fit. Connects to either unit.

Phase 1 prototype split plates hand component that connects to either unit tested universal left/right fit.
Phase 1 prototype solid plates fully covered palm fabric universal fit plates left fit.

Phase 1 prototype solid plates, lighter fabric hand component only, left hand fit.