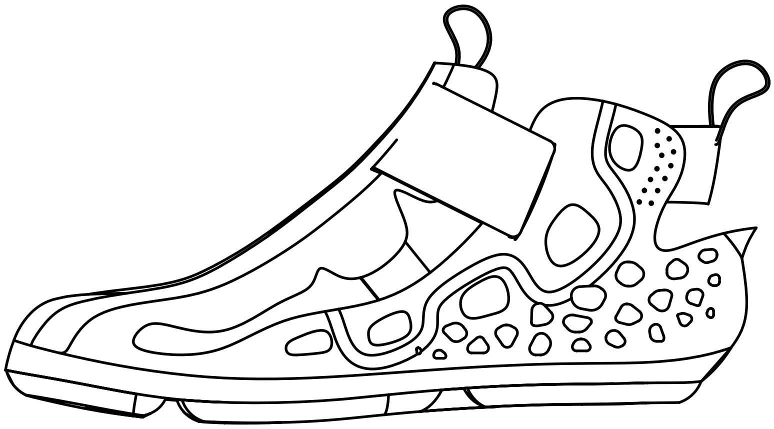
Exergaming for Lower Limb Stroke Rehabilitation



A Game controller for Lower Limb Stroke Rehabilitation

By RuiFeng Yeo

A thesis submitted to the Victoria University of Wellington in fulfilment of the requirements for the degree of Masters of Design Innovation

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Victoria University of Wellington

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This thesis is dedicated to my family

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Abstract

The success of stroke rehabilitation requires the patient engage in early, long-term high repetitions and intensive treatment. When comparing clinical and literature statistics, it is confirmed that clinical rehabilitation is not achieving required repetitions and intensity for effective rehabilitation of basic motor skills as prescribed in physiotherapy literature. It is then the patient's responsibility to carry out the rehabilitation at home without supervision. These exercises can also be very mundane and repetitive, which reduces the patient's motivation to exercise. Exergames have been found (Alankus et al., 2010, p. 21130, (King, Hijmans, Sampson, Satherley, & Hale, 2012 Deutsch et al., 2009), (Mortazavi et al., 2014), (Shirzad et al., 2015).to improve patients' engagement with their therapies at home.

Currently there are systems to facilitate lower limb stroke rehabilitation,but none includes Strength for Task Training (STT). STT is a novel physiotherapeutic method for lower limb rehabilitation and comprises of two main phases: first being the strength training (priming) and second being the task training. Priming is brief weight lifting to excite the neural pathways (neuroplasticity) in the affected region, which primes the brain for learning; this is then promptly followed by task training to maximise gains in the locomotor ability.

This project builds up on the research and development of a game controller by Duncan (2016) for lower limb stroke rehabilitation to facilitate STT. This project is a collaboration with Regan Petrie who designed the media aspect of the exergame system.

A game controller was developed and this was part of a complete exergaming system which was designed to specifically facilitate STT. This project compiles more research findings together with feedback from the user and the clinicians to help improve the system. This was to ensure that the design is aligned to the specific requirements of functional STT rehabilitation and contextual needs of the patient.

The final output is a pair of prototype shoes which included a sensor to measure movement, a pair of weighted sleeve and a pair of balance sole. The weighted sleeve has removable weights and facilitates the strength part of the training. The shoes are the adaptors which allow the user to the balance soles which is used to constantly challenge the user's balance. The sensors translate limb movement and are for the user to interact with the game. This system provides a simple and safe method to engage in unsupervised STT.

Feedback from clinicians indicates that the shoes can facilitate the strength part of the exercise, the sensors the task part of the training, and the balance sole is useful for challenging and improving balance. User testing sessions offer information about: the usability of the system, including ease of use and intuitive design; the aesthetics of the physical objects and whether the system is engaging patients in their therapies.

03

Introduction

"Everything is rehab and rehab is everything"

\- Participant 1.3

15 million people are affected by stroke worldwide every year (WHO, n.d.) and of those people, 5 million people are affected by long-term disability (Pinter & Brainin, 2012). Stroke can affect the survivors in a multitude of ways such as muscle weakness, restricted range of motion and paralysis on one side of the body (Alankus, Lazar, May, & Kelleher, 2010).

The only way people recover from the effects of post stroke is early and intensive retraining of the affected limb; thousands of repetitions (Alankus, Lazar, May, & Kelleher, 2010). The constant increase in incident numbers and lack of physiotherapists has created a bottleneck in the rehabilitation sector (Duncan 2016). Among those who receive treatment, only 31% appear to diligently carry out rehabilitation at home (Shaughnessy et. al, 2006, p.16).

In recent years, gaming consoles and exercise games (exergames) have been modified to be as tools to aid rehabilitation among users with long term disabilities such as stroke (Jack et al., 2001) & (Alankus, Lazar, May, & Kelleher, 2010). This method of rehabilitation has shown that it increases the engagement of the survivor while at home (Lohse, Shirzad, Verster, Hodges, & Van der Loos, 2013; Alankus, Lazar, May, & Kelleher, 2010). However, most commercially available home-based exergames for stroke rehabilitation target upper limb rehabilitation and there are only a few commercial home-based lower limb rehabilitation system.

In addition to the lack of home-based lower limb rehabilitation systems, none of the systems work in tandem with the Strength for Task Training (STT). STT is an innovative lower limb rehabilitation regime which incorporates the use of weight training (priming) and is promptly followed by task training. The aim of this training is to utilize the plasticity of neurons during priming to create new pathways around the affected region (Signal, 2014, p. 249). Currently STT is only practiced in a clinical environment but there is a demand for STT to be implemented into the homes of survivors.

The combination of home-based STT rehabilitation and the lack of lower limb exergame systems creates an opportunity for the development of a physical game controller which allows users to access unsupervised STT exergames at home. However, this system will be an addition to routine rehabilitation and used with guidance from physiotherapists at home; in the long term efforts to relieve the pressure on the public health care system.

04

Background Research

4.0. Background Research

Background Research

This chapter will examine the ways in which exergames are considered an effective method for providing positive outcomes for stroke patients' rehabilitation and the potential of employing Strength for Task Training (STT) to improve patient locomotion.

The exploration of these factors will influence the initial criteria for the design of the physical controller; which is part of a wider exergame system, that would facilitate home-based unsupervised lower limb stroke rehabilitation. Ergonomics, usability and requirements for home use will also be considered in the initial design criteria.

The original design criteria will also be guided by a comparison of current market devices, to address existing issues faced by current users.

The background research is split into several themes that aim to guide the design process. It is essential to note that even though this chapter will focus on the physical controller aspect of the exergame system, it is critical that both the physical controller and the game are designed as a whole to develop a coherent exergame system.

4.1. Stroke

Background Research

A stroke is caused by either a blood clot or a burst blood vessel in the brain which will result in a lack of blood in the affected region; thus causing the brain cells to start dying within minutes. The dead brain neurons leave the survivor with a void with no connections controlling their motor or speech skills. Survivors of stroke are most often plagued by hemiplegia (muscle weakness) or hemiparesis (muscle paralysis) down a side of the body. (Alankus et al., 2010, p. 2113)

The damage will cause the neural pathways that would normally be used for cognitive, visual and motor movements to break down. This sudden loss of control can increase the dependency on others to accomplish daily activities and tasks (Alankus et al., 2010, p. 2113).

4.1.1. Lower limb Rehabilitation

Background Research

The primary focus of rehabilitation is to allow the patient to regain their mobility. Post-stroke survivors who are stricken with hemiplegia or hemiparesis will often impede the survivor's ability to walk. The severity of impairment can vary with each survivor; which ranges from walking independently to wheelchair assisted movement or complete immobility. Thus it is up to the physiotherapist's discretion to determine the rehabilitation routine as there is no 'one size fits all' recovery regime that any individual survivor can undertake (Perry, Garrett, Gronley, & Mulroy, 1995, p. 988).

Current lower limb rehabilitation regimes include strength and coordination of the different muscle groups in the legs. There are currently several different motor recovery therapies:
Traditional multidisciplinary teams of physiotherapists; occupational therapists; and speech and language pathology.

Other emerging methods include:

- Selective Serotonin Receptor Inhibitor (SSRI) antidepressants;
- Constraint-induced movement therapy (CIMT);
- Noninvasive brain stimulation (NIBS);
- Mirror Therapy (MT); and
- Motor imagery/mental practice.

4.1.1.1. Strength for Task Training

Background Research

Survivors with hemiplegia or hemiparesis are often impaired by muscle weakness and the broken connections between the brain and the limbs. STT is a novel rehabilitation programme that has been found to be effective among stroke survivors (Signal, 2014, p. 209). It uses a combination of strength exercises and task-specific training. When the survivor engages in unilateral strength training, it primes the central nervous system for the relearning phase. When engaging in task-specific training, the primed central nervous system will begin to rebuild the neural pathways (Signal, 2014, p. 43, 60).

Strength training: Priming

The first phase of STT is to get the patient to lift weights (Signal, 2014, p. 25). The strength training not only increases their muscle endurance but it also excites the corticomotor related to the muscle in training which is called Priming (Signal, 2014, p. 47).

Priming requires the patient to exert themselves to the limit which excites the neurons in the corticomotor. This excitement primes the neural pathway to start rebuilding when promptly switching to task specific training; thus encouraging neural plasticity (Signal, 2014, p. 47). There are different forms of strength training requirements; which would normally involve a weight or resistance-band attached to the lower limb. Once the priming stage is over, it is promptly transited to task-related training using the same muscle groups (Signal, 2014, p. 53). In order to gain maximum potential excitement from the neurons, the strength training exercise must be intensive; strenuous exercises within a short period of time. The initial load is determined by the physiotherapist after an initial assessment of the patient's capabilities. The load can be changed constantly to keep the intensity up as the patient gets stronger (Signal, 2014, p. 47).

Task Training

The transition to task training has to be done within several minutes following strength training as the corticomotor excitability is lost within the first few minutes. Once the transition has been made the patient can make full use of the excited neurons to begin rehabilitation. (Signal, 2014, p. 47)

Task training is the final phase of STT. Much like priming, task specific training must be intensive in order to encourage improvements. The task specific training must also mimic real world tasks to enhance the learning process. The intensity of the training can be altered with repetitions or complexity of the task; which is dictated by the physiotherapist as the patient improves (Signal, 2014, p. 46).

The task training is broken down into nine different components and can be directed by the physiotherapist (Signal, 2014, p. 53, 55).

Components	Description
Part/Whole Task	Broken down parts of a single task or a whole single task
Speed	Comfortable pace which the task is performed
Accuracy	Stricter boundaries around target location
Sensory Availability	Utilizing other sensors to determine balance
Biomechanical Challenge	Physically challenging the limit of the affected limb
Cognitive Attention	Multitasking while performing a task
Physical Attention	Holding an object while performing the task
Environment	Area where the task is being carried out
Blocked vs Random	Components can be mixed or predetermined sets

Figure 4.1 - Nine components of task training.

STT has seven different activities. These activities are designed to engage all the muscle groups and tasks involved in locomotion. The exercises are conducted within a 60 minute period, with 30 second breaks between each exercise.

Strength for Task Training Exercises (Signal, 2014, p. 53)

Strength Training (Priming)	Task Training	Purpose
Toe ups (Dorsi Flexors/ Evertors)	Obstacles	Strengthen muscles for foot clearance
Hip Flexors	Walking & Stepping	Strengthen muscles at the front of the hip
Hip Abduction	Sideways walking & Stepping	Strengthen muscles at the sides of the hip muscles
Quadriceps (Seated Leg Press)	Standing Up & Sitting Down	Strengthen Muscles at the front of the thigh
Hip Extensors	Stairs & Steps	Strengthen the buttock muscles
Hamstring	Backwards Walking & Stepping	Strengthen hamstring muscles
Plantarflexors (Supine Leg Press)	Fast Walking & Slopes	Strength calf muscles

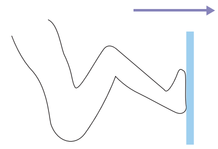
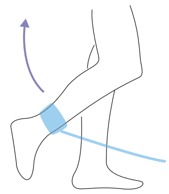
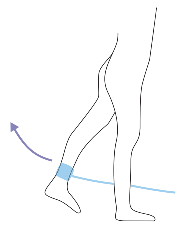
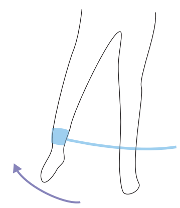
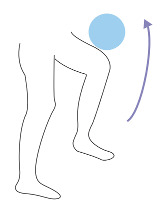
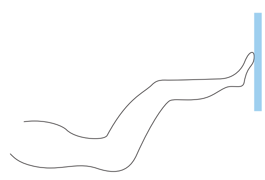
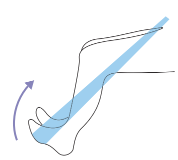
Figure 4.2 - STT exercises.

Modification and Progression

After a stroke, the road to recovery is not easy and it requires the patient to constantly challenge themselves to achieve improvements (Burke et al., 2009). The rehabilitation sessions can be modified in accordance with the patient's immediate goals and as they progress, the rehabilitation regime can be modified again. The regime can also be adapted to suit the different patients with guidance from clinicians. These modifications and adaptations can then keep the patient interested and constantly improving (Burke et al., 2009).

Priming Component

Adapted from Duncan 2016 (p. 10-11)

	Equipment	Motion	
1	Seated Leg Press Quadriceps	Extend legs to push weight away from body	
2	Westminster Pulley Hamstrings	Attached to ankle and flex lower leg backwards	
3	Westminster Pulley Hip Extensors	Attached to ankle and flex the leg backwards	
4	Resistant Band Hip Abductors	Move leg sideways from mid-line	
5	Rotary Hip Hip Flexors	Raise knee forward and upwards	
6	Supine Leg Press Plantarflexors	Push weight away using only the front of the foot	
7	Resistant Band Dorsiflexors/Evertors	Isolate ankles with resistant band and raise foot up together and hold	

Task Component

Adapted from Duncan 2016 (p. 10-11)

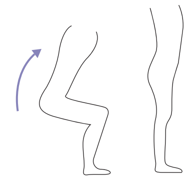
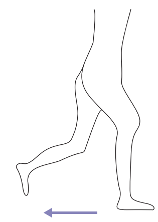
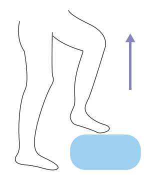
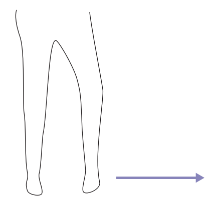
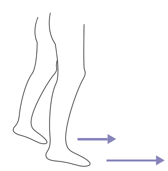
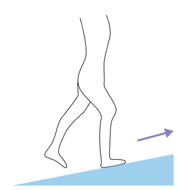
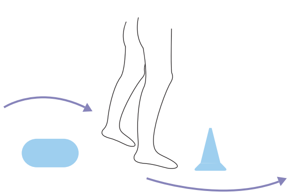
Transition	Equipment	Motion	
Getting out of the machine	Chair	Sit to stand to sit	
Removing ankle strap	Marked line on ground	Walking backwards	
Removing ankle strap	Stepping board	Climbing stairs	
Removing ankle strap	Marked line on ground	Walking sideways	
Stepping off the machine	Parallel walking bars	Walking (own pace)	
Getting out of the machine	Ramp	Walking (faster pace)/ ramps	
Remove resistant band	Low obstacles e.g cones or wooden blocks	Lifting foot over low obstacles	

Figure 4.3 - Clinical STT exercises and trask training.

4.2. Exergames

Background Research

Exergame is a term that is given to video games that involve some form of exercise. These games require the player to move their body in order to achieve goals in the game. Several types of controllers are used to track the player's movements such as accelerometers or camera motion tracking.

There are several games that require the user to move more than their hands. The Just Dance series in Playstation Move games require the player to dance rhythmically with the music and execute specific dance routines. Kinect Sports in Xbox Kinect requires the user to jump, swing their arms or kick to interact with the respective sports. Wii Play: Motion in Wii games require the player to manipulate the game controller to perform different actions to win the game.

There are also more games like these in the virtual reality realm in which players have to put on a headset and hold on to a pair of controllers to interact with the game. This form of technology is currently at an early stage of development and it is not yet commercially available.

Exergames for home use require several different criteria which are essential for the user to be able to use it independently. The exergame system has to be affordable to a large target market; intuitive design to allow for easy setup and troubleshooting; and convenient to move around small living environments.

Figure 4.4 - Kinect Sports in action.

Figure 4.5 - Older adult playing the Nintendo Wii.

4.2.1. Exergame for stroke rehabilitation

Background Research

Exergames are a relatively novel approach to stroke rehabilitation. Exergames are now employed as a tool which physiotherapists can use to help rehabilitate their patients (Alankus, Lazar, May, & Kelleher, 2010; Lohse, Shirzad, Verster, Hodges, & Van der Loos, 2013). The different types of motion tracking now available have given physiotherapists a wide spectrum of uses to suit different levels of rehabilitation.

There are two categories of the rehabilitation system; a clinical rehabilitation system which requires a physiotherapist to be around and a home-based rehabilitation system that requires a gaming console or a computer or a portable gaming device.

One example of a clinical rehabilitation system is the InMotion Arm Interactive Therapy system. It allows the user to accommodate elbow flexion/extensions, shoulder protraction/retraction and shoulder internal/ external rotation through two degrees of freedom ('InMotion ARMTM Interactive Therapy System', n.d.).

Home-based exergame consoles such as the Playstation EyeToy and Microsoft Kinect use a camera to track the user's gross movement within a limited designated area of the camera. These systems allow the user to exercise without having to hold on to any controllers allowing them to concentrate on achieving their tasks (Chiang, Tsai, & Chen, 2012).

In contrast to the motion trackers of the Playstation Eyetoy and Microsoft Kinect is the Wii [B1] remote, which uses haptic sensor-based controllers; and the Wii balance board, which uses a kinetic force plate that locally tracks the user's movements and weight distribution. Another bonus feature of the Wii system, is that it is able to accurately track movement despite the different aid being used, which in this case is a chair (Deutsch et al., 2011).

The advancements of wearable technology have also helped to create new devices which can help track the user's movement with extreme accuracy. Two such devices are the Youkicker by You Rehab and The Indee System by Duncan (2016). Both these systems use wearable sensors which detects the user's movements and translates them into the game; providing feedback to the user.

4.2.2. Adaptability

Background Research

The key feature in the design of home based exergaming controller is the ability to change the difficulty, intensity and complexity level at the discretion of the physiotherapist (Duncan 2015). This is because post-stroke motor function and recovery improvements over time vary amongst different patients (Flores et al., 2008). According to Levin et al (2015), traditional rehabilitation approaches are unable to fully utilise the potential of neuroplasticity due to the insufficient training, different levels of patients' impairments and lack of meaningful task training. These might lead to low participation rates amongst patients (Shaughnessy, Resnick, & Macko, 2006). Thus it is critical that the exergame system has customisable difficulty levels and parameters to keep challenging the patients (Alankus, Lazar, May, & Kelleher, 2010) and keeping them motivated, engaged and enjoyable (Levin et al., 2015).

Some exergaming systems offer adaptability to some extent. For instance, the Able-X is a handheld wireless controller for upper limb rehabilitation of stroke survivors. The controller physically challenges the user by retraining their motor skills as they play through a series of gradually challenging games. The collection of computer games gives the physiotherapists different options to prevent the user from losing interest and the tasks being perceived as mundane (Jordan & King, 2011).

4.3. Design Review

Background Research

In order to formulate a list of criteria for designing an exergame system for stroke patients, an evaluation of existing and conceptual devices must be done. This would then give an overview of what is available and what areas still need to be addressed in order to help facilitate unsupervised STT at home.

There are several factors that will direct the initial design criteria:

- Ease of use;
- Aesthetics and form factor;
- Tracking accuracy; and
- Adaptability.

Apart from the factors listed above, one critical factor that would encompass the overall design of the whole system is the target demographic of users post-stroke who are typically above the age of 65 and may or may not have any assistance around them.

The ease of use in a home based rehabilitation system should be intuitive and relatively easy to set up as suggested by Gerling et al (2010). A quick and easy setup is needed as the target audience has limited experience with electronic devices due to minimal knowledge and late adoption of digital devices. Modern gaming systems, in comparison with mobile gaming, can hinder older adults due to the lack of familiarity with the systems due to the use of gesture controls and might prove daunting to an older adult (Fritz, Peters, Merlo, & Donley, 2013, p. 219; Marinelli & Rogers, 2014, p. 1250), whereas the usability of mobile gaming can be specifically designed to cater to the target audience.

There are several examples that have re-purposed commercial gaming controllers. Examples of such include: Wii remotes (Alankus, Lazar, May, & Kelleher, 2010); the Wii Balance Board (Gil-Gómez, Lloréns, Alcañiz, & Colomer, 2011); Microsoft Kinect (Webster & Celik, 2014); and Playstation 2 EyeToy (Rand, Kizony, & Weiss, P, 2004). These examples are already proving to be successful and affordable exergaming controllers. However, the repurposed controllers have no aesthetic or ergonomic value and some modifications may be uncomfortable to wear after a certain period of time. Whereas in mobile gaming, the sensors are designed in specific housing which allows space for the sensor; is comfortable; and can be worn for the whole training session or possibly longer.

These specific housings would also allow accurate tracking of the user's target limb which is important in order to plot accurate data (Burke et al., 2009, p. 1088); and allow the user and therapists to keep track. The accurate tracking also helps to correct undesirable movements.

Using wearable sensors is a more beneficial route because motion trackers on the Xbox Kinect or Playstation Eyetoy are unable to track subtle movements or joint rotation which is needed when assessing precise movements (Webster & Celik, 2014).

4.3.1. Review of current market devices

Currently in the market there are several devices and apps which promote home-based rehabilitation. For example, “Saebo” is a company in the United States of America which mainly focuses on upper limb rehabilitation by creating different types of gloves which can interact with a game (Saebo, 2016). There are also devices which rely on electrical stimulation to activate the target muscles; one such example is BioMove 3000 or Biomove 5000 Pro. This product can be used for either upper or lower limb rehabilitation. The device detects the EMG signals in the muscles and amplifies it to reward the user with a physical movement (Biomove, 2016).

There are also apps such as “3D4Medical Rehabilitation for Lower Limbs”, which can guide users while they are at home. The app uses video and audio narration to guide the user and physiotherapists can also guide the user to which exercises are most suitable for them (3d4Medical 2016).

However, overall one device stood out by encompassing both lower limb rehabilitation and a gaming experience - “YouKicker” by YouRehab (2016). It has four motion sensors which can be attached using Velcro strips. These sensors detect movement in the x, y, z axes and reciprocate the motion in a game. This method of tracking the patient’s movement allows them to be in a comfortable position as they exercise rather than forcing them to be confined to a boundary.

In conclusion, these current market devices address problems ranging from users with severe muscle paralysis to users that are further along on their road to recovery. These devices also cater to the different users who have different rehabilitation styles ranging from professional care to home-based rehabilitation. The cost for the range of rehabilitation also varies largely from expensive (Biomove) to minimal cost (3d4Medical).

Despite these devices being helpful to users, one critical factor is that the user has to stop whatever they are doing and dedicate some time to focusing on rehabilitation. Unlike the proposed exergaming system in this project, which provides the user with a game that they can incorporate into their daily activities while continuing to monitor their progress through a mobile device.

4.3.1. Review of current market devices

Category	Device	Lower Limb (Targeted at lower limb rehabilitation)	Portability (Ability to be used anywhere around the house at any time)	Adaptability (Ability to be customised to different user recovery stages)	Ease of use (Can be understood and learnt regardless of technology knowledge)	Intimidating (First impression of the product before using)	Tracking Accuracy (Individual limb tracking capabilities)	Standalone (Able to be used without an electronic device)	Weight Training (Incorporated weight training prior to task training)
App Based	3D4Medical Rehabilitation for lower limb	✓	✓	✓	✓	×	NA	×	×
Computer Based	YouKicker	✓	×	✓	✓	×	✓	×	×
Console Based	Virtual Rehab Body	✓	×	✓	✓	×	✓	×	×
Technical Based	BioMove 3000	✓	✓	✓	×	✓	NA	NA	×
Technical Based	BioMove 5000 Pro	✓	✓	✓	×	✓	NA	NA	×
Technical Based	Saebo MyoTrac Infiniti	✓	✓	✓	×	✓	NA	NA	×
Clinical Based	Wearable Shoe-Based device for rehabilitation of stroke patients (Edgar, Swyka, Fulk, & Sazonov, 2010)	✓	✓	NA	NA	✓	✓	×	×
Clinical Based	Silver Balance (Gerling, Schild, & Masuch, 2010)	✓	×	✓	✓	✓	×	×	×

Figure 4.6 - Competitor matrix.

4.4. Designing for stroke rehabilitation

Background Research

The target audience for the exergame lower limb system is mainly stroke patients which have both cognitive and motor disability. According to Shirzad et al. (2015), not only does the exergame have to be engaging with the audience but also ergonomically designed to give the users full control and in turn provide a safe gaming experience. This unique user design challenge gives rise to several usability issues that will be addressed in the following sections.

4.4.1. Ergonomics and usability when designing for users with stroke

Background Research

The cognitive effects of stroke can influence the loss of memory and speech. The patient may also experience impairment on either sides of their visual field and motor functions. The motor functions include but are not limited to paralysis or muscle weakness on one side of the body (Alankus, Lazar, May, & Kelleher, 2010).

These impaired motor skills will affect the patient's balance and also cause spasticity or contracture in the upper and lower limbs. The lower limb consists of muscles that affect movements in the knees, feet and toes; which may cause muscle contractions in awkward positions and lead to imbalance (American Stroke Association, 2016). The balance of the patient is of the utmost importance in order for them to carry out their exergame rehabilitation safely. Gerling et al (2010) have suggested gaming interactions should cater to users who are both standing and seated. This would be safer for users who have balance impairment.

Spasticity, as described earlier, is the uncontrollable contraction of muscles which in turn affects the loss of finger dexterity and coordination (Huck & Bonhotal, 1997). Thus it is essential that one of the design considerations should focus on creating large surface areas for gripping. Also by limiting the fastening system to simple one action alternatives such as Velcro or magnets will make it easier for users (Duncan, 2016). Alankus et al (2010, p. 2119) have also stated that assumptions can be made that the user with stroke has no use of one of their hands when considering exergaming interactions.

Despite the fact that stroke can happen at any time during a person's life, it tends to happen more often in adults over the age of 60 (Dyall, Feigin, Brown, & Roberts, 2008). This is a key factor when designing an exergame system, as Gerling et al describe, age related needs are a critical concern to ensuring the user has a safe and enjoyable gaming experience.

In combination with the age related factors and the principles of universal design, there is a middle ground where certain principles outweigh the rest (Crews & Zavotka, 2006). However, all seven principles still need to be taken into account. There are seven principles of universal design:

- Equitable use
- Flexibility in use
- Simple and Intuitive use
- Perceptible information
- Tolerance for error
- Low physical Effort
- Size and Space for approach and use

Out of these seven principles: flexibility in use; simple and intuitive use; tolerance for error; and low physical effort are more critical to informing the design of the game controller.

In this case of designing a home-based rehabilitation exergaming system, Crews et al (2006) discuss that the environment should help accommodate the older adults which can help improve the daily activities. However, designing an environment will not be viable in this project, thus the design of the controller will have to accommodate the older user, with design considerations such as strength and flexibility (Crews & Zavotka, 2006). This allows the user to put on the game controller without major problems and operate the system safely.

Understanding that the controller will be worn for long periods and that exercising will cause the user to perspire, the proper material choice must be analysed. Materials that provide moisture wicking or are easy to clean would be the better choices.

4.4.2. Designing for domestic environment

Current designs of medical, assistive and rehabilitation products have been designed to solely function the way they are meant to and the aesthetic has been kept to a minimum. There are several design considerations to conceal the prominence of the medical device such as hearing aids or prosthetic limbs, but do these attempts at concealment indicate that the impairment is something to hide (Pullin, 2009).

Even though the advancements of biomedical engineering are ever changing, the design consideration have always been of secondary importance.

The secondary importance of aesthetic value has created a stigma around medical products in the public and domestic spaces (Vaes, Stappers, & Vereniging voor Studie- en Studentenbelangen (Delft), 2014). Vaes et al (2014) also further suggest that when a product is perceived, it is not the user that defines it as a stigma but instead the viewers are the ones making the associations. This poor consideration has led to the user's values, needs and self-image being reflected badly (Stipe, 2009).

When a user's confidence is affected, it is quite often that the user will stop using the product altogether. This would defeat the purpose of the product to help improve the life of the user and those around them (Blythe, Monk, & Doughty, 2005).

The product needs to be designed to suit not only the target user but also the environment in which they will be using it, and help with the transition from hospital or clinics to home or community. This is especially critical because of the increasing use of exergaming systems in the rehabilitation sector. As said before the design has to give the user confidence, to encourage them to keep using the product.

Stipe (2009) also discussed that by designing the product to not only reflect the user's confidence but also to allow the product to be better accepted and resulting in a higher usage. He also talked about the importance of the aesthetics to help break the stigmas involved.

Pullin (2009) further discusses that the aesthetics of the product should be able to enhance the user's confidence and the product should elude style. He used the design of prosthetics as an example and he stated that the design should be a stylish piece rather than disguised to look as close to a real body part. The prosthetics should also be part of the user and be designed with the user's attributes in mind.

An example of a widely accepted form of a medical device is glasses or spectacles. This form of design for a disability used to be classified as a medical appliance but over time the evolution and acceptance of the glasses have changed and now are recognised as stylish eyewear (Pullin, 2009, p. 16).

Another case by Blythe et al (2005), relates to monitoring systems and how they can be useful and yet stylish: resulting in older adults feeling proud to wear them all the time, which allows them to promptly call for help if needed. The constant use also provides accurate tracking of the user by their relatives or caregivers. One example that describes the importance having a stylish and useful product is the Lauren's Hope (medical ID bracelet) as described by Duncan (2016). This company designs and manufactures medical ID bracelets for males, females and children. The contemporary designs help promote the use of the products as the styling reflects the semantics and functions of commonly worn products such as watches or bracelets. The constant use of the products will then help the user in the event of an emergency.

The consideration of the controller's aesthetics should also be as important as functionality and usability. Upon gathering data from target users: material, form and colour can inform the final designs. Using the previously stated case studies and literature as precedence, the aesthetics should give users confidence and display their values and self-image.

Figure 4.7 - Fashionable eye wear.

Figure 4.8 - Lauren's Hope: Medical ID Bracelets.

4.4.3. Initial Design Criteria

Background Research

In conclusion to this chapter, there are several design considerations to address and with consideration to the literature review, review of existing systems and Duncan (2016) design criteria.

The physical exergame controller has two areas of importance; functionality and contextuality. These two areas consist of sub-categories that are broken down into the key headings. Functionality encompasses the use of the game controller to facilitate the different components of STT. Contextual aspects focus on the ergonomics, usability and the aesthetics of the overall gaming system. This aspect is exceptionally large and would include the design of the shoes, splint, weight attachments and charging dock for the user.

The following design considerations are an updated design criteria that were influenced by literature and Duncan (2016 p. 20).

Functional Considerations

- The controller should be able to allow the user to shift the weight placement around the foot
- The controller should be on both lower limbs in order prevent pelvic distortion
- The splint should support user with drop foot and not interfere with the priming exercises

Contextual Considerations

Ergonomics/ Usability

- The controller should not have any protruding parts to injury to the user
- The splint on the controller should be comfortable yet provide sufficient support

Aesthetic

- The design should not resemble a medical device
- The aesthetic should enhance the structure of the shoe
- The aesthetic should look like a lifestyle product

05

Methods

5. Methods

Methods

The aim of this research is to design a wearable game controller as part of an exergaming system that is able to facilitate unsupervised STT. This research will inform the different required functions of the controller which is needed to reciprocate the strength training away from clinical supervision. It will acknowledge the ergonomics, usability and concerns associated with using a medical device at home. The prior research done with Duncan (2016) has provided insights into the initial design criteria of the lower limb game controller. This information provides a new foundation on which to base the next level of iterative prototype exergame controller which addresses the issues of the first prototype and other added features. The final outcome will be a second iterated interactive and aesthetically considered prototype to facilitate STT rehabilitation at home.

5.1. Research Overview

Methods

Research Question

How can a lower-limb rehabilitation exergaming system assist stroke patients with independent Strength for Task Training (STT) rehabilitation?

Hypothesis

A UCD game controller as part of an exergame system would help facilitate unsupervised strength for task training in a domestic environment.

Aims and objectives

Aims	Objectives	Methods
1. Define the user requirements for a system to facilitate lower limb strength for task training rehabilitation through daily activities.	a. Investigate user requirements based on patients' views on rehabilitation .	• Semi-structured interviews
	b. Investigate user requirements based on clinicians views on rehabilitation	• Semi-structured interviews • Expert reviews
2. To iteratively design a game controller for lower limb to facilitate everyday use by patients	a. Assess a number of initial viable concepts	• Human centred design • Expert reviews with clinicians
	b. Iterate game controller through user testing	• Iterative design • User testing with stroke patients: System Usability Scale, • Thinking Out Loud • Semi structured interviews • Expert reviews by clinicians
	c. Produce and test final design	• Iterative design • User testing with stroke patients: System Usability Scale • Thinking Out Loud • Semi structured interviews with stroke patients • Expert reviews by clinicians

Figure 5.1 - Breakdown of aims and objectives of this research.

In order to achieve a functional end product, this research project will be continuously iterated through user testing. Iterations would allow for fine tuning of the design to suit the different users.

5.2. Semi-Structured Interviews

Methods

Semi-structured interviews are commonly practiced form of gaining feedback from users or experts. These papers have used semi-structured interviews to gain a greater understanding of the problem that might only be revealed when conversing with interviewees (Wood, 1997; Zimmerman, Forlizzi, & Evenson, 2007; Galna et al., 2014). The semi-structured interview will be conducted with both clinicians and users. The interviews with clinicians are to obtain expert feedback about the function, usability and details such as post-stroke disabilities. Interviews with users were to get the responses about how the product feels, the usability, ergonomics and aesthetics of the product.

5.3. User-centered Design (UCD) Research

Methods

The use of a user-centred design (UCD) approach has been suggested by several papers as it is a reflection of the patient's involvement with the devices and has been tested meticulously when developing previous exergaming systems (Billis et al., 2011; Alankus, Lazar, May, & Kelleher, 2010; Burke et al., 2009). These papers used a UCD approach involving clinicians and patients during the design process. This research method is an important tool in designing an exergame system for stroke survivors whose adherence to the system is crucial for improving the recovery rate.

The UCD approach has three stages as described by Shirzad et al (2015). These three stages are:

- Understanding contextual and functional needs.
- Generating feasible concepts and prototypes.
- Development of solutions and clinical assessment.

These stages will be utilized throughout this research. The first stage of the research consists of literature reviews, observation sessions and discussions with experts. This would then provide a background understanding of what needs to be in the design. The next stage would be generating a number of concepts and prototypes, with constant feedback from clinicians to ensure that the concepts can be used by survivors of stroke. Finally, the concepts would be narrowed down and finalized before clinical assessment; where users would provide first hand feedback regarding the function, usability, ergonomics and aesthetics of the product.

5.4. Research through Design

Methods

Apart from employing UCD, research through design was used to understand how the function of the design could influence its form. This could also be used to analyse past designs and further iterate the design to enhance its functionality or form. This method and combining results from semi-structured interviews can help guide future iterations (Zimmerman, Forlizzi, & Evenson, 2007; Jaspers, 2009; Gaver, 2012; Zimmerman, Stolterman, & Forlizzi, 2010; Rodriguez Ramirez, 2017).

Iterative design was crucial to this research because the physical controller needed to be ergonomically designed for stroke survivors. Post-stroke disabilities varied among the participants and designing something that could be used by a majority audience required a process of trial and error. Over the course of this research, iterative designs would involve physiotherapists and users providing feedbacks regarding function, usability and ergonomics and aesthetics.

5.4.1. Recruitment

Methods

Prior to user testing, an inclusion and exclusion criteria were been used to filter out the right participants to take part in this research. The recruitment of participants was performed with the help a private stroke clinic. Upon finalising the participants for user testing, an initial user selection criteria were used. The selection criteria is as follows:

Inclusion Criteria:

- Over the age of 18.
- Had experienced a stroke which impairs walking.
- Able to walk without standby assistance.

Exclusion Criteria:

- Significant cognitive deficit in the opinion of the screening physiotherapist.
- Unable to comprehend one step verbal commands.
- Unable to give informed consent.
- Medically unsuitable in the opinion of physiotherapists, general practitioners or medical specialist.
- Experience excessive joint pain.
- Other conditions which could influence the results such as e.g substance abuse, significant mental illness (e.g. major depression).

5.5. Usability Assessment (SUS Scale)

Methods

The prototypes then underwent user testing, in order to understand what did and did not work for the users. The participants filled out a System Usability Scale (SUS). SUS is a ten question overview of the product in question. It utilizes the Likert 5-point scale which ranges from agreement to disagreement.

Apart from the SUS scale, comfort was another key factor because stroke users have low or no sensation on their feet. Thus it was critical to know if there were any areas which would cause further harm to them.

5.6. Description of testing sessions

Methods

Initial observation and expert review by clinicians were held in Auckland. The observation session provided insights into what a typical rehabilitation session entailed. Because the session was conducted with actual patients, a fly on the wall observation method was applied to reduce complications between patients and observers.

After the observation session, experts provided feedback about early ideas that were presented by the researchers and discussed what happened during the physiotherapy session. This discussion session was conducted through expert review.

The second expert review by clinicians involved clinicians from AUT coming to Wellington and providing feedback about the different initial concepts and low fidelity prototypes that were developed after the first discussion session.

The final discussion with experts was to ensure that the system was ready for user testing. The prototypes that were shown to the experts were high fidelity to allow the experts to interact with the product before providing feedback. The session was conducted with six experts at a table openly exchanging ideas and concerns.

The first usability testing with actual users with stroke was to test the design of the system. The test was held in a test room in AUT. The system has been through countless iterations and this iteration for testing is the sum of all the feedback and concern from experts. The system was tested using naive testing at the start and ended with semi-structured interviews with the user.

The last user testing was conducted in the same place as the first test session. The prototypes in this test were developed with feedback from the users in the first test session. The test started with naive testing again and finished with semi-structured interviews of the overall system.

06

Design Phase I (Initial Design research)

6. Design Research

Design Phase 1

In order to begin drafting concepts, user requirements need to be understood and this is done through discussion with clinicians. The design research began with the physiotherapist's point of view and what they have experienced during a clinical rehabilitation and what their patients have experienced. An observation session of the patients contributed critical clues that the physiotherapists might have missed. This information and a breakdown of Duncan's (2016) foundation research were combined to construct the initial design criteria.

6.1. Observation Session

Design Phase 1

The observation session visited was a rehabilitation clinic. The particular class mainly consisted of senior citizens who have Parkinson's disease and are trying to keep active by continuously exercising specific movements to keep the neural pathways functioning well. The session was attended by approximately eight patients and the session lasted for about 45 minutes. The session was solely observational. The head physiotherapist split the observation group into two with help from her research colleague, and explained the following;

1. The class was also a social environment in which participants could interact with one another.
2. Activities which were carried out in the session were meaningful and related to ADLs.
3. Activities were constantly altered slightly to suit different participants; challenging the participants.
4. Physiotherapists were always next to the participant; either aiding or talking to them (this was to get the participants used to multitasking).
5. Music was played to keep the momentum going.
6. Classes consisted of high intensity and repetitions of different tasks.

During the observation session, the following was also observed;

1. Participants were not wearing proper footwear (boat shoes, dress shoes, etc).
2. Participants were motivating each other, challenging each other.
3. The whole session was light-hearted and enjoyable.

6.1.1. Clinician Overview

Design Phase 1

An initial discussion session was carried out with clinicians in the neurorehabilitation therapy research facility at a university. The three-hour discussion was attended by a group of seven experts which consisted of: stroke clinicians, physiotherapists, occupational therapists, and research officers.

The session began with a presentation of proposed ideas as to how to address problems in the initial prototype by Duncan (2016) and retraining of stroke survivor's balance. The feedback focused on improvements on previous designs and proposed features; the criteria of the whole system based on the literature review; Duncan's (2016) work; and an additional balance retraining component. The idea was inspired by Nike's experiments in natural motion at Milano Design week 2016 (figure 6.1). The discussion provided insight into what the physiotherapists were facing and the problems experienced by their patients.

After the presentation, there was an open discussion among the experts to collectively consolidate all the comments and questions. The session provided various points of view from different therapists and what did or did not motivate their patients as well as emphasising the uniqueness of each patient's situation.

Figure 6.1 - Nike's experiments in natural motion.

6.2. Reality of clinical rehabilitation

Design Phase 1

The ideal clinical rehabilitation would be to constantly keep the patient moving and exercising. However, after deconstructing a typical clinical rehabilitation session, it is only about one hour a day due to fatigue. This session is broken down into about 27 minutes of training, 9 minutes of conversation and 23 minutes of rest (Duncan, 2016). Thus in total, the patient only gets about 30 minutes of training a day, which is extremely low for what is recommended in several papers (Shirzad et al., 2016; Lohse, Shirzad, Verster, Hodges, & Van der Loos, 2013; Lang et al., 2009). These papers have recommended that the patients need thousands of repetitions in order for the brain to begin reorganizing itself.

Duncan (2016) has stated that despite all the literature suggesting that repetitions need to be in the thousands, it has been found that 400 repetitions are enough to see clinical results. Even though 400 repetitions are less than half the specified amount, in reality, patients are only practicing as many as 30 repetitions per session (Lang et al., 2009).

In relation to the high number of repetitions per session, the intensity is also lacking due to the number of patients each physiotherapist is attending to. The ratio of patients outnumbers physiotherapists reducing the amount of time and attention between physiotherapist and patient and therefore also reducing the amount of time each patient has to practice.

This reduced amount of interaction will continue to decrease as strokes are becoming more extensive in the first world population and there is a shortage of physiotherapists. Employing the help of rehabilitation technology can help to bridge this imbalance of supply and demand. The use of rehabilitation technology should also enhance the communication between patient and clinician.

6.2.1. Assessment of post stroke impairment

Design Phase 1

The rate of recovery of a stroke patient depends on the early onset of intensive lower limb rehabilitation. However, there must also be an assessment in order to determine what kind of exercise regime is appropriate as the objective of rehabilitation is to provide the support needed for the patient to recover to a point which they can move their affected limb as well as they can move their unaffected side (Alankus, Lazar, May, & Kelleher, 2010). According to Duncan (2016), achieving this end result requires sufficient stimulation of the patient's healthy neural connections. This stimulates the regrowth of the neural pathways around the affected region, rebuilding damaged neurons or utilizing unused neurons and neural plasticity can still take effect months or even years after the incident. (Kleim, 2011)

Providing appropriate rehabilitation is the key to giving the patient a fulfilling recovery process. Thus assessing the patient is the first step to assigning the right rehabilitation exercises and technology.

6.3. Selected Technology

Design Phase 1

In the literature review, many studies have talked about using different modern technology such as Microsoft Kinect; the Wii balance board; Wii remote and IMU; and desktop. The adoption of console technology has been largely adapted to accommodate rehabilitation task training due to its affordability and gentle learning curve. However, console controllers have vague movement tracking and are confined to the area where they are set up (Duncan, 2016). Thus, in the previous research done by Duncan (2016), a combination of an IMU and iPad was chosen as their choice of intervention. According to Duncan (2016), this was chosen because of its portability and the high level of accurate tracking and patient customisation.

In this updated research, the iPad will be swapped for a Lenovo Phab 2 Pro. This technology was chosen by Regan Petrie, a research partner in this thesis, because of its potential to fully immerse the user in the game. The Lenovo Phab 2 Pro main feature is its advanced Augmented Reality (AR) feature. This allowed the device to track different objects in the room and create an immersive environment. Another reason was that the device is portable allowing the user to move around a room and potentially outdoors as they progress through their rehabilitation programme.

The inertia movement unit is a low-cost sensor that can be attached to a limb in order to track movement, acceleration and rotation. A company, I Measure U (IMU), has incorporated this sensor with a low energy Bluetooth technology to provide live feedback of limb movement. This allows the sensor to be connected to any device with a Bluetooth function.

Figure 6.2 - AR capabilities of the Lenovo Phab 2.

6.3. Reality of clinical rehabilitation

Design Phase 1

Technology	Good points	Bad points
Microsoft Kinect	• Commercial User interface • Body tracking does not require wearable sensors • Large variety of games	• Designated spot in the room • Poor tracking when in low light • Tracking is not very accurate • Confined within an area • Requires unobstructed view between user and cameras
Playstation Eyetoy	• Commercial User interface • Body tracking does not require wearable sensors	• Designated spot in the room • Poor tracking when in low light • Tracking is not very accurate • Confined within an area • Requires unobstructed view between user and cameras
Wii (Wiimote and/or balance board)	• Commercial User interface • Accurate tracking when holding Wiimotes • Large variety of exercise games	• Designated spot in the room • Multiple Wiimotes needed to track different parts of the limbs • Confined within an area
Desktop/Laptop gaming	• Available at low cost • Large variety of games	• Designated spot in the room • Confined within an area
iPad Gaming	• Portability • User friendly • Commodity	• Too big to be held on to • Interactivity on a 2D screen
Lenovo Phab 2	• Added sensors inside the tablet • Customisable in game environment • Portability • Immersive	• Heavy to hold over long periods • Camera and sensors cannot be obstructed • Technology is new which may still contain software bugs

Figure 6.3 - Comparison chart of current exergame capable technology.

6.4. Defining Intervention

Design Phase 1

Stroke rehabilitation is not a general training routine, it must be customised to each patient. Modern home-based rehabilitation training follows a set of guidelines to give the patient the best outcome. Thus several factors facilitate a smooth transition between the home and clinic.

- Specific: This factor caters towards the patients and the training regime must be designed with the patient in mind. The PT needs to understand the patient's context alongside any other additional impairments such as cognitive or physiological factors.
- Salient: Following specific training, the PT also needs to consider tasks; especially tasks that can help or improve the patient's activities of daily living (ADLs). This would make the rehabilitation task more meaningful (Flores et al. 2008).
- Repetitious: Practicing a task repeatedly will help to improve the outcome of the rehabilitation session. (Alankus, Lazar, May, & Kelleher, 2010).
- Intensive: Constantly challenging the patient to prevent stagnating.

6.5. Final Design Criteria

Design Phase 1

The final design criteria will be constructed from a consolidation of the readings and deconstructions of the literature reviews and clinician feedback about previous designs by Duncan (2016, p. 37). The readings provided general design criteria in which to add or remove some of Duncan's initial design criteria. The feedback from the clinicians and Duncan's feedback will help to narrow down the design criteria further.

The initial design criteria presented by Duncan (2016) provided a quick summary of the criteria of the final design. However, after discussion with clinicians and Duncan, several design criteria have been edited.

The design criteria are broken down into several subcategories: Function, Ergonomics and Usability; and Aesthetics. The following points covered are the criteria that have been updated from the original design criteria.

Function

Facilitating STT: the purpose of the gamer controller is to help to translate the user's movements in the real world environment into the virtual environment. This game controller also has to be able to accurately track the minute movements of the user in order to map and compare against the past records and target records. The controller must also be able to cope with the weighted sole attachment which helps prime the user for task training and also easy removal for a quick transition to task training.

The design should allow the user to interact freely with the game:

- It should cater to both priming and task training.
- It should not hinder the user's movement.
- Different components of the shoe allow for quick removal.

Adaptable: The exergame controller must be able to adapt to different users of various ability and recovery stages. This would help encourage the user to continue to use the product:

- Allows for weight adjustment for different users.

Affordability: The cost of the whole system should be kept to a minimum in order to accommodate everyone who needs it. The growing number of survivors and the low number of physiotherapists, gives rise to the option of having a home-based system which can provide rehabilitation exercises:

- The system should cost about the same as a commercial console game.

Accuracy: Feedback is critical to provide the user with precise limb movement and track progress over time. This will not only encourage the user further but also prevent habituation of the wrong movements:

- Lower limb tracking must be accurate to provide correct feedback to users.

User friendly: Given the users are above the age of 50, the system mechanics should easy to grasp and comprehend. Thus allowing the user to independently operate the system:

- The system should be intuitive and easy to maintain, troubleshoot and setup.

Portability: The portability of the system allows the user to exercise in a space which they feel most comfortable in. Portability also means that the system can incorporate another level of engagement such as AR:

- The system should be portable to allow the user to move around and exercise where they feel most comfortable.

Ergonomics/ Usability

The ergonomics and usability for older adults will be guided by Kroemer (2005). He created a general design overview for designing for the elderly and designing assistive technology.

Post stroke cognitive, visual and motor deficits: Post stroke users will most certainly have an impairment which would inhibit normal actions. Thus it is critical for the system to incorporate basic and intuitive actions that require minimal operational steps:

- The system must be able to be worn with one hand.
- The user should be able to wear the product with minimal complications.
- The product should be easy to maintain.

Post stroke physical changes: Changes to the human body as it gets older is inevitable but this is especially so with post-stroke users as they might experience such things as numb feet, thin skin, sensitive skin or swollen feet.

- The design should be comfortable in terms of aspects such as breathability or no pinch points.
- The design should not have sharp edges that can cut their skin

Aesthetics

Aesthetics should be intuitive: The aesthetic should guide the user to understand how the product is used:

- The design of the product should be intuitive to operate.

Addressing stigma associated with medical products: The design should not portray the outlook of a medical device. The product should be designed to be used in the home and not in a hospital. The aesthetic of the product will be viewed by others and if it does not look like a medical device, there will be no association between the user and a disability or being unwell in some way:

- The design should look like a lifestyle product.
- The design should give the user confidence to use everywhere.

Overall, the whole system should be designed holistically with the user in mind. It should give them a sense of confidence and fulfilment when being used. The product should also function as it is meant to and in this case it has to be stable and safe for the user while in use.

These criteria formed a baseline of what the product should be like over the design process. The baseline, together with the feedback from the physiotherapists allowed for rapid concept generation and prototyping. Once an idea was chosen, the concept iterations would be put presented to the physiotherapists again and participants. The final concept would be the result of expert reviews and two participant testing sessions.

07

Design Phase 2 (Initial Design Concepts)

7. Initial Design Concepts

Design Phase 2

Once the initial design criteria had been drafted; the original design concepts could be generated. Expert reviews were required by the clinicians before recruitment of the participants and ethics only permits recruitment of participants through clinicians. Therefore, the designs needed to be approved by clinicians before recruitment.

These iterations were critical to working out the fundamental problems such as materials, design possibilities and fastening methods through low fidelity prototypes. After the primary issues had been addressed, the concept moved to high fidelity prototypes which physiotherapists would manipulate and interact with to figure out the details such as user interaction and problems in the designs.

7.1 Duncan's previous work

Design Phase 2

Initial design concepts were based on prior research by Duncan (2016) and early feedback from stroke clinicians and physiotherapists. These designs were trying to solve and improve some of the issues in Duncan's initial design.

Duncan (2016), "Indee Rehabilitation System" consists of smart footwear, a weighted sole, a removable IMU sensor and a charging dock. The intent of the system was to allow users to exercise at home without supervision. The design had several key features:

- The whole system is portable and allowed the user to exercise anywhere in the house.
- The shoe and weight sole was easy to put on and remove.
- The material chosen provided enough support and breathability for the user.
- Aesthetics were pleasing.

However, revising his design and through an expert review with physiotherapists about the system, there were some suggestions for further development such as;

- Several protruding points on the weighted sole.
- The weighted sole was bulky.
- First impression was intimidating.
- Uneven height when weighted sole is worn.
- Only two components of STT were addressed.

7.1.1. Overview of new system

This thesis is looking to improve on the suggestions and to add additional features to training session for the user. Thus in this new system, there are several components; a pair of shoes, a weighted sleeve, IMU sensor and one new component balance sole.

This new system also intents to achieve several criteria such as;

- Streamline the overall form
- Reduce the bulkiness of the overall form
- Redesign the weighted sole to accommodate even weight distribution
- Address more than two STT components

There are several criteria chosen when designing the shoes. The shoes should have:

- A wide opening
- High ankle support
- Easy to put on
- Large straps
- Additional straps on the front of the shoe

The shoe and weighted sole are being reworked in order to address several issues addressed by the physiotherapists and users in Duncan (2016).

This new system also intents to achieve several criteria such as;

- Streamline the overall form
- Reduce the bulkiness of the overall form
- Redesign the weighted sole to accommodate even weight distribution
- Address more than two STT components

The weighted sole have a set of design criteria as well.

- Streamlined; no protruding points
- Easy to put on and remove
- Able to hold a maximum of 5 kg

The two new components in this setup are a balance sole and an AFO. These components are to add value to the user's rehabilitation experience.

The purpose of the balance sole was to constantly challenge the user's balance. This idea was derived from watching patients exercising on a foam balance beam during a clinical rehabilitation session and Nike's natural motion experiments (figure 6.1). Signal's (2014 p. 55) task progression sheet also supported the incorporation of a balance sole as it stated several different progression levels for patients at different stages.

The AFO was added in order to support drop foot and to expand to a larger group of target users. The concept of AFO is to redesign the traditional designs and incorporate more aesthetics into the design. Incorporating the AFO within the shoe aims to reduce the stigma that is associated with medical devices (Vaes, Stappers, & Vereniging voor Studie- en Studentenbelangen (Delft), 2014).

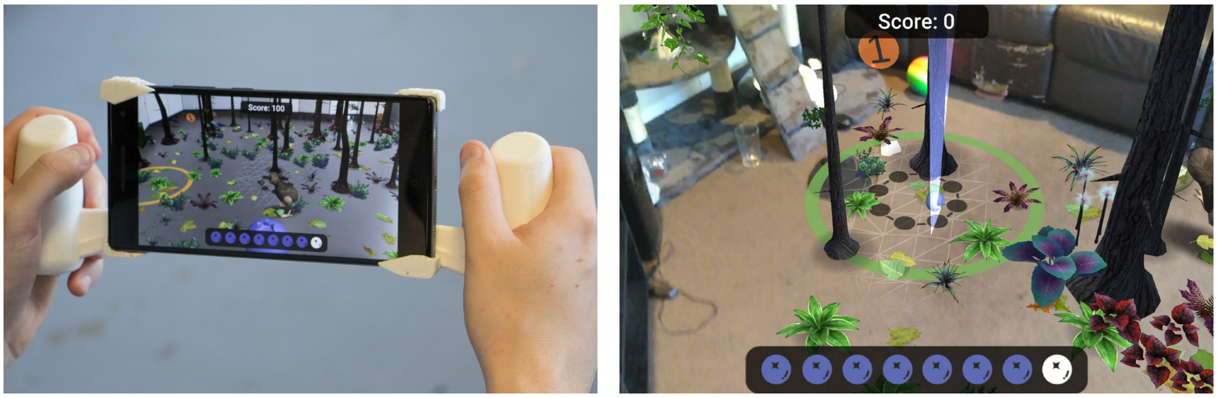


Figure 7.1 - Petrie's AR game, NZ Fauna.

The system would also have a game component and this would be designed by Petrie, a fellow research partner. His game utilises the AR technology in the Lenovo Tango Phab 2 phone. The objective of his game is to facilitate sit to stand task and walking exercises by offering immersive interactions with digital exotic wildlife. The game is able to track the user's progress with the in-built sensors in the phone and as the user's recovery progresses, the game can adapt to increase difficulty and keep the user engaged in the experience.

7.2. Expert Review 1: Clinician feedback on previous work

Design Phase 2

We carried out an expert review to help assess the precedent work by Duncan (2016) and initial design concepts of the new system with a Physiotherapist (PT) and an Occupational Therapist (OT) in Wellington. The PT has five years experience in the private practice as a rehabilitation therapist and the OT has over 18 years of professional clinical and private work both locally and internationally.

A PT and an OT were chosen because they cater to different parts of rehabilitation. The PT focuses on retraining the patient's gross movements such as walking and physical abilities and the OT focuses on the fine motor skills and activities of daily living (ADLs).

7.3. Expert Review 2: Clinician feedback on design phase 1

Design Phase 2

The team of PT, OT and researchers that were consulted consists of professional physiotherapists and occupational therapists and between them at least 20 over years of experience with stroke patients in the private and public sector. They are also specialised in lower limb rehabilitation which makes their comments and suggestion more valuable.

7.3.1. Low Fidelity Prototype

Design Phase 2

The objective of expert review 1 was to gain expert feedback on the initial design concepts. Session 1 was attended by two physiotherapists and the concepts were presented to them through sketches and physical proof of concepts. The low fidelity prototypes provided the physiotherapist hands-on interaction with materials and mechanism.

The two-hour session started with presentations of proposed ideas based on the feedback from both expert discussion and expert review session

7.3.1. Low Fidelity Prototype

Design Phase 2

Shoes

Figure 7.2 - Initial concepts of the shoes. These shoes are designed with a large opening and also provide ankle support. (More iterations on p. 129)

During this discussion session, the physiotherapists were agreeable that the initial shoe concepts (p. 129) were sufficient for the users with stroke. The large openings and high ankle support would be beneficial for the user. Another criterion was to ensure that the concepts allowed users to unstrap the shoes with one hand.

7.3.1. Low Fidelity Prototype

Design Phase 2

Splints

Figure 7.3 - Initial concepts of the AFO. AFO were designed to integrate with the shoes and reduce its emphasis.

However, they recommended that the design of the AFO would not be feasible. The reason being that drop foot can either be high tone (forced foot) or low tone (flaccid foot) and high tone foot will exert large amounts of force on the AFO. The concept AFO had no lever arm, the force acting on that user's calf or lower leg at any point would be too much. Therefore the concept AFO needed to be redesigned.

7.3.1. Low Fidelity Prototype

Design Phase 2

Embriodary patches

Figure 7.4 - Initial test swatches of embroidery patches.

The second concept was to incorporate embroidery patterns into the shoe in order to stiffen certain areas of the shoes to provide extra support. This would allow the fabric to conform to the user and yet provide support in key areas around the ankle and lower foot.

A two layered embroidery section is very stiff (bottom left hand corner) and this can be applied to stress points such as ankle bone or heel area. The amount of stretch and support can be designed according to different users.

The embroidery match consist of up to two layers because of the increased chance of tangling on the previous layer.

7.3.1. Low Fidelity Prototype

Design Phase 2

Balance soles

The incorporation of a balance sole concept was proposed to the experts. The aim of it was to challenge the user's balance as they go about their daily activities. Thus allowing them to carry out rehabilitation without dedicating a period of time to practice their balance and walking. The therapists also reiterated that the purpose of the balance should be fully defined as an assistive or rehabilitation device.

The balance sole concept was inspired by the Nike's natural motion experiment and observation of the physiotherapy session.

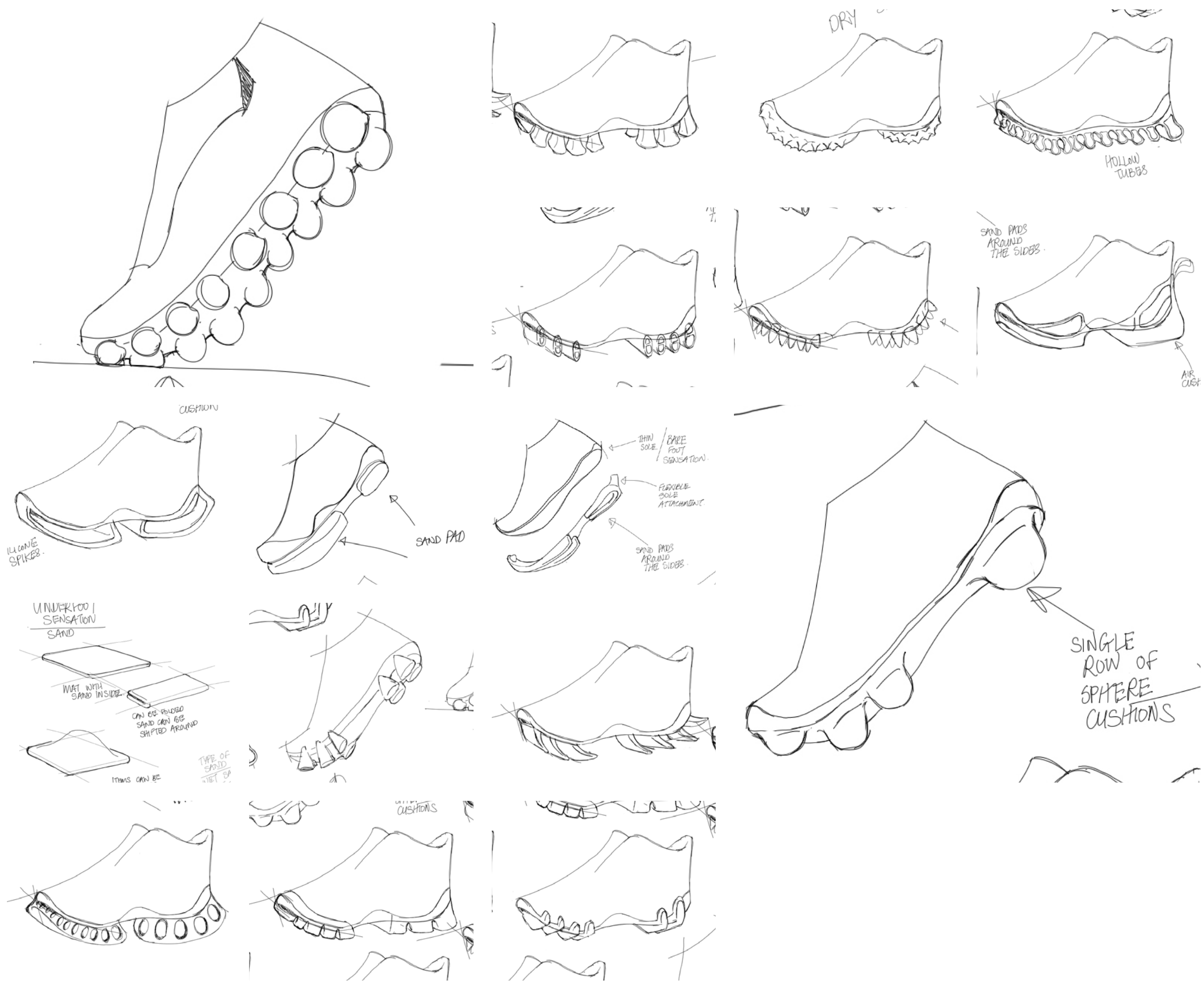


Figure 7.5 - The objective of the balance sole was to retrain the user's balance. The sole can be removed and worn when the user wants to train.

7.3.1. Low Fidelity Prototype

Design Phase 2

Balance soles

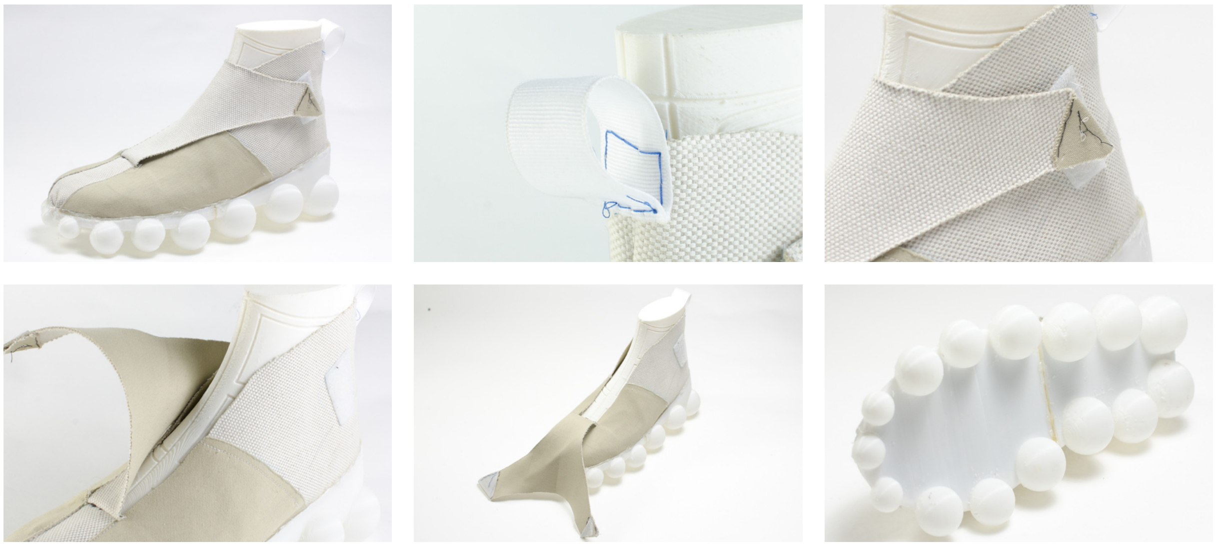


Figure 7.6 - First high fidelity prototype to convey the balance sole concept to experts.

This was the first high fidelity prototype was put together to provide the experts a visualisation of the new system and find out the good and bad points about the shoe. The material was a thick canvas material which was tough and heavy but it was breathable.

This prototype featured a large opening which allowed users to slide their foot in easily. The Velcro fastening points allows the shoe to be tighten with only one hand. The spheres around the sole of the shoe was the first iteration of the balance sole. In this prototype, the sole and shoe were permanently attached, reason being that it would allow the experts to try out the shoe and the sole together and provide feedback on it.

7.3.1. Low Fidelity Prototype

Design Phase 2

Wearable Sensors

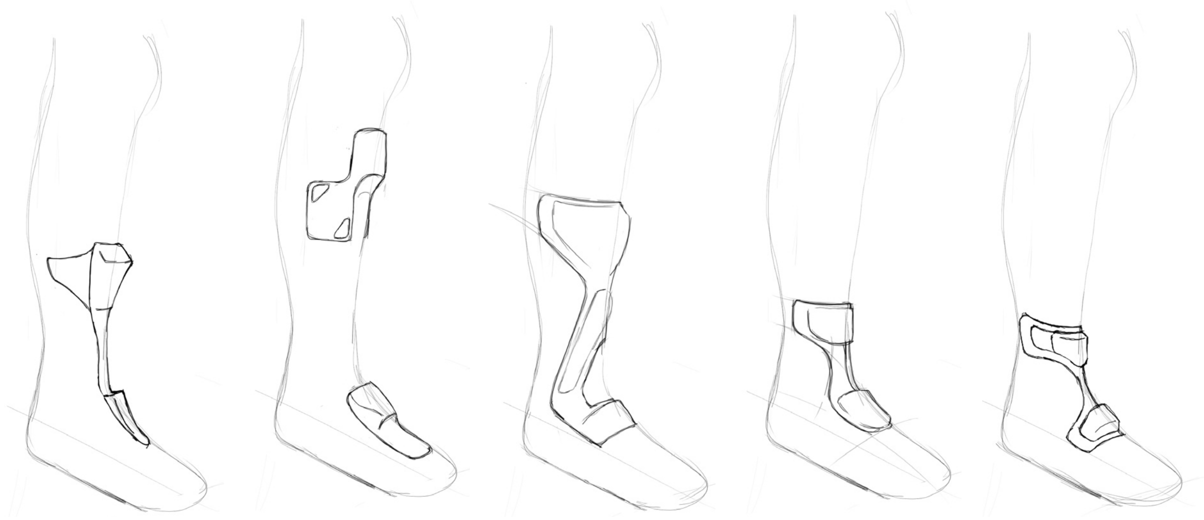


Figure 7.7 - These initial wearable sensor ideas were to designed to accommodate users at different recovery stages. In order to ensure that the user does not have to fuss over the placement of the sensors before every use, the sensor is designed to only fit in one section of the lower limb. (More iterations on p. 130.)

These initial concepts were shown to the experts and they explained that the wearable sensors should not have any sharp edges and should have enough ventilation to prevent users from getting skin irritation. Experts also suggested that the design of the sensors should be worn without complications such as accuracy of the sensor placement and difficult to attach.

7.3.2. Clinician Feedback

Design Phase 2

Overall the clinicians were interested in the potential that the system can offer for the users and the ability to carry out rehabilitation at home. The feedback given by the clinicians guided the final design criteria and was considered in the next stage of development. However, there was some critical feedback that influenced the overall concept such as the AFO. This was because the AFO needed to counteract the force applied by the foot and this force is different for each user. The experts also explained that the embroidery would not help because it is not rigid enough of hold the ankle in place.

Despite the AFO concept that needed change, the high ankle support and large opening of the shoes and the balance sole were key features that were continued throughout the research.

All the feedback given by the clinicians had guided the final design criteria and they were put into consideration in the next stage of development.

7.4. Expert Review 3: Clinician feedback on high fidelity prototypes

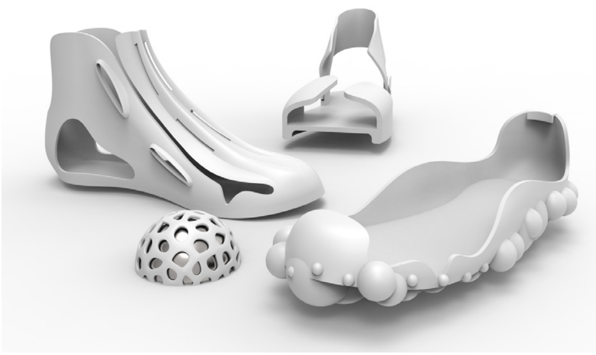
Design Phase 2

Expert Review Session 3 was attended by a larger group of seven experts which consisted of PT, OT and research officers. The session was a three hour session which was presented with high fidelity prototypes which the experts were able to interact with and provide first hand feedback on the concepts.

7.4.1. High Fidelity Prototypes

Design Phase 2

Between sessions 2 and 3, another concept which consisted of three options was created because of the size of the weights that needed to be attached to the weighted sole. These were the added options:



Option 1: Shoe, weighted sole, balance sole and charging dock

Option 2: Shoes, dorsiflexion weighted sole, balance soles, anchor and charging dock

Option 3: Shoe, balance sole and charging dock

Figure 7.8 - Three options that explored the different concepts for an STT system.

These options were deliberately designed to help streamline the overall form of the system. However, these options had to be put through the physiotherapists before any one of the options could be selected.

The options were laid out and explained to the physiotherapists at the meeting. The physiotherapists provided some feedback regarding the three options. The three options were broken down into its components and explained before discussing all components as a system. The feedback that was given was taken into consideration and would be factored into future iterations.

7.4.1. High Fidelity Prototype

Design Phase 2

The early prototypes of the shoes featured a fabric cover with a 3D printed thermoplastic polyurethane (TPU) sole. The shoe featured a large opening with Velcro straps to allow the user to slip their foot in with ease and the Velcro straps made it quick and easy to fasten.

Figure 7.8 - Three options that explored the different concepts for an STT system.

First Row: The initial TPU sole prints with embedded ankle support.
Second Row: Ribbing that were designed to increase stiffness around the ankle.

Figure 7.9 - Quick prototypes to understand the usability of the shoes.

First Row: Initial soft covering for the initial TPU soles.
Second Row: The various methods of a wide opening and fastening methods.

7.4.1. High Fidelity Prototype

Figure 7.10 - Concepts of an TPU shoe that allowed other components to be attached.

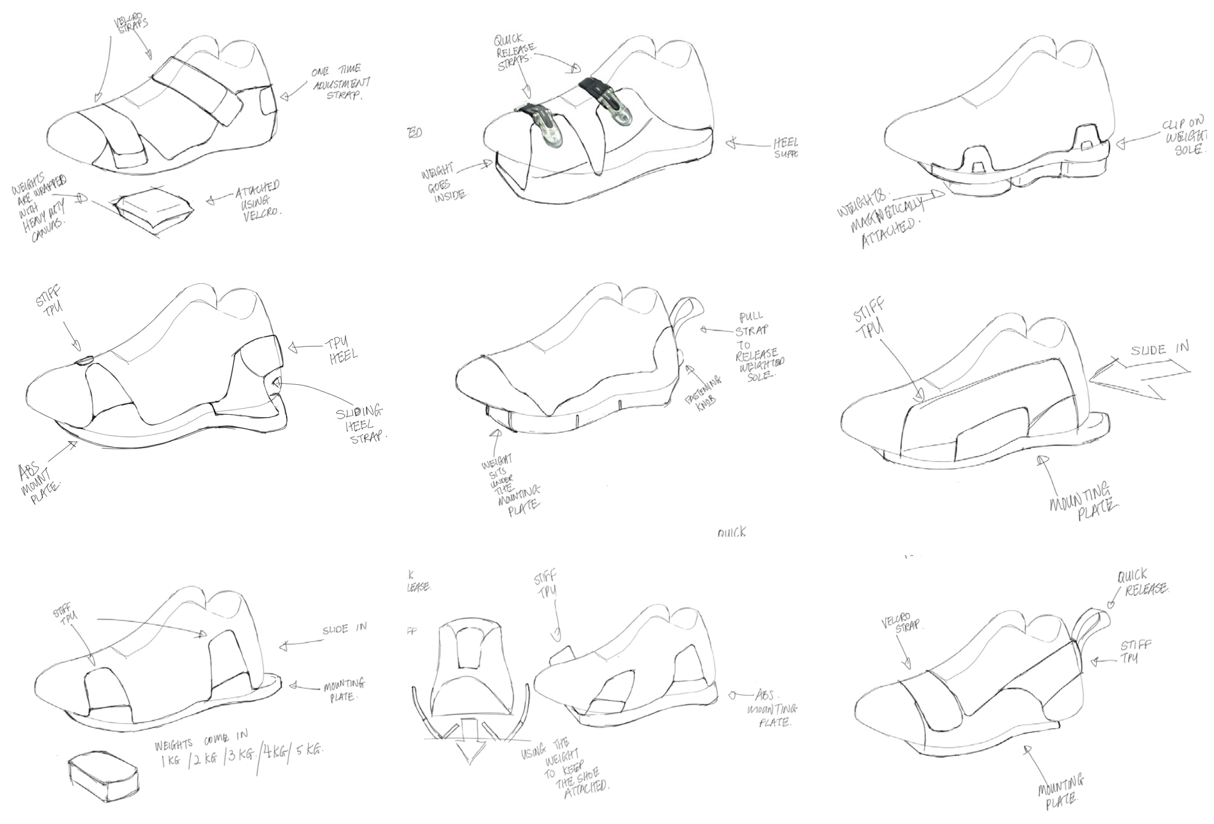
First column: TPU shoe without a tongue and designed with conventional Velcro straps
Second column: First prototype shoe that featured a wide opening and a Velcro strap that goes around the user's ankle.
Third column: Iterated of a TPU shoe which addressed the weakness in the strap holes and smoother transition of the stiffeners.

A second concept of the shoe featured a full TPU print. The concept main feature was a flexible and wide opening which the user could slide their foot into with a thick Velcro strap going around the ankle to provide ankle support. This concept also had a second Velcro strap that went over the midfoot to add extra support. There were also two stiffeners running along the shoe tongue which increased support for drop foot.

7.4.1. High Fidelity Prototype

Design Phase 2

Weighted Sole



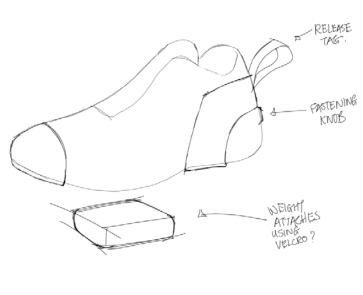


Figure 7.11 (this page) - Initial concepts of weighted sole design. These designs were designed to be worn with one hand or remove without any hands and the overall shape is streamlined to minimise injury on the user.

Figure 7.12 (opposite page) - Initial concepts of weighted sole design. These designs were designed to be worn with one hand or remove without any hands and the overall shape is streamlined to minimise injury on the user.

The second portion of the discussion session was about the weighted sole. This was a main problem of the previous design because of its bulk and users felt that it looked intimidating at first sight. In this reworked design, the aim was to look less bulky and holistically fit with the shoe. The redesign also involved redesigning the weight distribution.

7.4.1. High Fidelity Prototype

Design Phase 2

Weighted Soles

Figure 7.13 - Early ideas of weighted sole.

Prior to this expert review session 2, several concepts were chosen and worked on further. Several quick prototypes of the weighted sole and the shape of the weights were made to iron out any issues that were not feasible. The prototypes of the weighted sole proved to be a challenge due to a large amount of weight it has to carry in order to prime the user. Some changes had to be made, but all prototypes were explained to the physiotherapists.

7.4.1. High Fidelity Prototype

Design Phase 2

Weights

Figure 7.14 - The weights covered with various iterations of ABS covers. The patterns can be designed to be coherent with the gaming environment. Last photo is a TPU test print.

The weights were also redesigned to tie in with the balance soles, thus a hemisphere of steel was used as a concept and an outer cover was designed to simulate rocks or something heavy rather than just the raw steel finish.

All the concepts of weighted sole and weights were brought to the meeting and explained. The support structure of the weighted sole still posed a problem even after several attempts at trying to streamline it and appear less bulky. Velcro straps proved strong enough to hold up the weight of the new design.

7.4.1. High Fidelity Prototype

Design Phase 2

Balance Sole

The balance sole was then presented and feedback was given on its design. One expert suggested that "unpacking the principles of balance rehab might inform the design of your soles as well and what you are trying to achieve with the soles". Another expert added, "I mean each different sole can address a different problem". This balance sole was an addition to previous systems. The existing literature and the observation session had yielded results that balance was crucial to mobility. Initial balance sole concepts were a manual arrangement of the sphere along the spine of the sole. However, after further development, it was designed in such a way that the spheres could be done through an algorithm that allows the physiotherapist to arrange the spheres to a specific degree. The sole can also be designed with different infill to create different hardness (figure 7.17).

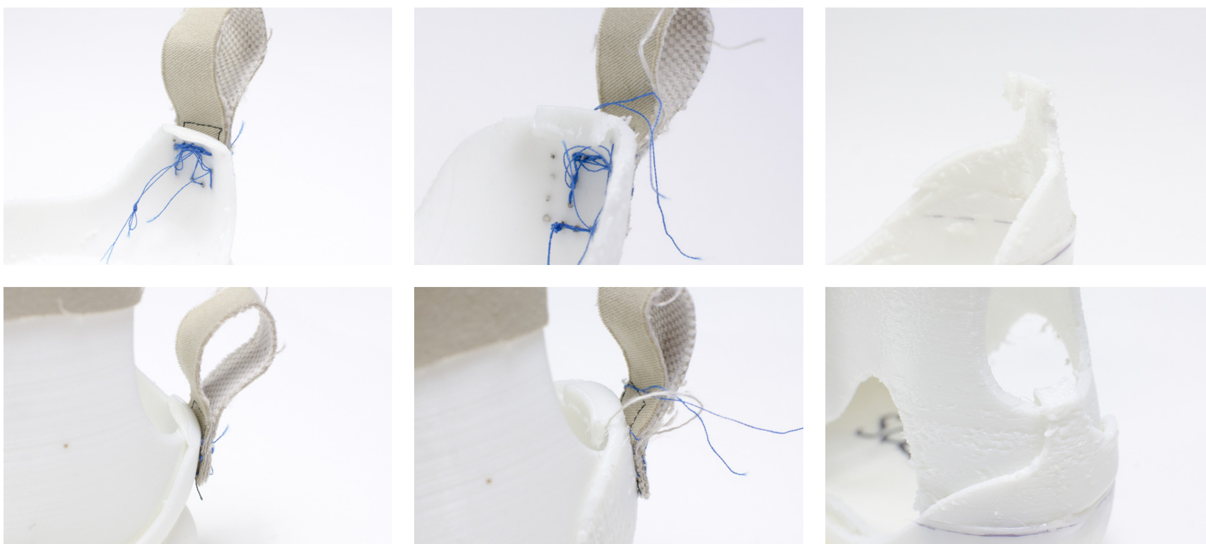


Figure 7.15 - Three early mechanism to enable the user to step into the sole and click on.

Left column: First iteration did not hold in place when test walking in the sole.
Middle column: Second iteration hooked on too tight and difficult to remove.
Right column: Third iteration was too flimsy and would not hold on tight enough.

7.4.1. High Fidelity Prototype

Design Phase 2

Balance Sole

Figure 7.16 - Initial balance sole prints as a proof of concept.

Top row: Initial balance soles which had spheres that were manually distributed.
Second row: The spheres were controlled to either magnify or reduce its appearance in the sole. This allows the sole be designed for different individuals. This arrangement was done through a grasshopper definition.

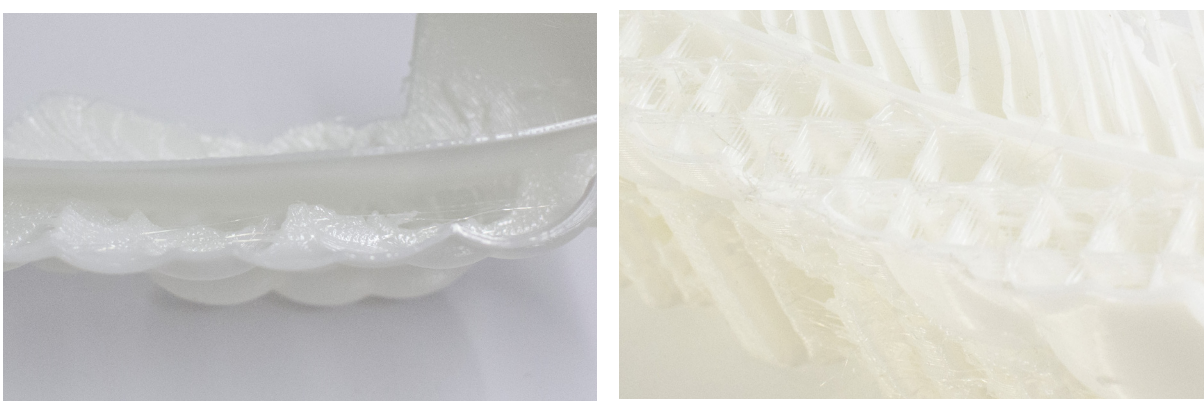


Figure 7.17 - Two different infill that affect the softness of the spheres.

Left: Zero infill in the sphere, this created a soft shell that deformed when stood on.
Right: 10% infill in the sphere, this created a harder surface and only deformed minimally when stood on.

7.4.1. High Fidelity Prototype

Design Phase 2

Lenovo Tango Phab2 holder

In addition to the shoe system, a holder was also developed in order to provide the user with a better grip of the device. The device holder was a two-handed controller which enabled users to stabilise the device and not block the rear sensors of the device. Another set of the controller was also designed to suit a user who has only use of one arm; the controller also featured an adjustable neck that allows the user to change the angle to their preference.

Figure 7.18 - Initial Phab 2 holder.

First prototype that was designed to prevent the user from blocking the cameras. The handles are interchangeable and are swapped for two hands or single hand controller.

7.4.2 Clinician Feedback

Design Phase 2

The feedback from this session of expert reviewing supported the original option of having a system consisting of shoes, balance sole and a weighted sleeve rather than the other two theraband options because a tethered limb could inhibit reactions of the supporting limbs and cause accidents.

These were some comments from the experts about the system: “This would be easier to get on”; “I can see this to be very appealing, the ease of getting it on and the nice big straps”; “The back entry to that is quite nice, like a slipper entry”; “it looks good though”.

The comments that the experts provided were analysed using thematic analysis and their comments helped to further iterate the next set of designs.

The PTs were excited about both concepts because of the large opening and the support provided by the shoes. However, they were more interested in the second concept for several reasons as the shoe provided enough support; was easy to put on; had large straps; might be good for low tone foot due to the stiffeners. The physiotherapists also mentioned that the tongue curvature was too narrow (PICTURE 1); the strap was too thin (PICTURE 2); the heel counter might need more height (PICTURE 3), and an AFO might still be needed in order to keep a high tone foot in the right position.

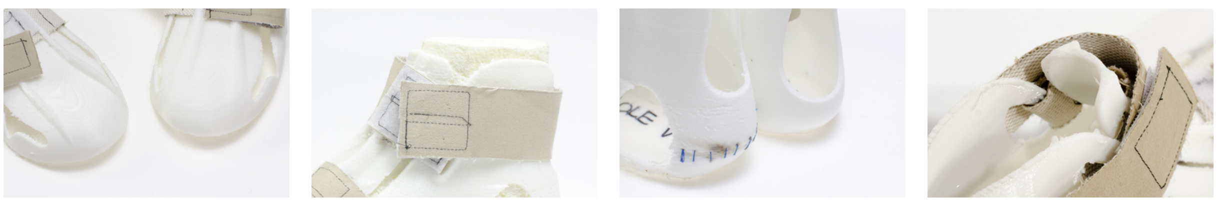


Figure 7.19 - Details that experts commented upon.

First Image: Blending the stiffeners to the shoe making it less abrupt and aggressive.
Second Image: Implementation of an ankle strap that wraps around the user’s ankle.
Third Image: Two iterations of heel counters. The height of the counters affected width of the opening
Fourth Image: The tongue curvature was too narrow and might hurt the user.

A physiotherapist suggested several ideas for the weighted sole; such as the weight could be lowered to 3 kg instead of 5 kg and the weights would not have to be placed underneath the foot but could be placed anywhere around the foot. It was suggested that it could be a wrap that goes around the shoe. These points were valuable to future iterations of the weighted sole.

Two physiotherapists were interested in the balance sole and provided insight into what balance is like for patients. They suggested that the balance sole would work better if the sole was soft rather than hard. This is because if the patient can rely on the sensation underneath their feet, they have to rely on other senses. They also said that the arrangement of the sphere does not matter as much as the density of the spheres, “It is harder (to balance) when the surface under the foot is unreliable. It is harder when it is soft.” Barbeau (2003, p.4) has also stated that locomotion cannot just rely on just practicing the motion, the patient also needs to rely on other sensory input to keep upright.

The physiotherapists also said that the game controller also enhanced the rehabilitation session because of the way patients were forced to square their shoulders to hold the controller and the controller was wide enough, making it comfortable to hold. Another point that they brought up was that the controller could help aid the affected arm by supporting it and mirroring what the unaffected arm was doing.

7.5. Further Iteration of high fidelity prototype

Design Phase 2

Weighted Sleeve

Subsequent to the expert review 3, the new concept of the weighted sole was changed to a weighted sleeve concept and the suggestion was to have the weights above the foot. This would not only mitigate the uneven height of the weighted sole but could also have the ability to withstand heavier weights.

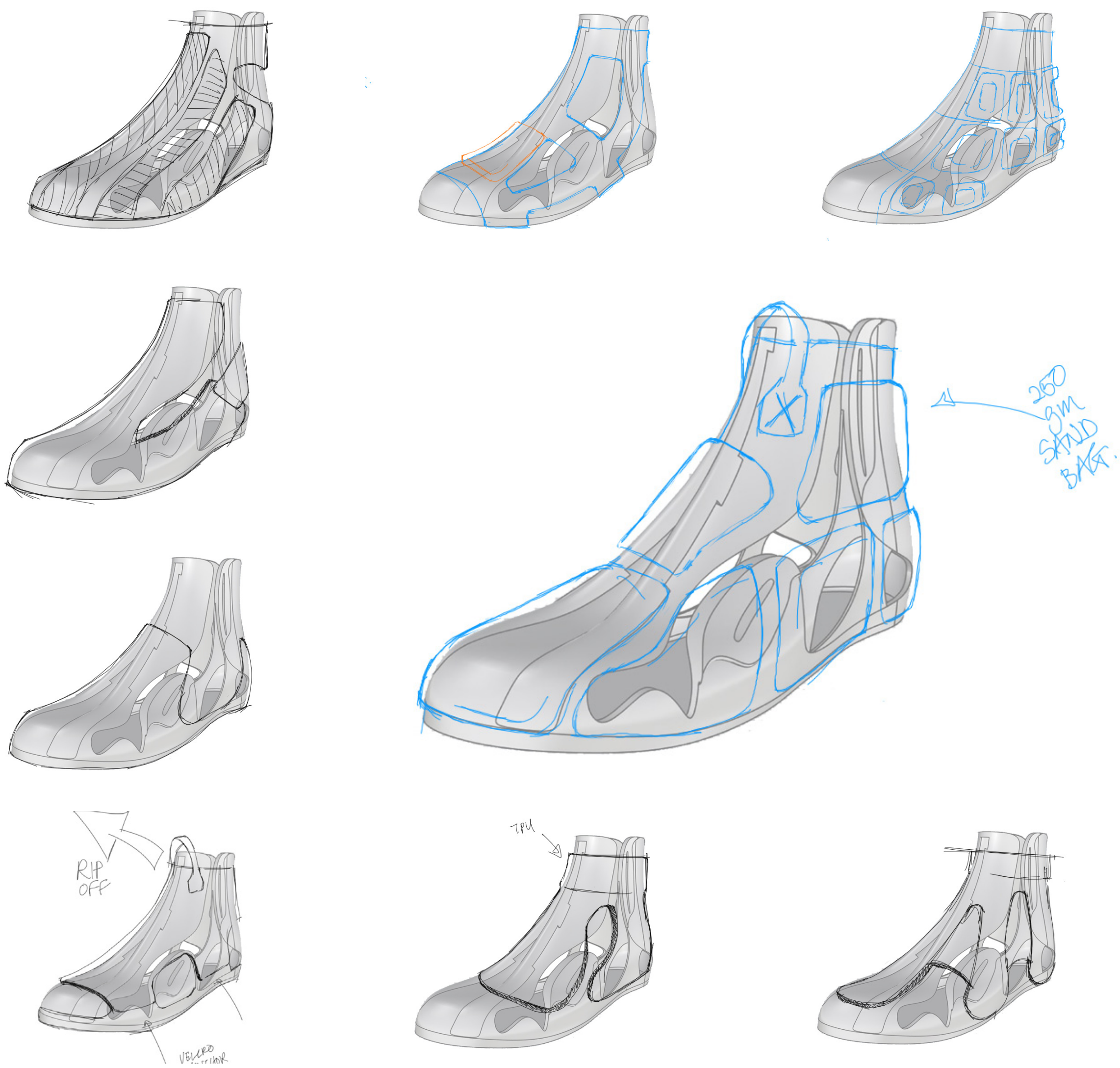


Figure 7.20 - Collection of sketches that considered a weighted sleeve that goes around the user's ankle.

These sketch iterations were based off the suggested given by experts. They were explaining that the top part of the foot is an used surface and the weights could sit over the top like an ankle weight.
(More iterations on p. 135)

7.5. Further Iteration of high fidelity prototype

Design Phase 2

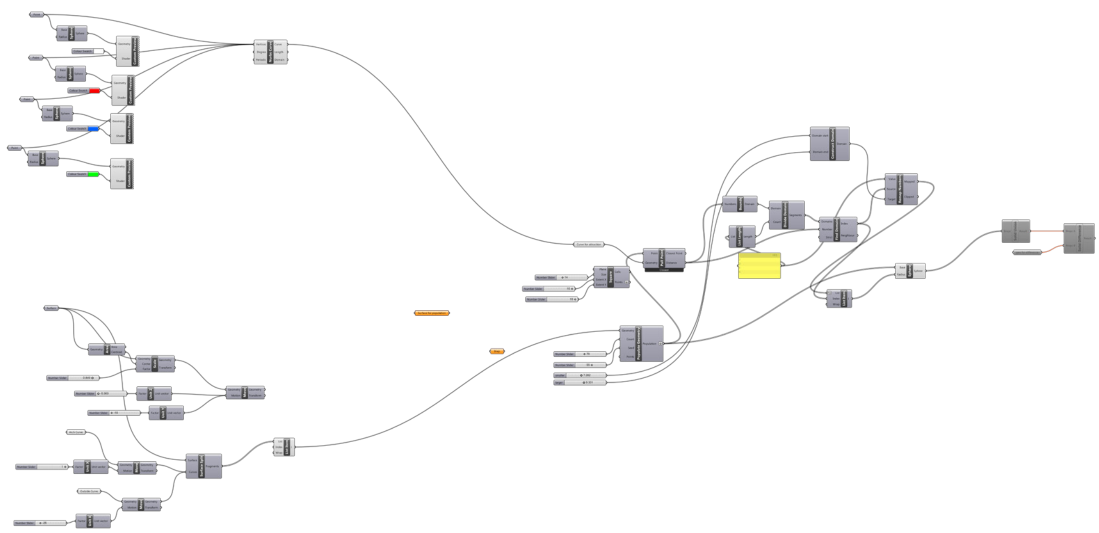


Figure 7.21 - Grasshopper definition to arrange the spheres.

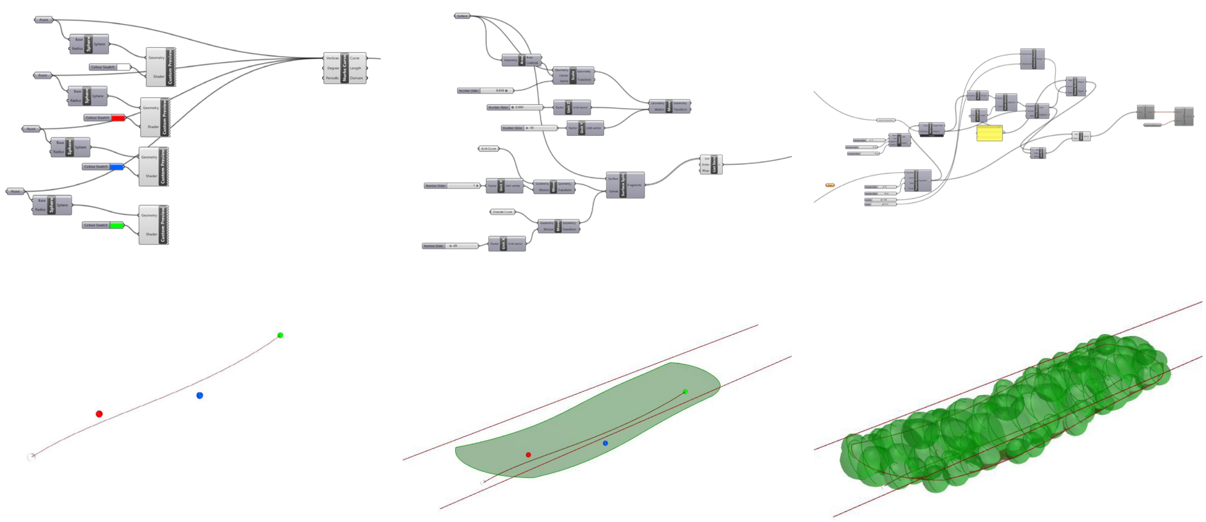


Figure 7.22 - Three parts of the grasshopper definition that creates the spheres.

Left column: An attractor line represents the balance line. Sphere will populate along this line. This line can be adjusted by dragging the colour dots around.

Center column: A surface which restricts the population area of the spheres. This surface can be adjusted using the trimming lines.

Right column: Spheres generation can be adjusted with the sliders to either expand or shrink the spheres.

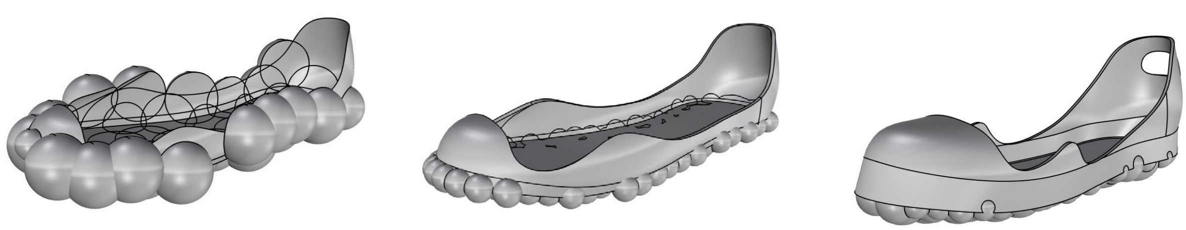


Figure 7.23 - Three models that have different restrictions applied.

Examples of different adjustments in the grasshopper definition. The spheres can be to be more prominent or subtle.

7.5. Further Iteration of high fidelity prototype

Design Phase 2

Balance Sole

Figure 7.24 - Collection of high fideilty balance sole prototypes.

The balance soles were also reiterated through the grasshopper definition in order to set some rules to control the population of spheres. The rules were the points generated would close to the attractor line (figure 7.22). This line can be adjusted to create more sphere in strategic places. The surface which spheres are populated can be altered to either increase or decrease population density. Finally, the spheres are trimmed and joined with the detachable sole.

7.5. Further Iteration of high fidelity prototype

AFO

Figure 7.25 - Iterations of various types of AFO. Designed according the feedback from experts.

More iterations on p. 136

The AFO design was changed based on the feedback from experts on the initial concepts. These iterated AFO designs were taller in order to spread out the force of the foot through a longer lever. The objective of the AFO was to clip on the outside of the shoes and work with the shoe to hold the foot up.

08

Design Phase III
(Testing and assessment)

8. Testing & Assessment

Design Phase 3

We tested the usability, comfort and aesthetic of the system using the following methods with participants: think aloud protocol, semi-structured interviews and System Usability System (SUS) ten-item scale.

User testing the exergame system involved the TPU prototype shoe, weighted sleeve, balance sole and Petrie's game. There were two user trials conducted over a period of 2 months. The findings from the first test influenced the future design iterations that we prototyped and assessed during the second testing session.

These tests were conducted in a university with a physiotherapy clinic. The participants were recruited through physiotherapists from a list of their clients based on the following inclusion and exclusion criteria.

8.1. Inclusion/ Exclusion Criteria

Design Phase 3

Inclusion Criteria

- Over the age of 18.
- Had experienced a stroke which impairs walking.
- Able to walk without standby assistance.

Exclusion Criteria

- Significant cognitive deficit in the opinion of the screening physiotherapist.
- Unable to comprehend one step verbal commands.
- Unable to give informed consent.
- Medically unsuitable in the opinion of physiotherapists, general practitioners or medical specialist.
- Experiences excessive joint pain.
- Other conditions which could influence the results such as substance abuse, significant mental illness such as major depression.

The physiotherapists contacted participants from their list of clients and five respondents agreed to take part in the research. These five participants' names have been removed for confidentiality reasons.

8.2. Protocol

Design Phase 3

Prior to testing, the participants were required to sign an ethics form and clarify any questions that they had. The whole testing session was facilitated by a physiotherapist in a clinical testing room. The test began when the participant signed the consent form and all questions had been answered. The test was approximately one to one and a half hours but was broken down into three segments; game testing, physical testing and interviews. Each segment lasted about 20-30 minutes.

The testing was done with naive product testing to understand the usability of the system. The system was given to the participants with the different components explained. They then began interacting with the product without any instructions: only when they had problems were instructions provided. The participant tested the components in the following order; prototype shoes, balance soles and weighted sleeve.

During the testing, participants were told to use the think-aloud protocol (Gambier & Doorslaer, 2010, p. 371) what they were thinking and if there were any discomforts. All this information was recorded and used to compare between the different iterations.

Upon wearing the shoe, the participants were then told to take a few steps forward and backwards and to describe what they felt as they walked. This was done if the participant felt confident enough to do so.

The participant was then asked to try putting the balance sole on and take a few steps forward, turn around and walk back and the describe what they had felt as they were walking. This was only done if the participant felt confident enough to do so.

Next, the participants are asked to put the weighted sleeve on and carry out three forms of exercises: hip extensors, knee flexion, hip abductors (only in the second test) and dorsiflexion exercises. These exercises were chosen because these movements were large and would require the weights to be secure and users with stroke might have problems with their dorsiflexion as they walked.

Before any questions and feedback were asked for, the participants answered a questionnaire which would list the SUS ten-item scale (refer to attached SUS).

Finally, the participants were asked to remove the components and move to the interview session about the different components of the system.

8.3. Data Analysis

Design Phase 3

The data that was collected from the test sessions were analysed by the design team and the physiotherapists through Thematic Analysis (Braun & Clarke, 2006, p. 79).Thematic Analysis was used in this research because it provided a quick overview of what the participants have said by grouping similar answers together and information can be retrieved promptly. Emphasis was placed on the following four key themes; function, usability, ergonomics and aesthetics.

8.4. User Testing 1

Design Phase 3

The first test provided a wide spectrum of five participants in different age groups and at various stages of recovery. Each of the five participants had suffered a stroke at different points in their lives and some had recovered much of their abilities but some still required aids such as an AFO.

During this first user testing, the game was not connected to the shoes because of the complexity of the game and only being able to achieve one task training: sit to stand. Despite that, user testing of the shoes, balance soles and weighted sleeve were carried out as normal.

Three pairs of shoes were made according to the individual shoe sizes of the participants, which would allow for accurate usability, ergonomics and aesthetic feedback.

Figure 8.1 - Components that were brought for user testing 1.

The prototypes that were made for the first user testing were:

- 1 pair of size 6 shoes;
- 1 pair of size 8 shoes;
- 1 pair of size 10 shoes;
- 1 pair of size 6 balance soles;
- 1 pair of size 8 balance soles;
- 1 pair of size 10 balance soles;
- 2 shoes of different colours
- 1 AFO for the left leg;
- 1 weighted sleeve;
- 1 two handed controller; and
- 1 single handed controller.

8.4.1. User Profiles

Design Phase 3

Participant 1.1 (P1.1) was a 74-year-old male who had a stroke in 2015, which affected his left side. He walks with the aid of a walking stick and has gross motor functions in both his left hand and leg. However, he has problems straightening his middle and ring finger. He also has an orthosis in his toes in order to prevent clawing in his toes as he walks.

Participant 1.2 (P1.2) was a 56-year-old female who had suffered a stroke in 1995 and has a severely impaired right arm and leg. She had minimal use of her right hand due to contractures and no gross motor control over her right leg and required an AFO to walk.

Participant 1.3 (P1.3) had suffered a stroke in 2010, which had affected her left side. She has recovered most of her gross motor movements in her upper and lower limb. Except minor clawing under her foot and was unable to fully extend her fingers.

Participant 1.4 (P1.4) was an 83-year-old female and had a stroke in 2008. However, now she has regained most of her gross and fine motor movement in her upper and lower limbs. However, she was suffering from hip inflexibility and swollen ankles. She was not having any problems walking short distances but she would use a mobility scooter for any distance above two kilometres.

Participant 1.5 (P1.5) was a 47-year-old male who had suffered a stroke in 2005 and was confined to his bed. The stroke caused him to lose motor function on the left side of his body. Post-stroke, he had been having trouble shifting his body on the bed. But at the time of research, he had the full range of motion in his legs but sometimes struggled with dorsiflexion due to fatigue. He also suffered from contractures in his left arm which he compensates for with his right arm and teeth.

8.4.2. User Feedback Session 1

Design Phase 3

Overall, the first testing yielded a lot of information and feedback that would be used for later iterations and also to understand the large diverse effects of stroke. The participants also provided feedback regarding the usability and overall comfort.

Figure 8.2 - Different iterations that were shown to participants.

The overall aesthetics received mixed reactions. P1.1 thought that it looked futuristic, P1.2 preferred other colours and would wear it out of the house, P1.3 love it, would personalize it further and would also wear it out of the house. However, P1.4 and P1.5 thought that the shoes were ugly and would probably only wear it at home.

Figure 8.3 - Participants wearing the prototype.

Only P1.3 could put the shoes on independently and P1.1 could do it with practice. However, everyone else required assistance when putting the shoes on. This was due to several factors; decrease in hip flexibility post stroke or age and belly size. Another factor might have been due to the wide opening which some struggle to open it wide enough to slip their foot in (figure 8.3).

Figure 8.4 - Participants who felt some discomfort.

Two participants had also reported the shoes being too wide or too narrow for them, which could result in blisters or pinch points on their foot. There was also physical difference between each participant's left and right foot; some physical difference might be more obvious between participants (figure 8.4).

Figure 8.5 - Strapping around the ankle was a problem for all participants.

The impression that the wrap around ankle strap would help to keep their ankle firm while they walked was quickly nullified because all participants struggled to do up the straps with one hand (figure 8.5). Some also commented that the Velcro attachment points could be bigger to make it easier to strap on. Only one participant could not do up the strap fully due to swollen ankles.

Figure 8.6 - Prototypes shoes that fit on participants.

Only three participants could comment on comfort because of sizing issues. The shoes were made according to the participants' shoe size but due to post stroke and age, their feet had slightly morphed and given that the shoes were 3D printed in TPU, which offered flex over large areas such as shoe tongue and side walls, it was still stiff around the toes. However, those three participants described the shoes as comfortable and a good fit.

Figure 8.7 - Balance soles in action.

The balance sole has been described as having a cushion like feel and felt better than just the shoes alone. Function of the sole did not go as planned because of the initial design, the sphere was too wide and provided more support than challenge. This was also due to the generic arrangement of the spheres and not catering to individual balance issues (figure 8.7). The fastening clip was easy to put on and remove (figure 8.8). Unforeseen feedback was that participant 1.3 said the sole increased her awareness and feedback.

Figure 8.8 - Putting on and removing the balance soles.

8.4.2. User Feedback Session 1

Figure 8.9 - Weighted sleeve can fit different types of shoes.

It was demonstrated that the weighted sleeve could work with the TPU shoe, any sports shoes as well. However, there were minor issues regarding the colour of the straps and overall fabric colour. (PICTURE) Participants suggested that different coloured strap would help to differentiate between the ankle strap and weight straps (figure 8.9).

Figure 8.10 - Interaction of the weighted sleeve.

The amount of weights that were brought to the test session were just enough to provide an understanding of the interaction and because each participant had a different maximum repetition. Despite this, most participants felt some level of fatigue after engaging in several exercises such as knee flexion and hip extensors. Participants also described that a pocket for the weights would have made the weights more secure (figure 8.10).

Figure 8.11 - Feedback about AFO.

Even though the AFO was not printed for or used during the testing. Participant 1.2 had a chance to look at it and a quick explanation was given. This allowed her to provide insights regarding the main problems, which included: bulky joint; irregular walking gait; and clipping the skin underneath the foot. She said that the concept AFO could help because of the flexibility and stiff areas and the AFO clips outside would mitigate the soreness under her foot.

Figure 8.12 - Game controller is working well with the particpants.

The game controller helped to enhance the interaction with Regan's game. The three users gave feedback that the controller was comfortable to hold and one said it was challenging to hold it. Participant 1.1 said that it was uncomfortable to hold because of the size of his hands. They were bigger than the other participants. However, the main concerns were dropping or damaging the device if they suddenly lost balance (figure 8.12).

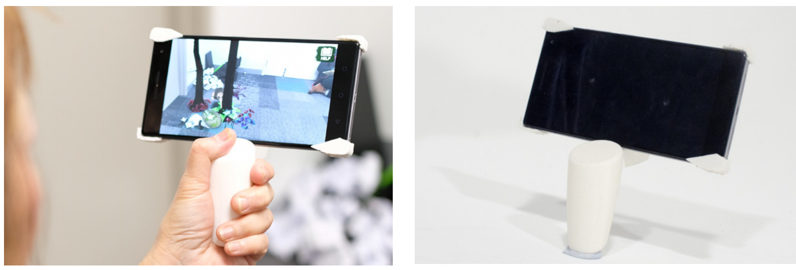
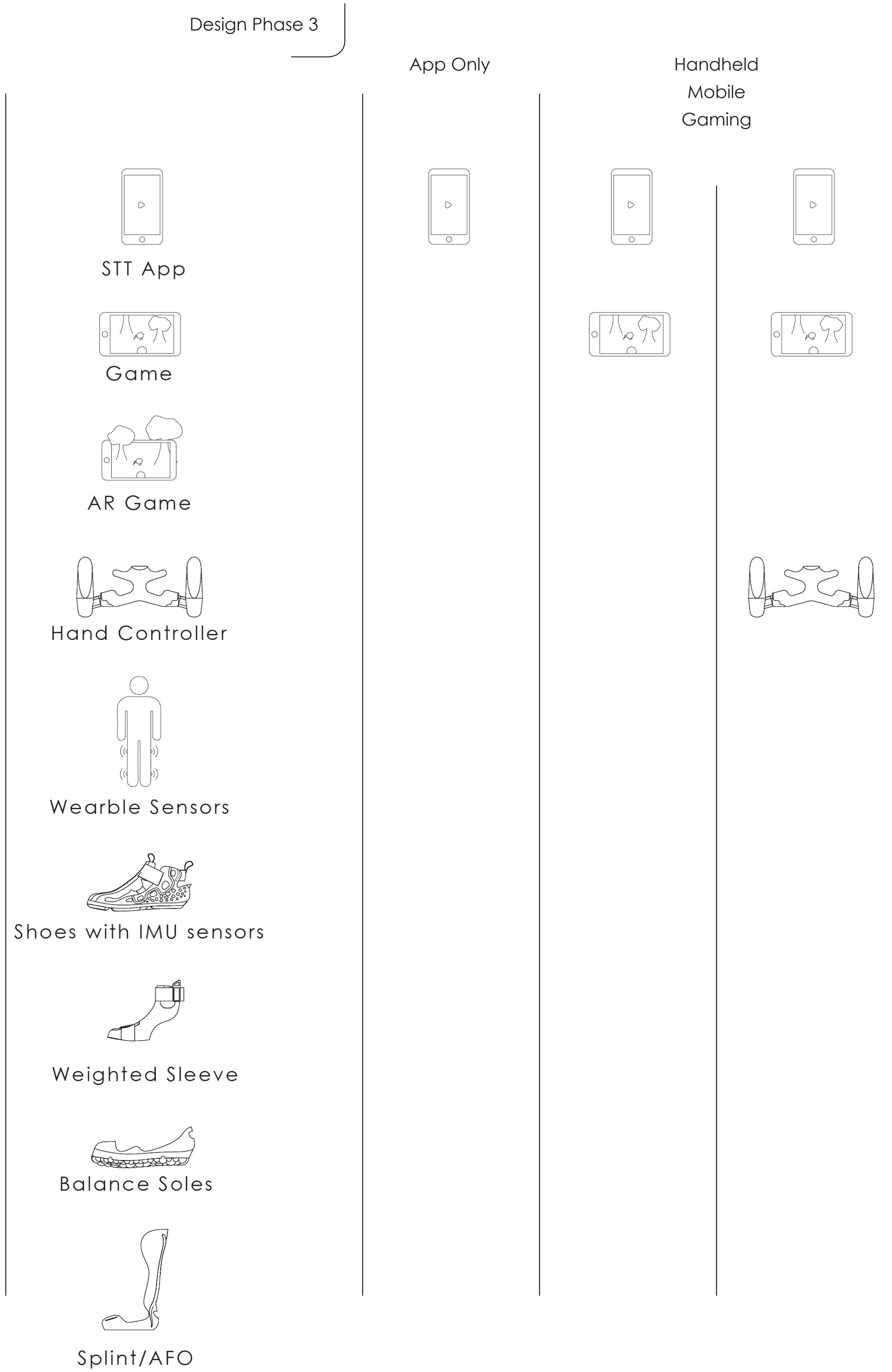


Figure 8.13 - Single handed game controller being tested.

A second game controller for single handed use was still in the initial stages of development but it was given to the user for testing. P1.2 stated that it was too heavy and their grip strength needed to be strong (figure 8.13).

In conclusion, this test also demonstrated that one system would not suit all users. This is also referred to in the literature that no one rehabilitation regime can be made to suit everyone. Thus there has to be a range of products in order to cater to a variety of users; and various components that can be chosen by the user according to their stage of recovery.

8.4.2. User Feedback Session 1



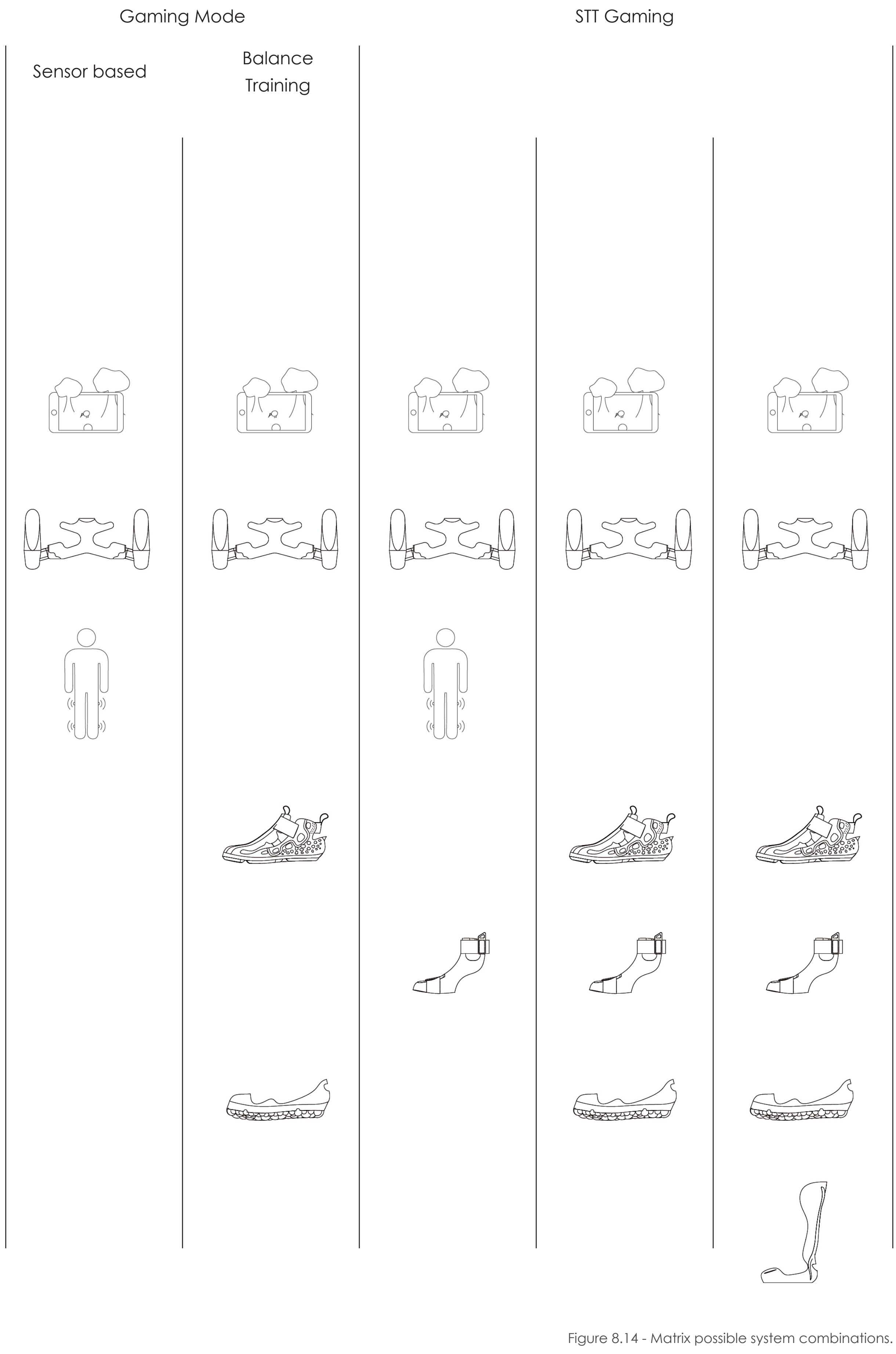


Figure 8.14 - Matrix possible system combinations.

8.4.3. Detailed user testing 1 breakdown

Design Phase 3

Participant 1.1

Figure 8.15 - Handles seem too small for P1.1.

The hand grips on the controller is too small for participant 1.1. His fourth and fifth fingers are in an awkward position and unable to grip it comfortably. He suggested a handles should have a curved surface for fingers placement. The gap between his grip and the screen fits well because his hands are large.

Figure 8.16 - Difficulty wrapping the strap around his ankle.

The participant attempted to put the shoes on but he was unable to put it on because he was unable to widen the top. The physiotherapy on hand assisted with putting on the shoes. He had no issues tightening and strapping, however, he did have problems with wrapping the strap around his ankles.

When both shoes were on, he pointed out that the shoes were too small for him and they were too uncomfortable to walk in. Since the shoes were too small for him, he was unable to test the balance soles.

Figure 8.17 - Weighted sleeve able to secure the weights.

The weighted sleeve was tested with his regular shoes and this was not a wasted because the objective of the weighted sleeve was to be worn with regular shoes as well.

P1.1 was able to reach over and put the sleeve on but could not differentiate the different straps because of the similar colours. Thus the on-site physiotherapist had to help put it on. When the sleeve was in place, P1.1 commented that it was comfortable.

He was able to reach over and strap the weights on the sleeve. However, when engaging in the exercises, the weights fell out. He suggested pockets in order to keep the weights in place while he tighten the straps and also stop them from falling out during exercise.

8.4.3. Detailed user testing 1 breakdown

Design Phase 3

Participant 1.2

Figure 8.18 - Prototype testing with AFO on and off.

The AFO that she wore provided a challenge when testing the shoes. Her left foot fitted a size 6 but her right foot needed a size 8. She wore the shoes and took a few steps forward and pointed out that the AFO was pinching her sole. She then tried the shoes without her AFO and said that it felt better but the width of the shoe was too narrow.

When she was shown a prototype AFO which affix to the outside of the shoes, she said that would drastically help reduce discomfort inside her shoe. However, it was not tested because the AFO was for the left foot.

Figure 8.19 - Balance sole testing without AFO.

P1.2 tried the balance sole with her AFO off. She was able to click the sole on easily. She took several steps forward and back; said that it did provide some challenge but because she was not confident, she only stood up and took a step forward and back.

Figure 8.20 - Weighted sleeve testing.

P1.2 had removed the prototype shoes and used her own because of the narrow width. She had no issues putting the sleeve on but strapping the sleeve securely proved to be a problem. However, she did not have any difficulty putting on the weights and carrying out exercises. She also suggested that pocket for the weights would be good.

Figure 8.21 - User testing of both types of controllers.

Participant 1.2 was the only one how tested both the two handed and one handed controller because she had limited movement of her right arm. When she held on to the two handed controller, she said that it was heavy but when she tried the single handed one, she said it was easier and felt more comfortable. However, over time it felt heavier and she also could not touch any of the controls on screen.

8.4.3. Detailed user testing 1 breakdown

Design Phase 3

Participant 1.3

Figure 8.23 - Controllers being tested.

P1.3 had trouble extending her finger on her left hand but gripping the handles were comfortable. The handles were too wide for her to touch the screen and had to release her right hand to interact.

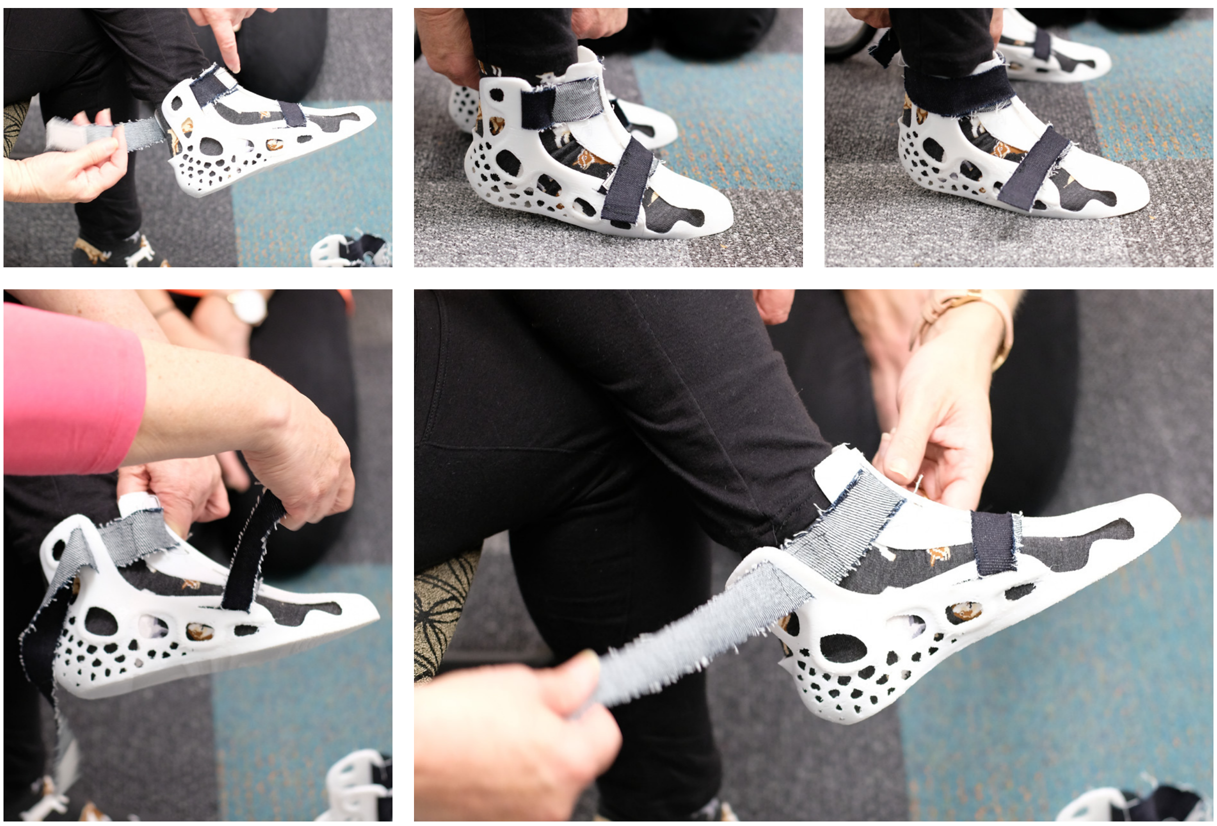


Figure 8.24 - Small struggle to get the strap loosen because of the Velcro placement.

P1.3 was able to the shoes on without much difficulty and was able to stretch to wrap the strap around her ankle. She was able to bring her left foot closer in order to put and secure the shoes but she kept her right on the ground when wearing her right shoe.

Figure 8.25 - Weighted sleeve also suited the prototype shoes.

The straps on the weighted sleeve was no problem for the P1.3 because she was able to utilise both hands to interact with the straps; despite her left hand could only extend her thumb and index finger. The sleeve also worked well with prototype shoes and exercises did not discomfort her. She also explained the weights on her toes help prevent her toes from clawing. One point that she suggested were pockets for the weights.

Figure 8.26 - Balance soles being tested rigorously.

She said that the balance soles were comfortable and did not feel challenged because her sense of balance was strong. The balance soles worked in a different way from the intended purpose because she found that it made her aware of her toes and stopped her from tripping over. She was able to remove the soles with ease.

8.4.3. Detailed user testing 1 breakdown

Design Phase 3

Participant 1.4

Figure 8.27 - Handles seem too small.

P1.4 felt that the controller was comfortable and her fingers were not in any uncomfortable position.

Figure 8.28 - P1.4 had swollen ankles.

P1.4 had swollen ankles and straps were too short to be fastened and it was found that the shoes were also narrow for her wide foot. However, the tongue of the foot did not constrict her ankles and movements.

Figure 8.29 - Weights fell out during exercise.

Wearing the weighted sleeve was problem for P1.4 because of she could not reach forward and put it on. The one site physiotherapist had to put it on, but P1.4 did not report any discomfort when being worn and while carrying out the exercises. She, however could not put any weights on the sleeve.

Figure 8.30 - Balance soles were very comfortable.

P1.4 was unable to step into the soles because she could not reach over or see over her knees when seated; thus physiotherapist had to put it on for her. However, after putting the soles on, she took a few steps around and felt that the soles made her lean over to her left side.

8.4.3. Detailed user testing 1 breakdown

Participant 1.5

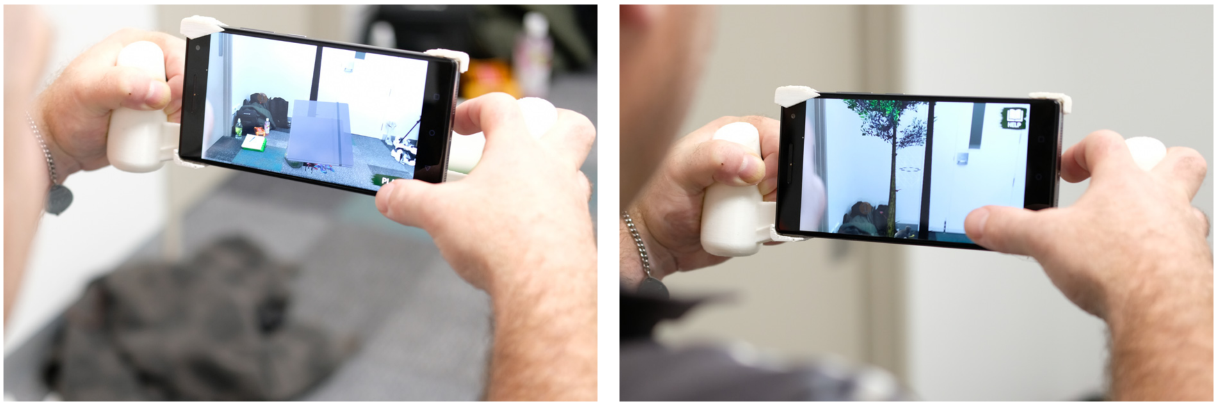


Figure 8.31 - Handles were too small for P1.5.

P1.5 gripped the controller with his affected hand and had gripped it in an awkward position. His fingers were not wrapping around the handles but against it. The handles were also too small for his hands.

Figure 8.32 - Uncomfortable when walking..

He was able to undo the shoes but had trouble widening the opening to slip his feet in. He did have some issues with the wrapping of the strap around his ankles. When he took a few steps around, he commented that the shoes did not provide any heel cushioning or support. He said they not made for comfort.

Figure 8.33 - More comfortable balance soles.

P1.5 tried the balance soles but because of the quality of print, it was not safe to carry out any activities in it. He did comment that it was more comfortable and did not challenge his balance because he stated that his balance was fine. He also stated that he goes on long hikes and has no balance problems.

Figure 8.34 - Could not put the weighted sleeve on.

He struggled to understand the orientation of the sleeve and the physiotherapist had to help him put the sleeve on because he could not attach the velcro. The sleeve around his ankle did not discomfort him but he did have problems with the dorsiflexion exercises.

8.5. Changes to prototypes

Design Phase 3

Figure 8.35 - Final prototype for testing. (More iteration on p. XX)

- The game controller was updated with the comments from user test 1.
- The handles were larger and moulded to the main body, which reduced instability.
- A cutout at the top to allow the user to press the power button.
- The handles were interchangeable with different sizes.
- The handles can only be removed in a particular angle to prevent users from pulling them out when in use.

Figure 8.36 - Final prototype for testing.

- The height of the shoes were lowered to make it easier to put on.
- There was a single large strap that goes on the front, reducing the complication wrapping around the ankle.
- Two finger loops were added to the user to pull the shoes into their foot.
- The shoes were lined with merino wool.

Figure 8.37 - Adjustment of the split down the shoes.

- Feedback from user test 1, that the last toe of the user kept sticking out. The cut was readjusted to keep the user's foot inside the shoes.
- The cut was also shortened but it made the tongue less flexible. Therefore, the cut was kept the same but less gaps.

Figure 8.38 - Final prototype for testing.

- The newly iterated weight sleeve featured a neoprene cover with large strap that go around the lower leg and around the front of the foot.
- Large white tabs to let the user know where to grip the straps
- Pockets that are bound with coloured fabric to tell there user where the pockets are.

Figure 8.39 - Final prototype for testing.

- The snap on mechanism had been widen to allow the user to remove the sole without any hassle.
- The sphere were also rearranged and made it less pronounced around the sides.

Figure 8.40 - Final prototype for testing.

- Additional soles were added to provide cushioning during locomotion.

8.6. User Testing 2

Design Phase 3

The previous participants were invited back again to take part in the second testing of the STT system. But only participant 1.3 and 1.1 responded to the second invitation. During this second testing, there was no change to the testing protocol and the naive testing was carried out again at the start of the test session. This session also included the same weight training, dorsiflexion, hip extensors and knee flexions. An extra weight training exercise hip abductors was added; because the weighted sleeve has shown to hold up during the previous testing.

Figure 8.41 - Prototypes for user testing 2.

The prototypes that were made for the second user testing were:

1 pair of size 6 shoes;
1 pair of size 11 shoes;
1 pair of size 6 balance soles;
1 pair of size 11 balance soles;
1 weighted sleeve; and
1 two handed controller.

8.6.1. User Profiles

Design Phase 3

Participant 2.3 (P2.3) is the same person as participant 1.3; suffered a stroke in 2010 which affected her left side. She has recovered most of her gross motor movements in her upper and lower limb. Except minor clawing under her foot and unable to fully extend her fingers.

Participant 2.1 (P2.1) is the same person as participant 1.1; was a 74 year old man whom stroke has affected his left side. He walks with the aid of a walking stick and has gross motor functions in both his left hand and leg. However, he has problems straightening his middle and ring finger. He also has a orthosis in his toes in order to prevent clawing in his toes as he walks.

8.6.2. User feedback session 2

Design Phase 3

Overall both participants enjoyed the interaction with the system. They described that the system could be easily worn without any help or through practice. Both of them also stated that the system is comfortable. (figure 8.41). The controller has also received mostly positive feedbacks; with regards to size of grips and sturdiness.

Game Controller

The gaming controller was iterated after the feedback from the first test. However, upon placing the phone into the holder, the controller snapped and there was not enough time to print a new one. The holder was instead used as a cosmetic model and the participants interacted with the model without the phone (figure 8.42 & 8.43).

Figure 8.42 - Controller testing.

Participant 2.3 responded that the controller grips were comfortable and were the correct size for her because they did not let her finger curl up. She also suggested that having a flat panel on the back to allow her fingers to straighten out and allowing them to stretch would be helpful.

Figure 8.43 - Grip sizing still was an issue.

For participant 2.1 the handles were too close to the holder and he felt that the handles could be longer to accommodate his larger hands. He was also wondering about the placement of his fifth finger because there was no space for it; but overall it was a better iteration than the previous one. He described that having his finger curled up was comfortable but he knew that it was not a good thing.

Shoes

P2.3 especially appreciated the elastic strap on the back of the shoe; it made it a lot easier to slip the shoes on (figure 8.44). However, she noticed her heel was slipping out on her right foot and could possibly get a blister. Tightening or readjustment did not help, however she suggested the heel counter could be higher. She also said that the elastic strap on the midsole helped to keep the shoe secure to her feet and the soles provided enough support throughout her feet. She also pointed out that the front strap appeared to cringle when it was strapped in which seem to be a material choice.

Figure 8.44 - Heel of shoe kept slipping.

Apart from that she said the shoe was comfortable and there were no discomforts at any point on her feet. She also said that merino wool lining was a good material because it kept her foot warm. However, she was unsure if the shoes would be cool enough for summer wear.

At first P2.1 struggled to put the shoes on and required help. Upon strapping in the shoes, he felt discomfort; which lead to the removal of his socks. He then proceeded to wear the shoes without any aid at all. However, he found tightness around his left midsole; which meant that his left foot was wider than his right. He utilized both his hands to put on the shoes; opening the top and loosening the straps (figure 8.45).

Figure 8.45 - Shoe felt tight around the toes.

Once he had put on the shoes, he took several steps forward and back to the chair. The shoes were comfortable in other areas apart from this left midsole.

There was an attempt to put on the balance sole on his left foot but he found the tightness around his left foot was too much thus the left shoe and balance sole were removed altogether. Despite that, the test continued with only utilizing his right foot.

Balance soles

P2.3 said that the balance soles were easy to put on and she also said that the previous design of the sole had looked weird but this new sole looked more eye pleasing. The way she chose to put them on was to lift her legs up and use her able hand to click them on; there was no difficulty putting it on.

Figure 8.46 - This version was working better than previous prototype.

She described the sensation under her foot as "weird", in terms of different and challenging. The soles have also enabled her to be more aware of her balance and focus on each step. However, she noticed that her left foot was rolling in and her right foot was more balanced. This was probed deeper when the onsite physiotherapist asked if the clawing on her foot was affecting it. She said the clawing made her affected foot roll outwards. The physiotherapist also discussed that the spheres could be designed to either manipulate how the person walks or create a surface which forces the user to use their balance. She also suggested that the sphere could be adjusted so it provided arch support to prevent rolling of the ankle.

Removing the balance soles were not a problem for her, she figured it out after one try. She also said that she would be able to do it in the future without thinking about it (figure 8.46).

Figure 8.47 - Only tested on right leg because left shoe was too small.

P2.1 tried the balance sole and when it clicked into place, he was prompted to take a few steps forward and backward. He described the balance sole to be more comfortable and unstable. He said that he had been challenging his balance and was working different areas of his legs in order to keep his balance (figure 8.47). He also pointed out that he felt safe wearing the soles, which were really helping him with his balance.

Weighted Sleeve

The weighted sleeve was easily worn and P2.3 did not find any problems wearing the sleeve. Apart from similar problems like P2.1; Velcro strap being too long, he did not feel any discomfort or irritation. The pockets were also made it easy to put the weights in and made it secure.

Figure 8.48 - Both could wear the sleeve without much issue.

The weighted sleeve was comfortable and the pockets made it easy to put on the weights. P2.3 did not need prompting as to the orientation and where the straps were attached to. But the two pockets on the toes was harder to put on because the pockets were sewn in line. P2.3 found it easier to do dorsiflexion with the weights as compared to without weights but was difficult for her hip abductors, hip extensors and knee flexions.

Figure 8.49 - Weights were difficult to remove.

She also suggested that the weights could have small tabs which would aid the removal of the weights because she could only get one finger inside the pocket to remove the weights..

Figure 8.50 - Weighted sleeve did not inhibit exercise movements.

P2.1 too did not need any form of guidance to wear the sleeve but needed help with pulling the strap past his heel. He, however did encountered the same problem when adding the weights on but he managed to put the weights in after one try. Participant 2.1 did not have any troubles with the dorsiflexors and hip abductions but felt challenged when engaging in the other exercises; hip extensors and knee flexion.

8.6.3. Detailed User testing 2

Design Phase 3

Participant 2.3

Figure 8.51 - Comparing both version of controllers.

Participant 2.3 found that the new controller was bigger size of the handles were easier to hold. Her fingers were comfortable against the controller but she recommended that there could be an surface for her fingers to sit in or a flat surface so she can straighten her fingers; despite curling her fingers were more comfortable.

Participant 2.3

Figure 8.52 - Shoes were easy to wear.

P2.3 liked this version because of the comfort from the merino wool lining and the ease of use. She was able to loosen the straps with both hands and the finger loop at the back of the shoe made it easy to slip the shoes on. The elimination of wrapping the strap around the ankle has reduce complications and made it more intuitive. The elastic straps around the midfoot made it secure and reduce the number of straps needed. The added feature of the sole also made walking more comfortable and provide sufficient support. But she did find that her left heel was slipping and could create a blister; in which she suggested a higher heel counter.

8.6.3. Detailed User testing 2

Design Phase 3

Participant 2.3

Figure 8.53 - Balance soles felt different than walking normal ground.

The spheres on the second version of balance soles have been made less pronounced and P2.3 said that it made the soles look better. The soles have also proved to be work as she felt that she felt her focusing on her balance on each step. She also noticed that her left ankle is rolling inwards; but normally, it rolls outwards. This is a finding that was not expected and it made her concentrate on aligning her ankle with every step.

One concern that she said was the use of the balance sole on the stairs; because she have to focus on gripping the handrail and taking one step and she said that she would not challenge it anymore.

She removed the soles very easily and mentioned that she could do it without help once she knows how the mechanism works.

Participant 2.3

Figure 8.54 - Weighted sleeve was comfortable.

The weight sole was a success with P2.3 because of she was able to put on the sleeve and weights herself. The pockets on the sleeve made it much easier for her to put the weights and secure the Velcro strap. She mentioned that removing the weights was tougher because of her fingers could not grip the weight. The material of the sleeve also did not bother her because it kept her feet and ankles warm; however she was not sure if it would be too warm for summer.

8.6.3. Detailed User testing 2

Design Phase 3

Participant 2.1

Figure 8.55 - Comparing both version of controllers.

The game controller was worked well for P2.1. The handles were wide enough for him to grip it comfortably, but it was not long enough and his fourth and fifth fingers were in an awkward position. He also stated that the controller felt more stable and had less sharp edges. He suggested having a surface to straighten his fingers as well.

Participant 2.1

Figure 8.56 - Shoes were quicker to put on.

P2.2 was delighted upon looking at the new designs; even though the 3D print was not perfect.

P2.1 had two tries with the shoes because the first try was too tight because of his socks and he had help because he said that it takes him more time to put shoes on and he did not have his shoe horn. The second try, he put the shoes on without help and he did it fairly easily and was a better fit without his socks but was still tight around his left toes because the tip of the shoes was too narrow and was wider than his right foot.

Despite that he still took a few steps to provide feedback about the shoes. He found that the his left foot was too tight but his right was fine. The soles also provided him with more cushion with each step.

Despite P2.2 saying that the shoes look like rehabilitation shoes, he suggested a different colour will help to change the outlook of it.

8.6.3. Detailed User testing 2

Design Phase 3

Participant 2.1

Figure 8.57 - Balance soles challenged his balance.

He could easily slip the balance soles on without any problem. But because the left shoe was too tight, test carried on with only the right foot. The sole was more comfortable and was challenging his balance. The sole made him utilise his balance control muscles as he takes each step. He also mentioned that the sole felt like he was walking on foam and it felt safe and beneficial to his recovery. He uncoupled the sole without any help and he did it very quickly.

Participant 2.1

Figure 8.58 - Weighted sleeve was comfortable.

P2.1 have no trouble putting the weighted sleeve on and felt that he could do it without any help. He did not feel any discomfort around the straps and his ankle. Adding weights to the sleeve also proved to be an easy task for him. The large white tabs also help him to grip the strap better. The blue bindings also made it easier to see where the pockets were.

He also mentioned that the sleeve kept his ankle and foot warm and he said he did not mind the heat.

P2.1 also pointed out that he really loved the sleeve as it is and that he would use it when he is watching television.

09

Results

9. Results

Results

This chapter is a summary of the final design and the user experience of the system which consisted of a pair of smart shoes, a pair of balance soles, a weighted sleeve and a collection of steel weights. The final design is only one of the many possible combination that the whole customisable stroke rehabilitation system can achieve.

It is possible to individualise the stroke rehabilitation system according to the user's post-stroke impairment. This system allows the physiotherapists to work closely with the user and design a system which can cater to their needs and as they progress the system can be altered, Therefore a matrix of different combinations can be selected to suit the individual.

Figure 9.1 - Final design.

9.1. Final Design

Results

The final STT system was called “Enhance Rehabilitation System”. The final design comprised of a pair of shoes, a pair of balance sole, a weighted sleeve and a collection of variable weights. A game controller for the Lenovo Phab 2 was designed to complement the user experience during gameplay.

The shoes featured a large opening which user can slip their foot into the shoe easily, and the large strap allowed the user to grip and tighten it easily. The divided sections on the tongue and elastic loop that encompassed the midfoot area provided additional stability and security when in use. The finger loops in the front and back of the shoe help when putting the shoes on and the elastic strap and the heel counter of the shoe were able to firmly hold the foot in place while in use.

The structure of the shoes has been designed to both add support and look aesthetically pleasing. The in-built tongue and the two stiffeners that ran up the front of the tongue of the shoes were to provide the users with flaccid drop foot with some form of support. While the sides of the shoes were structurally enhanced to keep the foot upright and prevent rolling of the ankle. The sole of the shoes was to provide cushioning when the user walked and to increase the friction when walking on smooth surfaces.

As previously stated, the aesthetics were there to enhance structure and to reduce its appearance as a medical device. The aesthetics of the shoes also helped guide the user to put the shoes on; the finger loops and the large strap with orange stitching acted as a guide. The coloured thread was to present the shoes as sporty and with the patterned holes to not only ventilate the user’s foot but to also add a design feature to the shoes.

The balance soles were designed to challenge the user’s balance and could be adjusted to each individual user. The challenge was derived from the uneven distribution of spheres and its unreliability forced the user to utilise other sensors to keep their balance. The shoes and the balance soles were clicked on easily, removed single-handed; and can be worn over long periods of time.

The weighted sleeve was a soft neoprene cover which can accommodate three shoe sizes; because of users with varying leg sizes. The generic design also allows it to be used with other types of shoes. The soft nature of neoprene reduces the bulkiness of the sleeve and makes it less intimidating to the user. The two large straps not only keep the sleeve secured to the user’s leg but also helps keep the weight secure inside the pockets. The pockets were strategically positioned to provide appropriate distribution of weight for different exercises. They also bind with a different colour fabric to stand out and tell the user where the pockets are.

The weights were steel weights that are shaped like the different cut-outs in the shoes to create a holistic system. The weights vary in weight to allow the user to add and remove weight in accordance to their needs.

The game controller was a controller that would click onto the phone and turn the phone into a portable gaming device. The rigid construction of the controller not only functioned to prevent the user from blocking the cameras but it also forced the user to utilise both hands when interacting with the game.

Figure 9.2 - Details of the soles.

Figure 9.3 - Patterning around the heel area.

Figure 9.4 - Zigzag stitching of the back strap.

Figure 9.5 - Power button for embedded IMU.

Figure 9.6 - Front finger loop is stitched into the tongue.

Figure 9.7 - Details of the back.

Figure 9.8 - Thicken section around the strap eyelet.

Figure 9.9 - Back finger loop.

Figure 9.10 - Heel counter support.

Figure 9.11 - Segment tongue and elastic strap to secure foot.

Figure 9.12 - Attachment of balance sole.

Figure 9.13 - Fully attached balance sole.

Figure 9.14 - Side view of the components.

Figure 9.15 - Balance sole slot.

Figure 9.16 - Locked in place.

Figure 9.17 - Neoprene weighted sleeve.

Figure 9.18 - Foot are both on the same level.

Figure 9.19 - Straps stay inside the buckle.

Figure 9.20 - Steel Weights.

Figure 9.21 - Collection of all prototype.

9.2. Results from testing sessions with participants

Results

The general feedback from the participants was that the system was easy to use and comprehend. The shoes were comfortable and easy to put on. The balance sole could be easily clicked on and off and the participants had no problem removing it on their own. The weighted sleeve was easy to slip on and the pockets were clearly differentiated from the rest of the sleeve.

9.2.1. Game Controller

Results

The game controller felt different in both user's hands generally because their hand size varied drastically. The controller was a comfortable fit for P2.3 because it allowed her to stretch her fingers and prevented them from curling. However, the handles were just slightly too small for P2.1 because his fingers were longer and his hands generally were bigger so his ring and last fingers were in an awkward position because of handle was not long enough. Both participants suggested a flat surface in which they could stretch out their fingers and still hold on to the controller firmly. P2.1 needed his right arm to support him as he stood up and used his left hand to hold on to the device; which he explained, "I have more control of my (left) hand now, that's good, good feedback."

9.2.2. Shoes

Results

Two participants described that they would wear the shoes out in public and one participant said that he would only wear it if it was beneficial to him. Two other participants described that the shoes were ugly and would not wear them at all.

The overall fit and feel of the shoes were described as comfortable. The finger loops and the elastic strap at the back were a big help for one of the participants because it allowed her to slip her foot in easily and helped keep the foot secure. P2.3 described the strap, "that is firm and that is comfortable." P2.1 also found that it was much easier to put on in comparison to the first testing. P2.1 thought that the shoes felt comfortable but had a problem with the shoes being too narrow on his left (affected) side but were a good fit on his right foot. He said, "That one is comfortable and this one is tight."

However, one concern from the physiotherapist was that the sides might rub on the ankle bones and over the long term might hurt the user despite have a merino lining inside.

9.2.3. Balance Sole

Results

The balance sole was quick to put on and both participants have said that the soles made them conscious about their balance during each step. P2.3 said, "I know that my brain will get very tired after focusing on walking this way." P2.1 explained that, "the stabilise muscles are working overtime, which is good". The physiotherapist explained, "The spheres should either manipulate how a person walks by the bubble distribution or whether or not you are trying to create a surface which forces the person to use their balance more." She also went on to say that the bubbles were not supporting the foot sufficiently and causing P2.3 to roll her ankle inwards.

9.2.4. Weighted Sleeve

Results

The weighted sleeve was tested and both participants spent about two minutes to understand how to put the sleeve on. However, once the sleeve was worn, both participants had no issues working out how the straps were fastened and where the weights would go. One difficulty that both of them encountered was the placing of weights in the front two pockets because they were too close to each other. One unusual finding from P2.3 was that the dorsiflexion exercises were easier for her without weights as compared to having two weights inside. She explained, "if I could walk around with a little weight on top of my foot, I would stop scuffing my toes like that, I would like that." P2.1 said the design of the sleeve was, "fine as is". One problem that P2.1 encountered was the leg strap was stuck at his heel, despite the longer strap and that required the physiotherapist to assist. An explanation for that could he was wearing his loafers and the heel was too wide.

10

Discussion

10. Discussion

Discussion

This research has produced a physical system to help facilitate lower limb Strength for Task Training (STT) rehabilitation at home. The findings gather from the user testing suggested that an unsupervised home-based STT system was feasible and working in tandem with an exergame, the system has provided an engaging method to encourage rehabilitation at home.

Employing user-centred design (UCD) (Shirzad et al., 2015) for the design physical controller of exergames in rehabilitation exergaming system have shown to be successful in this research and in the second test, the usability of the system had received good feedback, with comments like, "I like this loop here (finger loop at the back of the shoe), I wish all my shoes had this." "These new shoes are easier to put on as compared to the last one I tried."

One other important finding that was discovered in the second user testing was participants were using their affected hand to help loosen the straps rather than only relying on the unaffected hand. This finding went against the previous assumption of that the shoes had to be worn with only one hand.

The final system consisted of the Lenovo Phab 2 with controller attachment, a pair of shoes, a pair of balance soles, a weighted sleeve and a set of steel weights. The Phab 2 was to be used in combination with the smart shoes. The game will track the user's steps and motion with the embedded sensors in the shoes, while the Phab 2 utilised internal sensors to track the environment. The game was also designed to track the user while using the balance soles and the weighted sleeve. All this data will then be analysed and feedback to both the user and physiotherapist; which would allow them to keep track of their progress.

The user testing has provided data for understanding the different aspects of the system and how it may help facilitate STT. While current STT is conducted in a clinical environment, these tests have suggested that the system can help facilitate parts of unsupervised STT at home. Utilizing an exergame component can further engage the user to carry out STT consistently and intensively; which in the long run would help the user regain their mobility and independence.

The physical aspects of the system have demonstrated that there is no single system that can cater to all types of users with a stroke which is similar to rehabilitation training regimes, whereby all rehabilitation regimes have to cater to individual goals (Burke et al., 2009). This was reestablished in the first user testing where five participants at various stages of recovery required different components of the system. Thus there must be a user matrix which patients or physiotherapists can select to cater to the individual and promote better recovery.

The function of the system has been largely influenced by the stipulated STT requirements. Ergonomics and usability factors which are heavily guided by stroke survivors' cognitive and physiological well-being; in which addressing these aspects would then allow the seamless transition of the exergame system in an unsupervised environment. Aesthetics is the last factor providing users with a holistic experience by removing the stigma of a medical product and giving them the confidence to use it all the time. However, some said it still looked a bit like a rehabilitation device, which would elude a sense of stigma with onlookers (Vaes, Stappers, & Vereniging voor Studie- en Studentenbelangen (Delft), 2014).

Employing the use of the Phab 2 smartphone, users are able to immerse themselves in the Augmented Reality (AR) game. This handheld device can be connected to the smart shoes via Bluetooth and the portability of the smartphone allows the user to utilise different areas of the house for different levels. The portability of the phone also allows users to exercises anywhere in the house where they feel most comfortable.

The overall system has been described by the participants as something that they would wear if it benefits them. Feedback from the first and second tests, most users have described that the shoes were aesthetically pleasing; and they would wear it around the house and even outside.

10.1. Evaluation through design criteria

Below, we present an evaluation of the whole system against the final design criteria.

1. Functional Considerations

The shoes, balance soles and weighted sleeve through the testing have demonstrated that they can function as a holistic system. The shoes are able to support the user and allow articulation of the ankle and foot during locomotion and the shoe soles helped cushioned each step. The elastic straps that ran around the midfoot helped keep the foot tight inside the shoe and made the user feel secure.

The balance sole attachments are easily attached by stepping into it or slipping it on with one hand. The removal of the sole was also easy to remove by depressing the button at the back. Users have also described that the sphere beneath the soles made them conscious about their balance with each step. However, comparing the feedback of soles from both user testings, it was found that the balance sole that had fill performed better than an empty shell. This was not what the physiotherapist in expert review 3 described, “softer (surface) is harder to balance because you require your other senses”.

The weighted sleeve functioned well by holding up the weights while performing strength training. The pockets and straps both held the weights in place and sleeve did not slide down the user’s leg during training.

Findings from users about the game controller have shown that the controller helped to retrain the affected side with the help of the unaffected side. This was because the game controller had a rigid structure and acts as a mirror to reciprocate the movement of the unaffected side to the affected side.

2. Adaptable

The user matrix (p.75) enabled the user and physiotherapist to design the system according to what the needs of the user. Different components can be selected to create a system that is specific to the user. The system also allowed the user to upgrade the balance sole as they recover but adjusting the sphere to keep up the challenge.

The spheres on the balance soles can be adjusted to individual needs and this arrangement can be changed as the user improves. The sphere could be designed to challenge the user or to manipulate the user's walking, as described by a physiotherapist in user test session 2.

The weighted sleeve was able to accommodate the various amount of weights and also allows the users to add or remove weights according to their abilities.

3. Affordability

The shoes, balance soles and splint will be 3D printed and the embedded sensor will have to be designed to fit inside the shoes which means it will have to be specially made. The weighted sleeve would sew together.

Current 3D printed shoes in the market are priced around USD$300 for a pair. However, the final design, a pair of shoes and a pair of balance soles were 3D printed using Selective Laser Sintering (SLS), the cost was very expensive. But in the future, the shoes, balance soles and splint could be printed using Fused Deposition Modelling (FDM) which is a much cheaper alternative and allow the user to buy new parts as they progress through their rehabilitation programme.

The off the shelf IMU sensors cost ranges from USD$15 to USD$50 depending on the number of axes. However, because the sensor placement on the shoes is smaller than the commercial ones, custom sensors have to be designed and made to fit in the shoes.

The weighted sleeve is made from neoprene and could be sewn together. The costs can be brought down because the sleeve has only three sizes, small, medium and large.

The game controller is currently a 3D printed casing because it is still a prototype. However, in the future, the controller could be injection moulded to keep the costs low.

4. Accuracy

In earlier prototype games, Petrie had paired the IMU sensor and the Phab 2 together and they worked well together but that was only tracking dorsiflexion exercises. These tests have proven that the IMU sensors can track limb movements with fairly high accuracy. The areas that require reworking is the data coming from the sensor, one possible solution would be removing out random spikes in data through a filter in the game code. Another solution that can mitigate the wrong readings, would be having the sensor in the same orientation and spot on the body during each use.

5. User Friendly

The finger loops and large straps quickly prompt the user to how the shoes are worn. The single large strap on the front only had one orientation to secure which made it easy to understand on first sight.

The balance soles had one orientation and users have shown that the balance soles are straightforward to attach and the removal of the soles are fairly easy once they understand the mechanism.

The soft and fabric-like appearance of the sleeve makes it less intimidating and bulky but yet the slight stiffness of the neoprene gives the weighted sleeve has some bulk to it which allowed the user to quickly understand the orientation of the sleeve. The minimum number of straps on the weight sleeve reduces the number of steps for the user to attach the sleeve.

6. Portability

The employment of mobile gaming has made the system portable around the house and with the small setup, it is easy to move around with. The shoes and balance soles can be used while playing the game through the house.

7. Post stroke cognitive visual and motor deficits

The specific needs of users with stroke have been taken into account and the shoes allowed the users to unstrap and slide their foot in with the help of the finger loops and an elastic strap on the heel. The components of the system are designed to fit into each other in one orientation and the removal of the attachment has been mitigated to a minimum number of steps.

Upon tabulating the scores of the SUS it was discovered that the second test scored lower than the first test. The scores that were received from the user testing was a collective of the whole system as a whole, which helped to understand the system holistically. But a SUS is needed for each individual component as well, as this would provide greater clarity of the function and usability of each component.

The second test yielded results that showed the system was usable by the users themselves but needed work to rectify the usability of the overall system. The participants in user testing 2 had most of their dexterity of their affected hand and were motivated to retrain their affected hand, therefore they engaged the use of both hands to try and put the shoes on.

However, consideration for those who are unable to utilise both hands like P1.2 and P1.5 who struggled to get both the shoes on. Thus, the shoes require some modification around the opening in order to make it stay open and close only when the strap is pulled tight. This would allow the user to simply step into the shoes.

The pocket on the weighted sleeve also needed changes because of the pocket placement, both users in the second user testing could not add another weight when there was already a weight in the front pocket. P2.3 had some problems removing the weight because the pocket was too deep, but managed to remove it after all. This might prove to be different for users who have not regain fine motor skills. A possible change would be added a bright colour tab on the weight to allow users to hook their finger around it and pull it out.

8. Post stroke physical changes

Users with stroke experience physical changes such as swollen ankles, reduced sensations on the affected side, fragile skin, and so on. Considering the last two participants that tested the final design: one had a larger foot on his left, and the other had a lowered sensation level on her affected foot. The use of 3D scanning could help rectify this problem and creating customised shoes and balance soles that are shaped to the user's foot. This also mitigates the need for users to buy different pairs of shoes to accommodate their feet as described by P1.2, "I have to shop around for shoes and insoles that can fit me, comfortable for walking long distances and looks good."

9. Intuitive

The shoes had obvious colour differences in the finger loops and the large singular strap reduced the number of steps needed to put the shoe on. The bright coloured threads used not only served the purpose of making the shoes look sporty but also indicated to the users where the Velcro was.

10. Addressing Stigma associated with medical products

Stigma is caused by the product's appearance and the social enforcement of stereotypes. Vaes et al., (2014, p. 5) described that medical and assistive device is a symbol of the user being unwell. This is often not because the product is a medical device but it has the aesthetics that are associated with it. Vaes (2014, p.7) explained further that the designers are responsible for the outlook of the product and the product should factor in the experience factor; what the emotional aspect of the product can give the user.

The design of the shoes was intended to emulate the style of sports shoes with the combination of patterns, bright colours and layering of material. The white colour of the prototypes still eludes a sense of medical product. However, when shown a previous prototype that had been dyed black or with any colour suggestions, they preferred black to white. Only one participant liked the white version. 3D printing allows the user to select their favourite colour because it is simply feeding the selected colour into the machine for printing and as 3D printing continues to advance, more materials and 3D printing techniques can help customise the product for the user. 3D printing also allows the user to customise their product by having it 3D scanned and fit exactly to their feet.

10.2. Research Limitation

Discussion

Both user testing has provided insight into participants' different experiences with stroke and to understand what their concerns were when it comes to rehabilitation. A key factor to note about the participants was that they are self-motivated and they chose to come for the testing sessions, thus these participants have already taken the first step to recovery.

The research has based its findings on qualitative and quantitative data from the SUS and the data collected represents what the participants felt. The data is therefore subjective to each individual and could also have been influenced by the way the participant was feeling on the day of testing.

The participants had to be recruited through the inclusion and exclusion criteria and only those who were eligible for user testing were contacted. Only a handful of those contacted responded to the invitation and they only represented a small portion of the stroke survivor community and therefore not all forms of post-stroke disability are represented in this research.

A key factor during the second testing session was that both participants used both hands (figure 10.1) to try and put the hardware on because they were motivated to retrain their affected side. This was an interesting find because early in the research, it was assumed that user with stroke have minimal to no use of their affected side and would always compensate with the working side. But these two participants had high motivation to get better and recover and like P2.3 said, "Rehab is everything and everything is rehab."

Figure 10.1 - Participants using two hands to use the shoes.

Thus when designing this home-based stroke rehabilitation system, one criterion was the shoe had to be worn with one hand. But after both user testing, it was quickly realised that rather than not encouraging the use of the affected side, the shoes should be designed to be worn with one hand but also assisted by the affected hand in the easiest way possible. This would allow the user to incrementally get back into exercising the affected side.

One key factor that was not accounted for during the user testing is the user's own motivation. This factor is highly subjective to each individual and few factors can change that. Thus having said that, the participants that came down for the user testing sessions are highly motivated to rehabilitate and return to their normal lives. Each participant had their own unique way of retraining themselves. Some are inspired by others; some are self-motivated; while some are motivated by family.

Lastly, the IMU sensor has been shown that it can track and translate this information to the Phab 2 but the data is still jittery and a filter had to be used in order to get clean tracking. This large amount of cleanup needed has taken up a lot of time and Petrie, the fellow research partner, is investing more time into creating a better immersive game instead of fixing the technical issues.

11

Conclusion

11.1. Conclusion

Conclusion

Currently, stroke is one of the leading causes of long term disabilities. It often causes paralysis on one side of the body, muscle weakness and restricts the range of motion. Exergames have been explored as a new form of rehabilitation and the results are encouraging because users were more engaged in the rehabilitation process. STT is an innovative lower limb rehabilitation programme that intends to use neuroplasticity of the brain to help users with their stroke recovery; however, it is currently only practised in a clinical environment.

Throughout this research, there were three design phases and these phases employed several methods that would feedback in the designs:

- Design Research (Phase 1)
- Design Concepts (Phase 2)
- Testing and Assessment (Phase 3)

Design Research and design concepts phases engaged the expert review and semi-structured interviews. These two methods were used to gather feedback about the initial design by Duncan (2016), initial design concepts, low fidelity prototypes and high fidelity prototypes.

Throughout phase 1 and 2, iterative design and user-centered design methods were used to iterate the concepts with consideration to the feedback from experts.

Due to the ethics requirements, the different designs had to be validated by the experts before they could begin recruiting participants.

Testing and assessment phase saw the use of user testing, System Usability Scale (SUS), Thinking Out Loud, naive testing and semi-structured interviews. The participants for user testing were recruited by the physiotherapists through a private clinic. User testing consisted of two parts, testing and interviews.

During user testing, Thinking Out Loud method was engaged for the whole testing phase, in order to understand what was going on inside the user's mind while using the product. Naive testing was used to gather insight about the user interaction of the product.

SUS and semi-structured interviews were done in the second part of the testing. The SUS was given to the participant before the semi structured interview began in order to prevent any bias feedback. Semi-structured interviews were used to prompt user to elaborate on function, ergonomic, usability and aesthetics. After the test session, the interviews were analysed and a thematic analysis was conducted.

1. Functional Considerations

The function of the physical controller should translate the user's movement between the real world environment and the virtual environment. It should also allow the user to carry out STT at home safely and independently.

The shoes were able to support the user and also allows articulation of foot and ankle. The soles also provided support as the user walked. The number of straps were reduced to one and the second strap was replaced with an elastic band which kept the user's foot secure. P2.3 and P2.1 described the shoes to be comfortable and secure.

The different components of the system could be worn and remove easily, without any issues. This was what P2.3 said about the balance soles, "First time I would have to think about it, but subsequently, I can undo without looking." P2.1 said, "This (shoes) is much easier to wear than the last one."

The weight sleeve can be removed easily by releasing the large velcro straps and sliding the sleeve off and it could hold up to about 3 kilograms of weight.

2. Adaptable

The system should be adaptable to the various recovery stages of user with stroke.

The whole system was adaptable to each individual. The physiotherapist or users can select several components which they need to enhance their recovery process. Their chosen system can continuously be changed as they progress, thus continously challenging themselves.

The weighted sleeve can accommodate a number of weights and user are able to add and remove weights in accordance to their ability to carry maximum repetitions.

The parametrically designed balance soles can be continuously adapted to different user or as the user progress with recovery. The spheres can either be arranged to challenge the user or arranged to manipulate the user's walking.

3. Affordability

The price of the whole system should not cost more than a commercial console system because some users are unable to receive government aid.

At the time when this paper was written, a pair of Fused Deposition Modelling (FDM) 3D printed shoes cost approximately USD$300 and the cost of the balance soles should be about the same price. Cost of off the shelf IMU sensors ranges from USD$14 to USD$50, a specific IMU sensor will be needed in order to fit inside the shoes. However, the weighted sleeve is stitched together and this can be done at low cost.

The game controller was a 3D printed prototype, however there is a possibility of injection moulding the controller casing. The handles will have to be manufactured differently due to the large amount of plastic.

Overall, the approximate cost could be USD$1000, which is about the same cost as a brand new console.

4. Accuracy

The tracking accuracy needs to be accurate in order to track and record the user's progress. This would also prevent habituation of wrong movements.

The IMU sensor had posed many problems throughout this research, but the main issue was the sharp spikes in the data. These spikes in data have caused the sensor to continuously crash the game. However, when the sensor was working well, it was able to track when dorsiflexion exercises.

5. User friendly

The system should be easy to comprehend and easy to learn. This was because the average age of the user would be above the age of 50 years old. This would also help promote independence.

The shoes and balance soles were easy to comprehend its orientation. Added features of finger loops and reduced number of straps made it easy to understand.

The balance sole only has one orientation which would fit into the shoes. But P2.1 exclaimed, "Oh it goes over this (shoes)." he assumed the balance soles were another shoes. Despite that, once he knew where it goes, he had no problem putting it on

The weighted sleeve does not collapse flat and this gives the user an idea of the orientation of the sleeve. Once they understood how it goes on, the large white tabs indicated where the straps were.

6. Portability

The system should allow the user to exercise anywhere they feel the most comfortable and the compact size allowed for another level of engagement technology such as AR.

The compact size of the Lenovo Phab 2 was small enough for the users and the weight did not affect them. However, it did affect P1.2 because she had almost no use for her right hand and she had to hold it with her left, this made it extremely uncomfortable for her.

7. Post stroke cognitive visual and motor deficits

The after-effects of stroke can affect the user many ways and it is key to minimise the number of steps and complicated actions.

The early assumption that users with stroke would only use their unaffected side. This was not the case with P2.3 and P2.1 as both of them used both hands to loosen the strap and to put on the shoes. P2.3 went on to commented that she liked the finger loops and it was easy to slip her foot in.

8. Post stroke physical changes

The human body goes through some change after a stroke and this varies for different people. Some experience swollen ankles, sensitive skin or minimal sensations.

The shoes were described to be generally comfortable and there were no pinch points or constriction. However, there were several key findings such as P2.1's affected foot had widened because of stroke, while his right had no change. He did not realise it until the test.

9. Intuitive
The design of the system should be self-explanatory and should guide the user to put the shoes on.

The strategically placed finger loops and straps on the shoes gave clear instructions about wearing them. This was clearly observed as both P2.3 and P2.1 instinctively used it to pull the shoes up.

The balance soles had only one orientation and the hook mechanism could be operated by both P2.3 and P2.1, easily removing it with one hand.

The weighted sleeve had two white tabs on it and P2.3 and P2.1 instantly knew where the Velcro was and knew how to tighten it. The pockets also made it clear where the weights were to be placed.

10. Addressing stigma associated with medical products
The design should not have the outlook of a medical device because the stigma surrounding medical devices.

The feedback about the shoes was it had a hint of a medical device and P1.2 said, “ The does not look much a rehabilitation shoe but with the ankle-foot orthosis (AFO), it definitely looks like one.”

Despite all that, most participants have recommended that the shoes could be in a different colour and that might help to remove the association to a rehabilitation device.

In conclusion, this research has gathered user feedback and created an exergame system that allows for unsupervised home-based STT rehabilitation. The system is intuitive and gives the user confidence to carry out rehabilitation independently at home. The adaptability of this system allows the user to constantly update their components to keep improving. This system has the ability to accommodate other types of muscular disabilities and expanding its ability to help other recover independence.

12

Design Iterations

12.1. Low fidelity shoes

12.2. Low fidelity wearable sensors

12.3. High fidelity wearable sensors

12.4. High fidelity shoes

12.5. Dorsiflexion attachment

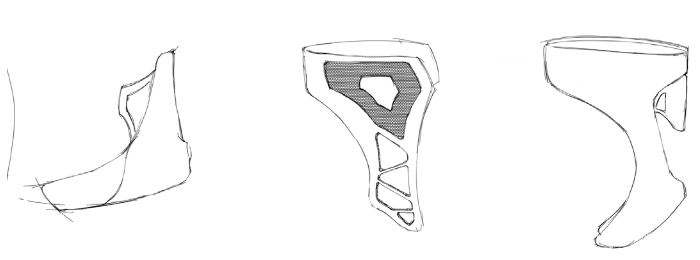
12.6. AFO

12.7. Lenovo Phab2 game controller

This group of sketches are initial concepts of the shoes. These shoes are designed with a large opening and also provide ankle support.

12.2. Low Fidelity Wearable Sensors

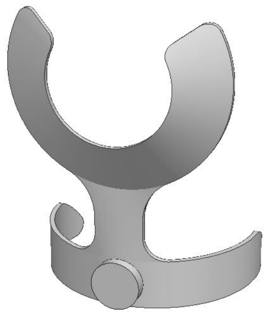
Design Iterations



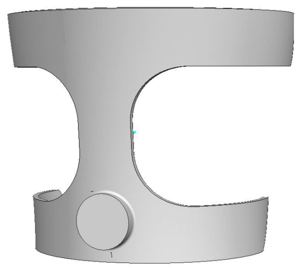
Iterations of wearable sensors. The placement of the wearable sensor was designed into the form which only allowed users to wear the sensor in a specific part of the lower limb.

12.3. High Fidelity Wearable Sensors

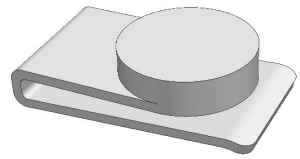
Design Iterations



To be worn just at the knee

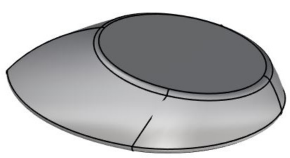


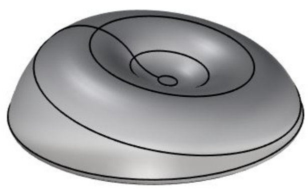
To be worn just at the knee

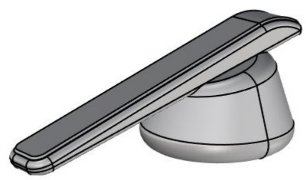


To be worn in between shoe laces or straps

These designs are the wearable attachments which users can attached to points on their lower limb. In order to get an accurate point of reference in every use, they are designed so that it will only be comfortable in one spot of leg.

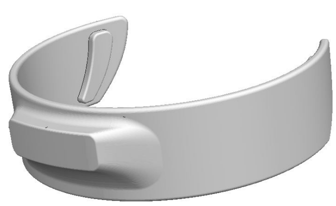




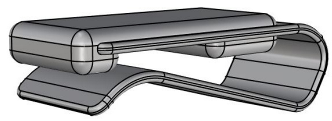


These are different sensor covers which users can choose which would give them more choice to customise their rehabilitation devices.

These are different sensor covers which users can choose which would give them more choice to customise their rehabilitation devices.



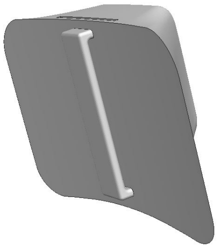
This concept is a cuff which is designed to only be worn just under the knee joint.

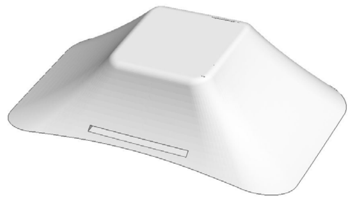


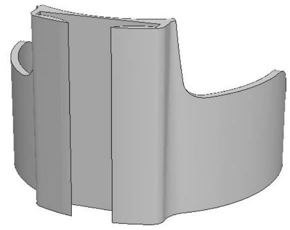
This wearable sensor was designed a clip which can be attached to any part of the user. This also meant that users can attach them using one hand.

12.3. High Fidelity Wearable Sensors

Design Iterations

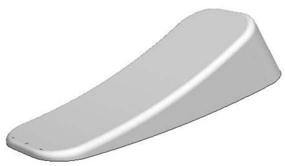




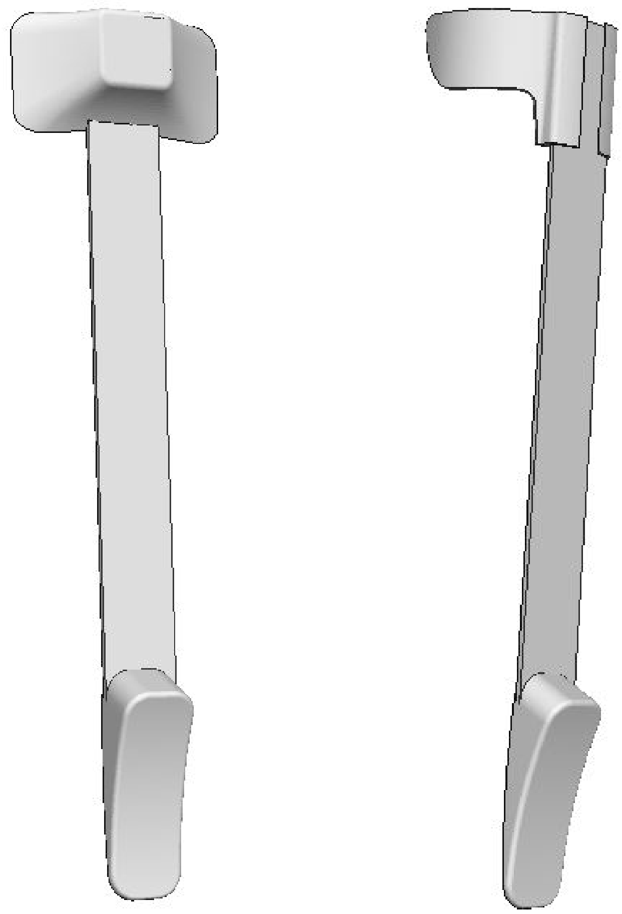


These design works in relation with a velcro strap that goes around the lower leg

This is a shin cuff and its meant to be worn halfway up the shin.



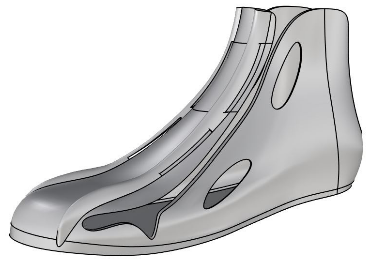
This is the sensor slots between the user's shoe laces; in order to get a constant position every use.

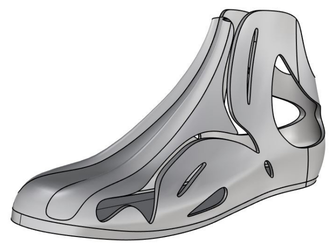


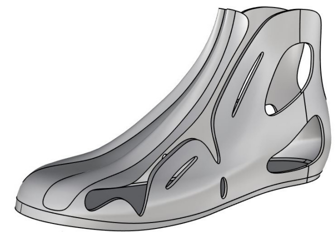
This is the overall design and how the different parts sit together. The long strip in the centre could potentially be a flex sensor which is able to track the user's flexibility over time.

12.4. High Fidelity Shoes

Design Iterations

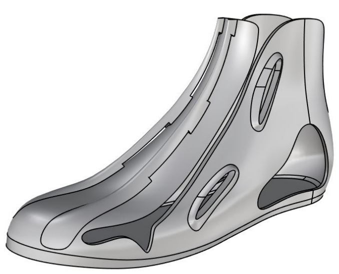


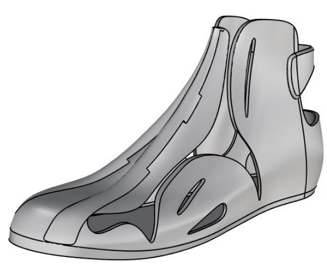


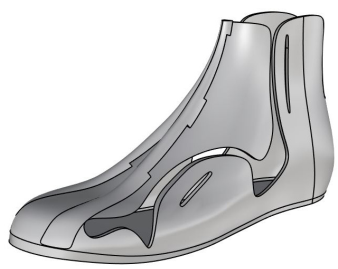


This iteration featured two stiffeners on the front that run parallel to each other and the ends of them are too abrupt. The strap loops are too large as well.

These iterations was the redesign of the stiffeners; making it merge into the shoes at the toes. However, the stiffeners did not merge but made to come to a point above the shoes.



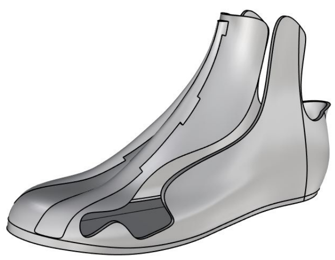


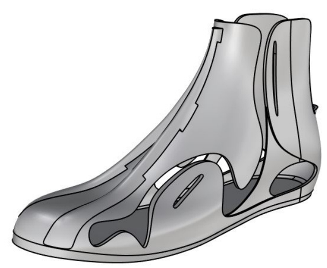


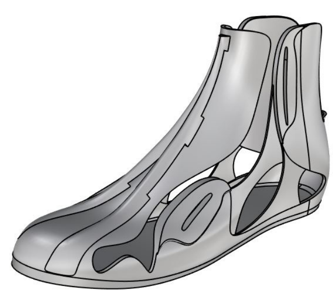
This iteration introduces an isolated thicken area around the straps holes. The thicken areas would blend out with the rest of the shoes.

These stiffeners merged into one at the top and an attempt to reduce the bulkiness of the shoes by introducing layering and removal of material.

This iteration explores the possibility of having the shoe tongue to be wider in order to sit comfortably over the user's midfoot.





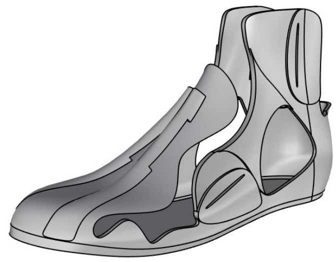


A rework of the fastening mechanism for the shoe and balance sole. The fastener is at the heel which clicks on but pressed to be released.

This iteration is a combination of a flexible tongue and a layering of material to cut the bulk of the shoes.

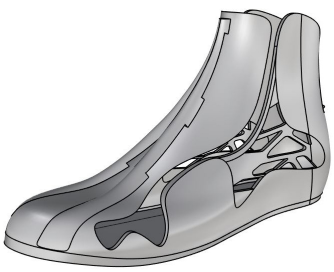
12.4. High Fidelity Shoes

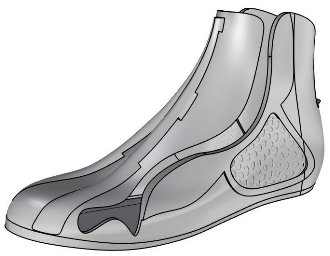
Design Iterations



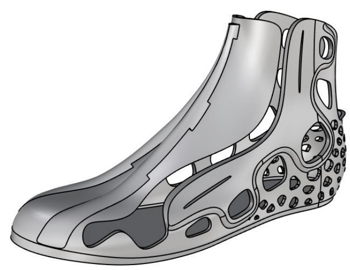
This iteration is a combination of a flexible tongue and a layering of material to cut the bulk of the shoes.

This iteration featured a shorter tongue that only reaches the midfoot and the combination of layering of material.





This iterations was experimenting with the possibility of a voronoi design on the sides of the shoes. The voronoi is too abrupt and it does not blend with the rest of the shes.

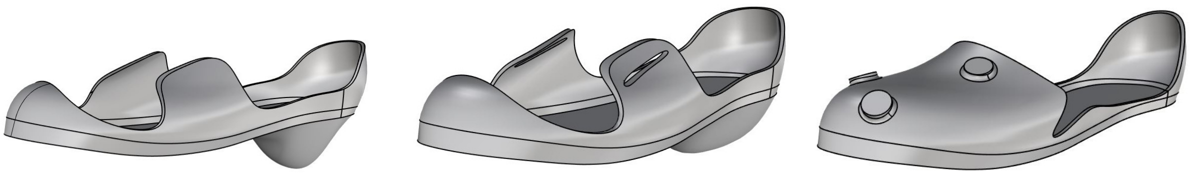


These two iterations were attempts to homogenise the large voronoi and smooth out the holes. The thickness around the straps have also been thickened as from earlier experiments that a lot of force is acting on it. The thicken sections also had to be blended into the whole shoe.

This was the final iteration that featured major changes. The voronoi is now dispersed over the back of the shoes.

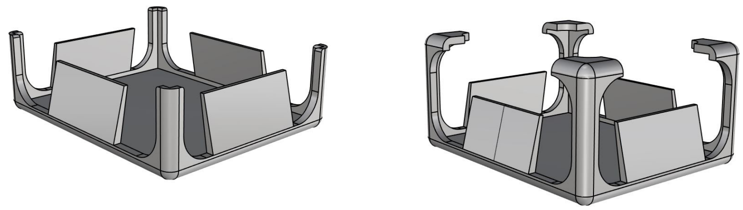
12.5. Dorsiflexion attachments

Design Iterations

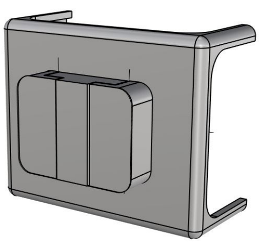


Early iterations of one of three options proposal; the option of including a theraband and dorsiflexion weight attachment in the design research phase (PG XX); . These concepts were designed in preparation prior to the meeting, however physiotherapists were not keen on using therabands, thus this concepts were dropped.

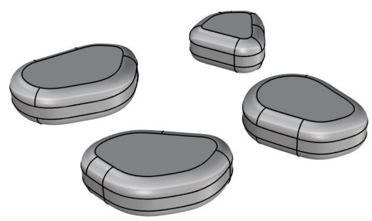
This iteration was proposing a designed weight that sits on top the weighted sleeve. However, its shape may not fit everyone.



This weight covers were designed in to not only provide aesthetics but also as a form of attachment to the weighted sleeve.



This attachment mechanism was designed to slot into a plastic slot on the weighted sleeve.

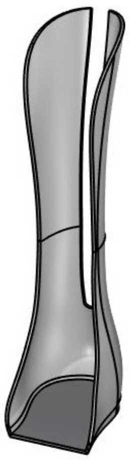


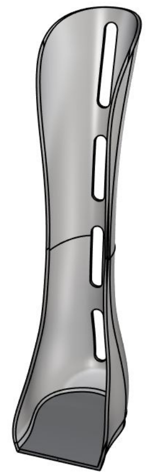
Final proposed designed of the weights are shaped like the cut out from the shoes, with a radius around the edges.

This was a test print using a TPU cover. The cover was 1.5mm thin, which made it flexible but was a problem when it was being printed. The cover was also too weak to hold up more that 250 grams, thus this idea was put aside.

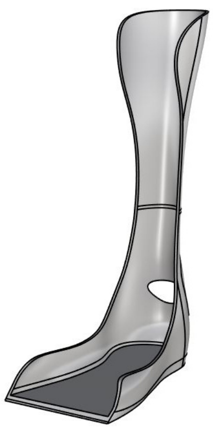
12.6. AFO

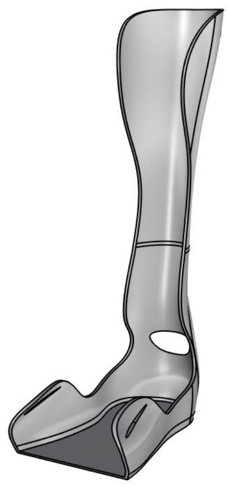
Design Iterations

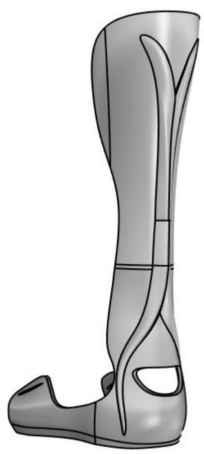


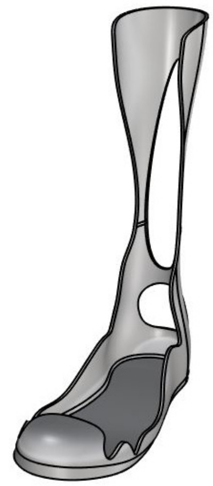


These two images are iterations of the AFO with a short sole.









Second Row: AFO with longer soles which sit in the middle of the foot. These iteration also featurde a spine that runs along the back of the AFO to stiffen it.

Third Row: The aim of the AFO was to keep the foot up, so this concept was have the AFO sitting in the front of the leg. But further considerations, this method might inhibit normal leg movement.

12.7. Lenovo Phab2 Game Controller

Design Iterations



Version 1 was the first design and was brought to user testing 1. The holder only anchored at the corners and did not block any buttons or part of the screen.



Version 3 was the second printed model. This iteration blocked the volume button on the side and the top clips are in an awkward position. The handle support was now incorporated into the main body and that prevented wobbling when in use.



Version 5 was featured a wide support structure behind the phone and one clip at the top. But the clip covered the power button which is critical to the phone.

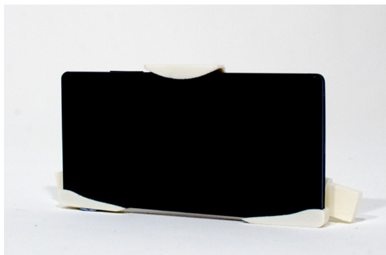
Iterations of the handle after user test 1. The first handle is the first iteration and the last hand is the latest version.

12.7. Lenovo Phab2 Game Controller

Design Iterations



Version 6 had the whole design offset to the bottom of the phone but that meant that the everything was lobe sided, which felt awkward.


Version 7 was a remake of version 5. But the main focus was on the handles because the handles were intruding into the camera's field of view. (refer below)



Version 9 was the final iteration and the handles did not block the camera and the small cutway was made to expose the power button.

In early prototypes of the handles supports and handles were blocking the camera's field of view and that would interfere with the AR game. This meant that the handles were sitting to far behind the phone and need to be moved forward and out of the camera field of view.

13

Attachments

13.1. References

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13.2. Figure List

Attachments

All unlisted figures belong to the author.

Figure 4.4: Kline. D., (2011). E3 2011 - Kinect Sports 2 (Xbox). Retrieved from https://commons.wikimedia.org/wiki/File:E3_2011_-_Kinect_Sports_2_(Xbox)_(5831103912).jpg

Figure 4.5: Waag Society. (2012) Exergaming. Retrieved from https://waag.org/en/project/exergaming

Figure 4.7: Unknown. (2017) Vintage Combination Browline Glasses Retrieved from https://www.etsy.com/nz/listing/263704560/vintage-combination-browline-glasses?ga_order=most_relevant&ga_search_type=vintage&ga_view_type=gallery&ga_search_query=&ref=sr_gallery_15

Figure 4.8: Unknown. (n.d.) Trooper Paracord Medical ID Bracelet Retrieved from https://www.laurenshope.com/trooper-paracord-medical-id-bracelet

Figure 6.1: Unknown. (2016) *Experiments in natural motion*. Retrieved from http://news.nike.com/news/experiments-in-natural-motion

Figure 6.2: Seifert, D. (2016) *Google Tango on Lenovo's Phab 2 Pro: A work in progress*. Retrieved from https://www.theverge.com/2016/12/29/14102316/google-tango-on-lenovo-phab-2-pro-ar-smartphone-review

Figure 7.1: Courtesy of fellow researcher, Regan Petrie.

User Testing 1

Weighted Sleeve.

System Usability Scale

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

Shoe + Sleeve

System Usability Scale

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

Shoe and weighted Sleeve.

System Usability Scale

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

Shoe + Weighted Sleeve.

System Usability Scale

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

SH02

System Usability Scale

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

User Testing 2

System Usability Scale Game + Controller

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

Shoe / ~~Sleeve~~

System Usability Scale

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

Shoe system.

System Usability Scale

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

Appendix: Interview Guide

The questions below serve as examples of the kinds of prompts we might use to encourage the participant to talk about their experiences and opinions. These prompts will only be used as required.

The interview will focus on participant reports of perceptions of the device and their experience using it.

Example prompts

Video game and game controller

- Can you describe your thoughts about the Video game and game controller you used today?
- What have you liked about the Video game and game controller?
  - Physical issues, suitability, support, effectiveness, visual desgin
- What have you not liked about the Video game and game controller?
  - Physical issues, suitability, support, effectiveness
- What improvements would you suggest?
- How did you feel when you were playing the video game? (in control?)
- While doing the game, how did you feel about exercising? (Were you aware you were exercising, make it more enjoyable?)
- How would you envisage the Video game and game controller being used in rehabilitation?
  - When could you imagine using the game (at home, outpatient clinic, ?AUT clinic, Susimudges clinic) would you imagine using this game?
  - Who do you think the Video game and game controller would be suitable for? (people who have met through rehab, or other people you know with a stroke)
  - Who is it not suitable for?
  - Would a person who has had a stroke need help using the game or could they manage it independently
  - Who would the help come from (family member, therapist)

Shoe and weighted sleeve

- Can you describe your thoughts about the Shoe you used today?
- What have you liked about the Shoe? Weighted sleeve? Balance shoe?

  - Physical issues, suitability, support, effectiveness, comfort, ease of use, ability to put on with one hand,

- What have you not liked about the Shoe? Weighted sleeve?
  - Physical issues, suitability, support, effectiveness, comfort
- What improvements would you suggest?
- How would you envisage the Shoe being used in rehabilitation?
  - When could you imagine using the shoe (at home, outpatient clinic, ?AUT clinic, Susimudges clinic) would you imagine using this game?
  - Who do you think the shoe would be suitable for?
    (People who have met through rehab, or other people you know with a stroke)
  - Who is it not suitable for?
  - Would a person who has had a stroke need help setting up the shoe, or using the shoe or could they manage it independently
  - Who would the help come from (family member, therapist)

13.4. Feedback from P1.2

- Holding the game, in the central position as the one-handed system allows, put pressure on my left hand; a lighter material, if possible, could be of benefit for the one-handed patient.

Shoes:
- flexibility, comfort, fit-for-purpose - fantastic, if it can all be addressed simultaneously in stroke rehab. The hinge is crucial for me, as I found the fixed-AFO locked me in, and I walked with an unnatural gait (much more than normal). 3D-Shoes: was chafing at the sole where the AFO ends and the shoe begins (metatarsal area); though I hadn't been able to go for a longish walk in them. Definitely insoles, ...moulded, memory-foam insoles(?), perhaps, as I find loose insoles slip out and are uncomfortable.

- I was just thinking: the material of the 3D- shoe may be slippery when wet, or even when dry..? As I understand it: foot, 3D-shoes, the transparent-AFO to be clipped-on/moulded... or foot, 3D-shoes; could be worn outside. Similarly whether the transparent AFO is worn, or just the white 3D shoes, I have videos on my website showing how I walk: on sand, gravel path, etc. If the 3D-shoes/t-AFO were put in the same situation ..? - I hadn't been able to test it, as I had the wrong-size shoes, and they were pinching somewhere. Slippery surfaces (marble floors, polished floors in showrooms, even lino) can cause me to slip and fall, which I have done before (in NZ, and elsewhere). Shoes have to have quite grippy soles. Looks are one thing, functionality (unfortunately) is my choice of any footwear nowadays.
: Video-Selector showing my walking in 6 situations - I'll be adding to the walking-videos later this year. Orthotists have used them in training, as well as given them to clients; balance & shoes is video 6.

- I've been trying to break-in my new black shoes - the brand is ECCO (the ones I wore yesterday), with Quechua insoles (Spanish brand in Decathlon stores) which I obtained from other shoes, as well as memory-foam, in my left shoe, for bringing to Europe with me. The other NZ-made brand, I mentioned, is Ziera, which after a few go-s with their in-store, shoe-stretcher, and my wearing thick socks when I got them back to further stretch the right side, I find are comfortable. I've had other shoes which were fine when we bought them... but caused an ache (undefined) somewhere in my right foot after a day or so wearing them; so I do not use them anymore.

After the stroke, as I explained yesterday, left and right foot (with the AFO) are different sizes and a challenge to find shoes that fit in the first place, ... are comfortable to walk in for long distances, ... as well as look good to boot.

13.5. Forms

Participant Information Sheet

Study title:	**A Game for Physiotherapeutic Rehabilitation for Stroke Survivors**		
Locality:	**Wellington**	Ethics committee ref.:	**16/CEN/15**
Lead investigator:	**Brian Robinson**	Contact phone number:	**(04) 463 6155**

You are invited to take part in a study a digital game system on the recovery process from stroke. 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.

This 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, whānau, 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 computer controllers and computer games 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 are wanting to know how you find using the computer, the controller and the game. Our aim is that these will be easy to use and understand as well as challenging and rewarding for you. It is also important that the movements made when using the games will help with stroke rehabilitation.
These devices and games are 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 (463 6155)
This research has been approved by the Health and Disability Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We asked you to take part in this research because you have had a stroke that affects your walking but you can walk without someone, beside you, helping you.
The research study will take place at AUT Akoranga North Shore, Physiotherapy Department.
We will ask some questions about you such as how old you are, your ethnic background, how long ago you had the stroke and how the stroke affects you now.
We will show you a computer, a computer controller and a game
You will be asked to use the computer and the control device to play a computer game.
You can play this game for as long as you like and can tell us when you want to stop.
We will take a video and photographs of you using this computer controller and game. This is to make sure that using the controls and the game in ways that will be useful for stroke recovery and not cause harm. Stroke rehabilitation physiotherapists will review these recordings. We will keep the video and photographs securely in the University. Because other researchers will be interested in our research we may show the photographs or a video of you. Your involvement in the study will only be known by the researchers. All photographs and videos will be taken using cameras belonging to the School of Design. The images and videos will be taken off these cameras and immediately after this session and then kept secure in the University computer system.
If we do use photographs or videos of you for presenting our research we will not show any part of you, such as your face, that can tell other people that you have taken part. We will do this by blurring parts of the images and videos.
We will ask you for your thoughts on using the computer control and game. 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 using the game or device. We realize that this can be tiring for you so we ask you can tell that you are wanting to rest or to stop the session. You may be invited to take part again if you would like to help us test changes.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We know that people who have had stroke cannot access stroke rehabilitation therapy regularly. They have to travel to clinics or hospital. We also know that rehabilitation is more effective when it is carried out for several hours throughout the day, every day.
This study is to support people who have had a stroke to provide stroke rehabilitation therapy in their home. This can be by themselves or with the help of carer support or family members.
We are wanting to find out whether this device or game may be useful in stroke rehabilitation. This research is finding out whether you can use it and what you think of it.
This does not replace any other therapy you may be receiving. We are not using the device and game as part of your therapy at this stage. We want to find out whether this might be usable as a therapeutic device.
While you are using the computer and playing the game you will be sitting in a chair. We will want you to stay sitting. We may also ask you to carefully walk while using one of our devices. We will make sure there are no hazards around that may make you trip.

WHO PAYS FOR THE STUDY?

This study is funded by Victoria University of Wellington and the School of Design through medical technology research grants from the Centre of Research Excellence of Medical Technologies.
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 be if you were injured in an accident at work or at home. You will have to lodge 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 anytime.
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 device and game.
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 (the design student) or the lead investigators (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 student's 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.
Work phone: (04) 934 9321
brian.robinson@vuw.ac.nz

24 Hour contact numbers:
Dr Robinson: 029 776 9321
If you cannot contact Dr Robinson, please contact
Associate Professor Edgar Rodriguez: 027 563 6544

If you have other questions, concerns or complaints and wish to contact a Māori support person, you can contact:
Katherine Reweti- Russell, Research Advisory Group – Māori, CCDHB
Work phone: (04) 806 2524

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

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

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

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

Phone:	0800 4 ETHICS
Email:	hdecs@moh.govt.nz

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 ☐	
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	
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 ☐	
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 ☐	
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	
I consent to the research staff taking pictures or video recordings of me and I understand that if used in presentations, these will be altered so that I or my involvement cannot be identified.	Yes ☐	
I understand the compensation provisions in case of injury during the study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	
I understand my responsibilities as a study participant.	Yes ☐	
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: RuiFeng Yeo, Regan Petrie, Amy Buell

Signature: Date:

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

21 April 2016

Dr Brian Robinson
Graduate School of Nursing, Midwifery & Health
PO Box 7625
Newtown 6242

Dear Dr Robinson

Re:	**Ethics ref:**	**16/CEN/5**
	Study title:	Developing Interactive Devices and Games for Physical Therapies in Stroke Recovery

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

— The Participant Information Sheet (PIS) was not tracked, making it difficult to check. Please ensure future submissions are supported with tracked versions of documents.

— The section in the PIS headed, "What are the possible benefits and risks of this study" still does not include benefits and risks to participants therefore this section's title should be changed.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your **next progress report** is due by **20 April 2017**.

Participant access to ACC

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Helen Walker
Chairperson
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
Covering Letter: New Covering Letter indicating to responses and changes made	1	05 April 2016
CV for CI: CI CV	1	11 December 2015
Evidence of scientific review: Peer Review	1	11 December 2015
Protocol: Updated Protocol for Research	2	04 April 2016
Survey/questionnaire: Demographic questions and examples of questions for semi-structured interviews and recruitment information	1	11 December 2015
PIS/CF: Example of Participant Information Sheet and Consent Form	1	05 April 2016
Application		
Response to Request for Further Information		06 April 2016

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

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 *RuiFeng, Yeo* 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 video games that help stroke patients carry out their physical rehabilitation. This research has been approved by the Victoria University of Wellington Human Ethics Committee *[23011].*

How can you help?

If you agree to take part, I will interview you in your office, a meeting room in the School of Design's campus or in a public place, such as a café. 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 designs 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 take 30 minutes. You can stop the interviews at any time, without giving a reason. You can withdraw from the study up to four weeks after the first interview. After this 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, the 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 I will read the notes or transcript of the interview. The interview transcripts, summaries and any recordings will be kept securely and destroyed *3* years after the research ends.

What will the project produce?

The 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.

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 do decide to participate, you have the right to:

- choose not to answer any question;
- ask for the recorder to be turned off at any time during the interview;
- withdraw from the study up until four weeks after your 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:

Student:

Name: RuiFeng, Yeo

University email address: yeoruif@myvuw.ac.nz

Supervisor:

Name: Dr Edgar Rodriguez

Role: Programme Director Industrial Design

School: School of Design

Phone: 04 5636544

edgar.rodriguez@vuw.ac.nz

Human Ethics Committee information

If you have any concerns about the ethical conduct of the research you may contact the Victoria University HEC Convener: Associate Professor Susan Corbett. Email susan.corbett@vuw.ac.nz or telephone +64-4-463 5480.

TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI
VICTORIA
UNIVERSITY OF WELLINGTON

Designing a System for Stroke Rehabilitation

CONSENT TO INTERVIEW

Researcher: *RuiFeng, Yeo , 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: ________________________________