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A Human-Centered Design of a Connected Health System for Older Adults



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At NUI Galway

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Declaration

This thesis is presented in fulfilment of the requirements for the degree of doctorate of Engineering. I declare that this is my own work and has not been submitted to any other university or high education institute, or for any other award in this University.

Where other people have been involved in the work, they have been fully acknowledged. Where use has been made of the work of other people it has been fully acknowledged and fully referenced.

Signature: _____ (Richard Harte)

Month/Year: _____

Abstract

The work outlined in this thesis explores the design of Connected Health devices, analyses the user characteristics of older adults and suggests a design methodology which was then applied to the design of two elements within a Connected Health system. The details of the application of the methodology are described and the effect of its application on the usability, human factors and user experience of the Connected Health system are analysed and discussed. The measured outcomes show that the methodology had a positive effect on the user experience of the tested devices within the system, indicating that taking a Human-Centered Design approach when designing home health devices, particularly for older adults, can be beneficial and can increase the likelihood of technology acceptance. This acceptance could lead to the more efficient and effective delivery of healthcare within the Connected Health domain, thereby easing the burden on more traditional healthcare delivery vectors.

Chapter 1 – Introduction

1.1 Usability, Human Factors and User Experience

Usability, Human Factors and User Experience are all terms that refer to how a user interacts with a product and how the product should be conceived and developed to provide a satisfactory, useful and safe experience for the end user, with the end user defined as the person that receives and ultimately uses the product or service [1]. Usability is a property which describes the extent to which a product can be utilised by end users to achieve specific goals effectively, efficiently and with satisfaction in a particular context [2]. Human Factors (HF) is the field describing human capabilities and constraints, investigating human features, structures and processes involved in interacting with designed artefacts and environments [3]. User Experience (UX) describes all aspects of a user's experience with a product, including the user's perceptions and responses that result from the use or anticipated use of the product [4]. A positive UX provides the user with feelings of pride, value or self-efficacy while on the other hand a negative UX can generate feelings of frustration, disability or stigmatisation [5].

1.2 Connected Health

Connected Health is a healthcare model that focuses on the use of health informatics, communication technologies and home health technologies to enhance and extend care and case management to improve the health of designated individuals and populations with the specific intent of providing the right care in the right place at the right time [6]. Connected Health care is a form of 'collaborative' care, where patients and health professionals work in partnership, promoting self-management of disease and is seen as an alternative to the traditional healthcare model [7]. Connected Health has become a term which represents other similar terms for this model, such as telemedicine, telehealth, mHealth and eHealth. Connected Health devices which allow patients to manage their own health can include blood pressure monitors, diabetes monitors, thermometers, activity monitors, weighing scales and fall monitoring systems. These devices and systems, when combined with an appropriate clinical based Information Communications Technology (ICT) infrastructure can allow users to take control of their own health and wellness in their homes while maintaining contact with a healthcare professional. Connected Health

devices are intended to be used unsupervised in the home by the primary user and may also be coupled or tethered to a smart device such as a smartphone, laptop or tablet. This model of healthcare is becoming increasingly important and popular in order to ease the burden on traditional healthcare services [8, 9] and as such there is a need for well-designed devices which meet the needs and requirements of the user in terms of usability, human factors and UX.

1.3 The Older Adult User

Older adults are a population group increasingly utilising Connected Health products to take control of their own healthcare monitoring and to maintain independent lives [10, 11]. The need for smart technologies, which can provide safe and independent healthcare for this increasing demographic has been one of the main driving forces behind the Connected Health revolution [12]. It is estimated that the world older adult population, those aged 65 or more, will increase by a factor of 3 by 2050 [13]. The older population is growing faster than the total population in practically all regions of the world and by 2050 those aged 65 and over will outnumber those under the age of 14 [14]. In the USA alone, the number of older adults (65+) will double between now and 2030 to 71 million [15]. This population group is more likely to live with multiple chronic diseases, such as heart disease, cancer, stroke, and diabetes thereby requiring more healthcare monitoring and treatment [16]. As a person progresses into older age, perceiving, comprehending and acting upon information from interactive electronic systems can become more difficult. Interfaces on hand held devices can often be crowded with text and characters, have poor contrast, contain many different colours and have small buttons. Age-related declines in visual acuity, contrast sensitivity and ability to discriminate colours can affect reading rates, character and symbol identification and button striking accuracy, even with optimal corrections in place [17]. Age related decline in cognitive domains such as reasoning and memory can affect the ability of the user to process feedback from the device [18]. Deterioration of psychomotor processes such as fine motor control and dexterity can cause problems for users attempting to interact with the physical hardware of the device [19]. Typically between the ages of 60 and 80, a human can expect up to a 50% decline in visual acuity (particularly in low luminance, low contrast and glare environments), a reduction in hearing sensitivity

up to 20dBs, a 14% decline in short term memory and a 30% decline in power grip strength, all of which can impact how one interacts with Connected Health devices [20]. These challenges mean that an older adults' UX with a product can be compromised if the design does not meet their individual needs. It is expected that if this reduction in capabilities is not accounted for in the design of the device, then the user will reject the technology [21].

1.4 Human/User-Centred Design

In order to optimise the degree of fit between the needs and requirements of the user and the demands of a Connected Health device or system, the end user must be placed at the centre of the design process. Human-Centered Design (HCD), also referred to as User-Centered Design (UCD), is a multi-stage design process with roots in the fields of computer science and ergonomics. It is heavily focused on usability engineering, human factors engineering and UX optimisation [22]. The International Standards Organization (ISO) 9241-210 standard describes HCD as an 'approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ ergonomics and usability knowledge and techniques' [4]. The ISO standard specifically recommends six process requirements which a HCD process should meet:

- Explicit understanding of users, tasks and environments
- Involvement of users throughout the design and development process
- Consideration of the whole use
- User-centered evaluation driven/refined design
- Iterative process
- The adoption of multidisciplinary skills and perspectives

HCD especially recognises the importance of incorporating as much human input and end user testing into the process as early and as often as possible. The application of such design approaches has been shown to improve the usability and user experience of many different kinds of systems such as Computerised Order

Entry Systems [23], library web-sites [24] medical imaging devices [25] and mobile health Apps [26]. While these examples show the benefit of HCD and while numerous standards and guidance documents for usability and human factors exist, particularly for medical devices [27], industry practice often sees structured usability and human factors testing as costly and delay-inducing, sometimes leading to failed products or leading to products which are unfit for human use [28, 29].

1.5 The Need for a HCD Approach for Connected Health

While the terms UCD or HCD are often invoked in literature, there does not appear to be a standardised approach [30-32]. This may be due in part to the fact that many guidelines have traditionally been difficult for designers to interpret and use [33]. More recently it was identified that there is a need for guidelines on how to conduct the design and development process for Connected Health devices in terms of usability [34]. Further to this, it has been previously observed that developers of Connected Health solutions are in many cases more engaged with the technical innovation in their systems rather than with their usability [35, 36]. Additionally, the Connected Health industry is seen as a fast moving highly competitive industry [37], highlighting a need not only for devices that achieve adequate levels of usability, but also for devices which can have rapid development cycles associated with them. These cycles need to include efficient and effective HCD activities.

For these reasons, the author recognises a need for a HCD methodology which is grounded in the principles of ISO 9241-210 and which provides designers and engineers with the appropriate guidance on how to apply HCD to Connected Health devices or in their own particular domain. This thesis will propose such a methodology and provide examples of its application to a Connected Health system. The HCD methodology will be applied to the iterative design of a Connected Health system entitled WIISEL (Wireless Insole for Independent and Safe Elderly Living). WIISEL is a wireless smartphone based instrumented insole system which was designed to measure fall risk and detect falls and is specifically aimed at older adult users.

1.6 Thesis Summary

This thesis is comprised of 8 chapters which are outlined below. In the case where a chapter is made up of work from a published or submitted article, a reference to the journal and date of submission/publication was made on the chapter cover page. However, this thesis was not intended to be a ‘thesis by publication’ style thesis.

Chapter 1 – Introduction: This chapter introduces the concepts of usability, human factors, user experience, Human-Centered Design, Connected Health, the older adult user and presents the opening arguments for why a customised HCD methodology is required for Connected Health devices.

Chapter 2 – Human-Centered Design Considerations for Connected Health Devices for the Older Adult: This chapter presents a review of current literature related to Connected Health devices, the older adult user and usability and human factors. At the end of this chapter a structured methodology is presented which was used to influence the design of the WIISEL system.

Chapter 3 – A Literature Review of Human-Centered Design Methodologies Applied to Connected Health Devices and Systems: In this chapter a brief structured review will present the state of the literature in the field of HCD as applied to health technology.

Chapter 4 – A Human-Centered Design Methodology to Enhance the Usability, Human Factors and User Experience of Connected Health Systems: In this chapter a methodology is derived based on ISO 9241-210 which will be applied to the design and development of the Connected Health system WIISEL.

Chapter 5 - Application of a Human-Centered Design Methodology to enhance the Usability of a Smartphone Based Fall Detection System: This chapter presents the results of the Application of the Methodology derived in Chapter 4.

Chapter 6 - A Multi-Stage Human Factors and Comfort Assessment of Instrumented Insoles designed for the Continuous Personalised Assessment of Falls Risk of Older Adults within a Connected Health Infrastructure: In this chapter, a version of the

methodology is applied to an instrumented insole to be used as part of the WIISEL system.

Chapter 7 - Can Home Health Smartphone App Usability Challenges be minimised by a Period of Concurrent General Smartphone Training? A Usability and Learnability Case Study: In this chapter we explore the effect of concurrent smartphone training on a group of older adults who are learning to use the WIISEL system for the first time.

Chapter 8 – Discussion and Conclusion: The thesis finishes with a discussion of the major findings of the thesis, the observed limitations, recommendations for future work and closing remarks.

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Chapter 2 – Human-Centered Design Considerations for Connected Health Devices for the Older Adult

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Connected Health devices are generally designed for unsupervised use, by non-healthcare professionals, facilitating independent control of the user's own healthcare. Older adults are major users of such devices and are a population significantly increasing in size. This group presents challenges due to the wide spectrum of capabilities and attitudes towards technology. The fit between capabilities of the user and demands of the device can be optimised in a process called Human-Centered Design. Here we review examples of some Connected Health devices chosen by random selection, assess older adult known capabilities and attitudes and finally make analytical recommendations for design approaches and design specifications.

2.1 Introduction

When designing healthcare products (systems, devices and services), knowledge of the end users' capabilities and expectations are key design considerations. In order for a product to be successful, these considerations must be addressed before and during the design process. For a new product where no brand loyalties exist, accurate knowledge of how end users will interact with the product may be the key factor separating it from rival offerings. This knowledge can also eliminate design problems and reduce potential user frustration before product release [1].

Usability, User Experience and Human Factors are all concepts that refer to how a user interacts with a product and how it should be conceived and developed to provide a satisfactory experience to the end user. Usability is a property which describes the extent to which a product can be utilised by users to achieve specific goals effectively, efficiently and satisfactorily in a particular context. A usable product is easy to use, easy to learn how to use and easy to remember how to use. The concept of usability was first employed in 1983 for software design and was first described in detail in 1985 [2]. Human Factors (HF) is the field describing human capabilities and constraints, investigating human features, structures and processes involved in interacting with designed artefacts and environments. HF provides models and knowledge to feed the process of developing products that fit human requirements. The basic sciences on which HF is based are physiology, anatomy, cognition and affective and social psychology. User Experience (UX) is the

experience provided by using a product or service. UX encompasses not only the functionality related aptness, addressed by product usability, but the affective and hedonic dimension of ownership and use. A positive User Experience provides the user with feelings of pride, value or self-efficacy while on the other hand a negative User Experience can generate feelings of frustration, disability or stigmatisation. The most widely used definitions of the above terms are summarised in Table 2-1.

Table 2-1: Definitions of terminology employed in User-Centered Design.

Term	Source of Definition	Definition
User Experience	ISO 9241-210 [3]	1 "...a persons' perceptions and responses that result from the use or anticipated use of a product, system or service" 2 "...all aspects of the user's experience when interacting with the product, service, environment or facility"
Usability	ISO 9241-11 [4]	"...the extent to which a user can use a product to achieve specific goals with effectiveness, efficiency and satisfaction...."
Human Factors (Ergonomics)	ANSI/AAMI HE75 2009 [5]	"...the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations"

The three terms described in Table 2-1 are similar but each term can be clearly distinguished when put into context. However, the relationship between all three is not so easily distinguishable. Usability and human factors should be considered the main components of user experience. Table 2-2 on page 14 presents some example observations of the aspects of usability and human factors associated with the use of everyday products and how these affect user experience.

Table 2-2: Common devices and the inter-related roles that usability and human factors play in creating a positive or negative user experience.

System/ Device/ Service	User Experience (UX): What is the overall impression and response?	Usability: How easy is it to use?	Human Factors: How does it look, feel, sound?
Water Faucet	Positive	User is able to turn on the tap and control temperature, on-time and power without hesitation and without instruction	Finish on the taps affords comfortable and effective grip; no great force or awkward physical movement is required to operate the tap
	Negative	Unintuitive controls; no means to effectively control power and on-time; no natural mapping of functions	Sharp edges on taps, slippery surface; user must exert unnecessary force to activate controls
Car Rental Website	Positive	User can freely navigate menus and can navigate intuitively to where they want to go, errors are limited and are easily reversed	Buttons, links and lists are clearly visible, font size is easy to read, colour scheme is agreeable, excessive clicking is minimalised
	Negative	Options are not clearly presented; users have to randomly explore to find correct paths. User has to depend on search bar/help menu	Font is difficult to read, colour schemes make it difficult to process information, users need many clicks to complete tasks
Blood Pressure Measurement Device	Positive	User can put on device easily and quickly initialise measurement through button press or switch; intuitive feedback from display	Font on screen is easy to read; screen brightness is adequate; button requires little force to operate; alarms or beeps are clearly audible and adjustable;
	Negative	Device is not easy to put on; Measurement sequence does not initialise easily or quickly; readings takes too long to show on screen; no audio/tactile feedback	Buttons and strappings are cumbersome and uncomfortable, alarms beeps are too faint or too loud, screen text is difficult to read;

In this chapter, we set the scene for Human-Centered Design, its general role in healthcare and Connected Health design. We will also explore the importance of Human-Centered Design considerations with Connected Health devices specifically with reference to some commonly used devices used by older adults. We will then present an analysis of older adult user capabilities and the changes in perception, cognition, psychosocial and psychomotor performance that occur with ageing. Next we will look at the challenges and design approach that is recommended when designing for older adults. Finally, we will conclude on the benefits of Human-Centered Design guidelines in providing a comprehensive framework for the role of usability, human factors and user experience in the design of any product.

2.1.1 Human-Centered Design: An Umbrella Term

Human-Centered Design (HCD), commonly known also as User-Centred Design, is a multi-stage design process which is heavily focused on human factors engineering, usability engineering and user experience optimisation. Therefore, HCD can be used as an umbrella term to describe how the three terms defined in Table 2-1 are incorporated into the design process. Furthermore HCD also recognises the importance of incorporating as much user input and user testing into the process as early and as often as possible. The definition of HCD is outlined in the ISO standard *Human-Centered Design for Interactive Systems: ISO 9241-210* (Table 2-1). The term “Human” is used as opposed to “User” in order to acknowledge product stakeholders that may not be users and as such the term HCD will be now be used throughout this paper [6]. The guidelines of Human-Centered Design as per the guidelines in ISO 9241-210 are as follows:

- (a) Understand and specify the context of use
- (b) Specify the user requirements
- (c) Produce design solutions
- (d) Evaluate

2.1.2 The Importance of HCD in Healthcare

Humans are prone to errors and some level or instance of error is sometimes unavoidable during technology interaction. Technology must be designed, especially in safety critical situations, to reduce the chance of making an error while also providing the opportunity to recognise and recover from errors when they are made.

The use of technology in the field of medicine and healthcare can compromise safety if the product does not meet high HCD standards. For example, in a usability study of a hand held device for filling out prescriptions it was found that usability associated errors with the device directly contributed to the wrong medication being prescribed to patients [7]. Use errors included incorrect data entry and screen object selection errors. A study of mortality rates before and after the implementation of a Computerised Physician Order Entry (CPOE) showed that mortality rates had in fact increased since the implementation of the system, with data entry related errors cited as a major factor [8]. These examples and others [9, 10], have served to heighten the awareness of HCD and how its successful incorporation into healthcare technologies is of paramount importance.

A lack of adherence to HCD during development can lead to a product recall. For example in a very recent case, a prescription infusion pump (Hospira Symbiq, Hospira Inc., Lake Forest, IL, USA) used to deliver a range of therapeutic agents either by intravenous, intra-arterial or epidural means was recalled by the FDA due to an error with the touchscreen interface [11]. The problems would be familiar to anybody who has experience with a low-medium quality smartphone or a touchscreen kiosk. Sometimes the touchscreen would not respond to user selection, would produce a delayed response or would register a different value from the value selected by the user. Failure of the touchscreen to respond appropriately to user input resulted in delays and interruptions in therapy as well as excess delivery or under delivery of medication.

The advantages of optimizing device design through application of HCD extend beyond improved safety. An FDA report on the importance of Human Factors and usability engineering in medical device design concluded that many device manufacturers have found that the application of a user-centred approach in the design of their products reduces the need for modifications and costly updates after market introduction and offers competitive advantages [12]. The report also added that

“With increased safety, the likelihood of your incurring expenses associated with product recalls or liability is reduced; when Human Factors Engineering/Usability Engineering approaches are used in the design of

devices, particularly if the perspective of users is taken into account, the overall ease of use and appeal of a device can simultaneously be enhanced.”

2.1.3 Connected Health

With healthcare technology in the home, HCD becomes even more critical as patients could be using devices without supervision. Connected Health is a term used to encompass healthcare concepts such as eHealth, telehealth, telemedicine, smart home technology (SHT), digital health and remote care. These terms all refer to the use of health technology to deliver effective healthcare to patients remotely. The first Connected Health centre was founded in Massachusetts General Hospital by Joe Kvedar who defined it as the use of messaging and monitoring technologies to bring care to where the patient is, when the patient needs it through the use of health related data, devices, communication platforms and people [13]. All stakeholders in the process are ‘connected’ by means of timely sharing and presentation of accurate and pertinent information regarding patient status [14]. An increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the Connected Healthcare market. Connected Health is allowing people to independently take control of their own healthcare, all the while enjoying the comfort of their own home. In a study by Geisenger Health Plan it was found that using Connected Health monitoring post-discharge for heart patients reduced readmission to hospital by 44% [15].

A primary user group of Connected Health products are older adults and the need for smart technologies which can provide safe and independent healthcare for this increasing demographic has been one of the main driving forces behind the Connected Health revolution. It was estimated in 2012 that the world older adult population, those aged 65 or more, will increase by more than three times by 2050 [16]. In the future there will be more ‘older adults’, both in absolute numbers and as a percentage of the population. The older adult population is growing faster than the total population in practically all regions of the world (Figure 2.1) [17, 18]. This population group is also more likely to live with multiple chronic diseases [19].

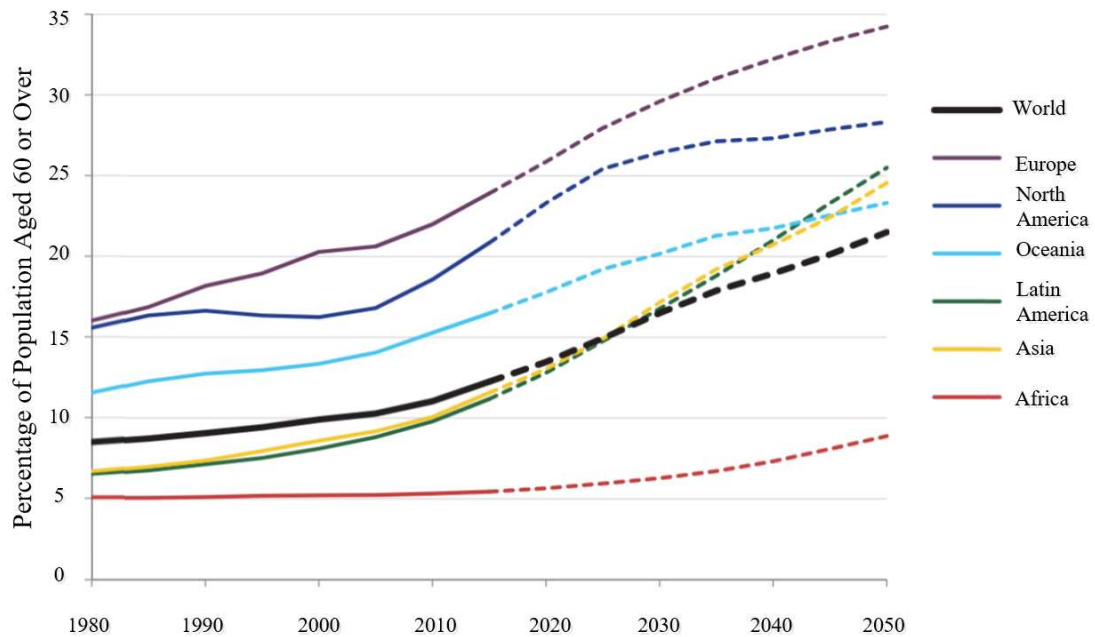


Figure 2.1: Percentage of people over the age of 60 years as percentage of total population by major regions and the world since 1980 to current time and the projected trend to the year 2050 [17]

The need for Connected Health products which can provide effective healthcare for the older adult is considerable given these demographic projections. The success of the Connected Health model and the impact that it can have on people's lives depends on the design of smart usable products that meet high standards of human factors, usability and user experience. These standards can be met most effectively through the pursuit of Human-Centered Design.

2.2 Connected Health Devices for the Older Adult

There is a vast range of Connected Health devices currently available today which are used by the older adult. These devices share many common features; they are typically compact, electronic modules that carry out at least one specific healthcare function. They generally have buttons, switches, screens and speakers *etc.* and are designed to measure some aspect of a person's health status. There may be different levels of interaction, both in terms of complexity and regularity, across a range of devices. It would be useful to identify how the user currently interacts with typical Connected Health devices. We have randomly selected a range of commercially

available today, commonly used Connected Health devices and examined some of their features in the context of the capabilities of the older user.

Common Personal Connected Health Devices

Many Connected Health devices share common features (Table 2-3). Glucometers for blood glucose measurement, usually consists of a device module and an accompanying lancing tool. The lancing tool is loaded with a one use only sterile lancet and cocked, usually by pushing or twisting the base of the pen and also has a feature for setting the depth to which the lance will pierce the skin. Blood pressure monitors typically consist of an inflatable cuff which is wrapped around the arm or wrist with or without a hand held module which displays both systolic and diastolic blood pressure and heart rate.

A pulse oximeter is intended for the non-invasive measurement of arterial blood oxygen saturation and pulse rate. Typically it uses two LEDs (light-emitting diodes) generating red and infrared light. The display typically shows both the percentage of oxygen in red blood cells (SpO₂) as well as the pulse rate. Lung function can be measured using a peak flow meter or spirometer, which measure air flow and lung volumes respectively. Peak flow is measured by simply blowing sharply into the tube and reading off the embedded scale. Some models have indicator lights that illustrate good or bad results. More modern spirometry devices such as the Spirodoc® (<https://www.spirometry.com/>) have multiple built in tests available for comprehensive remote respiratory analysis. The device is the latest in smart home health technology, complete with a touch screen interface. The device has similar functionality and interface to a common smartphone as well as similar weight and dimensions. This kind of device also has a built in activity monitor which can correlate level of activity with respiratory assessment providing information on peak flow and lung volume.

Portable ECG scanners are used within the Connected Health framework to check pulse and to monitor ECG output. The HCG-801 E from Omron is a common example of a portable ECG recorder. Although any weighing scale can be used to record weight at home, the latest in Connected Health weight devices allow readings to be sent to any device via Bluetooth. The PMP4 scale from Omron is such an

example. Body temperature reading is an important part of health monitoring. There are various forms of thermometer available as Connected Health devices. Ear thermometers such as the GentleTemp from Omron are capable of producing an instant read and are convenient for all types of user. Under arm/oral thermometers such as the I-Temp from Omron work simply by placing the tip of the device in the appropriate site and waiting for a period of time, before taking the reading from the LCD display. A pedometer is a continuous monitoring device for measuring step count. It is a useful way to establish activity levels in a given day and over more prolonged periods. Although now commonly available on smartphones, standalone pedometers such as the HJ-720ITC from Omron are still widely used for both casual sports and health care management.

In relation to the kind of Connected Health devices listed in Table 2-3, the general framework of human machine interaction still applies where the user perceives information from a display/device (limited by perception abilities), they process the information to form an impression of the device state (limited by cognitive abilities), they then physically interact with the device (limited by psychomotor skills) this process is illustrated in Figure 2.2.

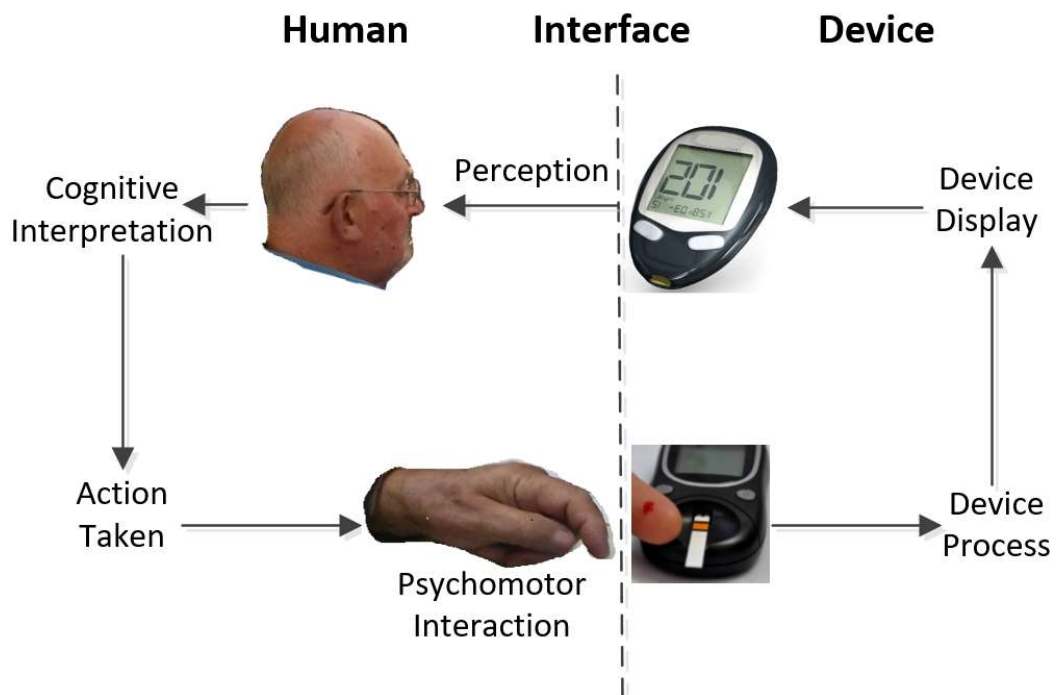


Figure 2.2: The general framework of human machine interaction can be applied to Connected Health devices such as a blood glucose metre.

Thus, effective interaction by the user with the Connected Health device requires that the demanded perceptual, cognitive and psychomotor elements associated with the device do not exceed the skills of the user. As the normal aging process impacts on perceptual, cognitive and psychomotor skills, it is clear that the skill level demanded by the device must be carefully designed to reflect this change. This is the basis of Human-Centered Design. With proper application of HCD, the design of a device can be modified to be either less dependent on the abilities of the user or more accommodating of changing capabilities. The next section will characterise the older adult user group by discussing and highlighting the various changes that occur in terms of perceptual, cognitive and psychomotor abilities as one ages.

Table 2-3: Examples of Connected Health Devices, the typical input and outputs of the devices and the general level of interaction required

Connected Health Devices	Functional Analysis	Device Controls	Device Output Elements
Blood Pressure Monitor	User must sit still in an upright position and place the cuff on the bare skin ensuring that the arm is in such a position that the cuff height is level with the heart. User reaches and presses the start button on the unit when complete readings will then appear on screen. The displayed value is read, interpreted, and acted upon.	Buttons, arm/wrist cuff	Screen symbols and alpha/numerical characters, audible tone indicators, light indicators
Glucose Meter/Lancet	Device is powered on via main button. The lancing device is cocked and the depth set. The head of the device is pressed against the skin and a button is pressed which fires the lancet. Blood sample is placed on a test strip and inserted in the device. Blood glucose level in the sample is measured and value is displayed on screen, audio feature also reads out measurements. The displayed value is read, interpreted, and acted upon.	Buttons, insertion of plastic strip, depth gauge on lancet	Audio tones and verbal feedback, alpha numeric screen characters

Connected Health Devices	Functional Analysis	Device Controls	Device Output Elements
Blood Oxygen Monitoring	Power on the device is typically initiated by simply placing device over the finger tip. Once aligned reading will commence and take a matter of seconds. The fingernail must be right under the LED lights and the finger must be kept still during the measurement. Readings will be displayed on screen. The displayed value is read, interpreted, and acted upon.	Button for power, Finger input	LED light, small screen with alpha numeric characters
Pedometer	Device is initiated using main power button. Variables such as the weight and stride length of the user must be inputted. The device is placed in a pocket, a closely held bag or attached to the belt. Readings are displayed on screen. Audio feedback can also indicate when certain milestones have been reached. The displayed values are read, interpreted, and acted upon. Most devices can store a number of days of measurements and are USB enabled to upload data to a computer.	Buttons for input settings and power	Screen, beeps, small screen with alpha numeric characters, screen symbols, some models with verbal feedback
Spirometer	Unit is powered on via power button and users input their anthropometric details. User can carry device around like a pedometer To enter spirometry mode the user simply clips on the mouthpiece and selects the required spirometry test from the user menu. User breathes into the mouthpiece as per the instructions on the display. Test results are displayed on screen. The displayed values are read, interpreted, and acted upon. User can save the reading on the device under their name or upload it to a computer for further software manipulation via USB or Bluetooth.	Breathing input mouthpiece, buttons, Spirodoc is touchscreen	Screen display, graphical readings, alpha numeric characters, audible tones to signify breathing test sequences
Weighing Scales	The device pairs up automatically with any available Bluetooth device. To initiate the reading the user has only to step onto the scales. The scale calibrates and produces a reading within 3 s and automatically sends the reading to a nearby device via Bluetooth. The displayed values are read, interpreted, and acted upon.	Stand on scales, calibration/mode change possibly required with buttons	Reading appears on screen numeric display, voice feedback

Connected Health Devices	Functional Analysis	Device Controls	Device Output Elements
Thermometer	Device initiated by pressing the On Measure button. Place probe under tongue or in arm pit. When the reading is ready, the device will emit a tone to indicate reading complete, the displayed values are read, interpreted, and acted upon.	Buttons, placement of metallic strip at indicated site	Tones to signify reading, numerical output on screen
ECG Scanner	Powered on by pressing power button on the front of the device. User presses their index finger on the metallic electrodes on one end of the device and then presses the other end of the device against their chest. User presses the start button and must hold position for 30 seconds for the measurement to complete. Readings are displayed on screen. The user is asked whether they want to store the data. The display will show the ECG waveform, the heart rate and a letter from a-m corresponding to what the waveform reading entails about the condition of the heart. The displayed values are read, interpreted, and acted upon.	Power and settings button, placement of finger on metallic strip	Tones to signify reading, alpha numerical characters on display

2.3 The Older Adult User

The rapid evolution of Connected Health has been primarily in response to the increasing need to deliver effective healthcare to the homes of an expanding population of older adults. Before proceeding it is important to define the terms ageing and older adult. Aging refers to the biological, psychological, and sociological changes occurring in human beings as they advance in chronological age [20]. Age related changes in the ability to detect, interpret and respond to visual and auditory information are often sufficient to compromise performance on a wide range of daily tasks [21, 22]. These deficits are sometimes profound but more often are moderate in degree. There is some ambiguity as to what defines an older adult in terms of age given the different rates of change exhibited by individuals. As such chronological age is useful only as an indicator of changing social roles [23]. In the developed world, chronological age plays a prominent role in classifying older adults as a population group. The age of 65, roughly equivalent to retirement age in most developed countries is said to be the beginning of old age although in many

developing countries it is seen to begin at the point when active contribution is no longer possible which may be a more fitting definition [24]. The rate of age-related change is also a function of other factors such as environment, training and the effects of chronic disease and indeed multimorbidity which is the rule rather than the exception in this population [25].

Numerous studies have explored the potential role of technology to help motivate older adults to adopt a healthier lifestyle. The use of mobile devices and real time computing to collect and provide appropriate information can assist users in managing their own healthcare and to motivate them to improve their lifestyles [26]. This is particularly true in the management of conditions such as obesity, diabetes and heart disease [27]. In terms of activity management, pedometers have been shown to help establish reasonable and visible goals for increasing the physical activity levels of older adults [28]. The same has been shown for wearable accelerometers [29]. Smart home technology can provide two-way communication that can be used for monitoring, health alerts, and other services. Designing technology for the older adult user requires greater effort in understanding the distinctive needs and capabilities of the end user. It is suggested that designers should become familiar with the effects of ageing at several levels [30]. Older adults are a diverse population group with extremely varying degrees of ability and for the most part, are an independent age group in terms of daily living and the associated tasks. There are a range of other factors that influence if a technology will be adopted, often in spite of its demonstrable benefits to users health [31,32]. While beyond the scope of this review consideration should also be given to why some users don't choose the healthy option when it is available and why more people don't use existing proven technologies. A challenge for designers is that current older users are more familiar with mechanical and electro-mechanical devices as opposed to purely electronic devices i.e. smartphones. In the not too distant future we can expect an internet generation of older adults which will no doubt have implications for gerontechnological adoption [33].

In Section 2.2 (Common personal Connected Health Devices, Table 2-3) examples and scenarios of use for common Connected Health devices which the older adult population may utilise are presented. User capabilities will vary across chronological

age in terms of their perceptual, cognitive and psychomotor capabilities and users will respond differently to the demands of the device depending on these capabilities. A useful framework of capability versus demand is shown in Figure 2.3 [34].

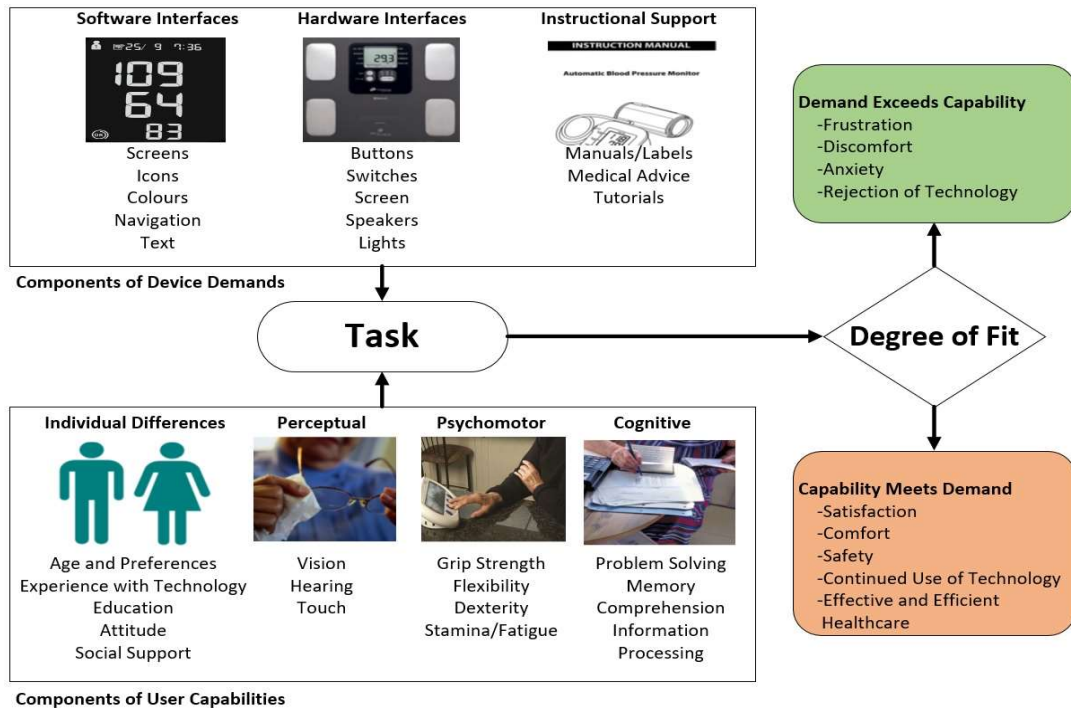


Figure 2.3: User capabilities *versus* device demands

The framework identifies the user components of the device that will create a demand on the perceptual, cognitive and psychomotor capabilities of the user. One of the goals of the design process from a HCD point of view is to create a balance between demand and capability in order for a product to reach a high degree of acceptance. This balance is also referred to as degree of fit. The user capabilities outlined in Figure 2.3 may well change with the chronological age of the user and as such the design of Connected Health devices for the older adult population must be carefully considered. We have already addressed the scenarios of use for various Connected Health devices. We will now identify what kind of changes a person might expect to their user capabilities given a change in perceptual, cognitive and psychomotor abilities.

2.3.1 Perceptual Changes with Ageing

Perception refers to the function of the physical senses such as sight, hearing and touch, smell and taste. In the context of device interaction sight, hearing and touch are the three senses that are responsible for the majority of the interaction with the surrounding environment.

2.3.2 Vision

Nearly all interactions with Connected Health devices involve dynamic visual activities. A measurable degree of vision loss is inevitable as a person ages. Visual acuity is the term used to describe the clarity or sharpness of vision, and can be assessed under different environmental conditions. There are many components to functional vision that are utilised during human machine interaction (Table 2-4). A comprehensive study of 900 subjects between the age of 58 and 102 carried out by Brabyn *et al.*, illustrates the different rates of decline for each of the visual components listed [22]. Table 2-4 shows the “normal young” values for each of the components and then shows the factor by which the components will have generally deteriorated for each of the age groups. High contrast acuity, the standard measure of vision, declines very little even into very old age. The median value for the oldest group is no more than a factor of 2 worse than visual acuity for young adults with a steep marked depreciation only occurring after the age of 75. Components such as LCALL and LCAG show a sharp deterioration after the age of 75

Table 2-4: Measures of Vision performance under different conditions and effect of aging. Numbers indicate the factor by which visual components decline from normal.

Component	Description	Age Profile							
		Norm.	60–65	65–70	70–75	75–80	80–85	85–90	90–95
Low Contrast Acuity (LCA)	The clarity of vision when viewing low contrast surfaces, for example grey scale images are considered low contrast.	20/27	1.1	1.2	1.5	1.8	2	3	4

High Contrast Acuity (HCA)	The standard measure of visual performance	20/20	1	1	1.1	1.2	1.3	1.5	2
Low Contrast Acuity in Low Luminance (LCALL)	Similar to LCA but in poorly lit environment. Home lighting can be as much as 4 times dimmer than a work or office environment.	20/40	1.5	1.7	2	2.5	3	4	6
Acuity in Glare (AG)	The ability to focus vision when competing light sources are present in the environment, sometimes referred to as disability glare.	20/40	1.9	2	2.5	3	3.5	6	18
Colour Discrimination (CD)	The ability to distinguish between different colours.	10 (D-15 Score)	1	1	1	1	1	2.5	5
Contrast Sensitivity (CS)	The ability to visually distinguish an object that is poorly contrasted with its visual surroundings.	1.85	1.1	1.2	1.3	1.5	3	3.5	6

Implications for Interaction with Connected Health Devices

During interaction with Connected Health devices, the loss of visual sensitivity and acuity can lead to difficulties for the older adult when:

- Discriminating colours and contrast on a screen, particularly in low luminance settings.
- Reading small, decorative or poorly weighted fonts.
- Distinguishing between similarly shaped software icons on screens or icons on labels.
- Coping with glare on a screen or maintaining concentration when glare from external sources are present in the environment.
- Reading scrolling text.

- Taking in information from a large field of vision, lack of peripheral vision could have implications for flashing warnings.

2.3.3 Hearing

The decline of auditory function in relation to age is well documented [35, 36]. In the U.S.A., 1 in 6 adults report hearing problems while for people aged 75 years or older this rate rises to 1 in 2 adults [37]. Hearing loss has been linked to fall risk [38] and to cognitive decline [39]. Auditory function is generally measured by the subjective behavioural measurement of hearing threshold. Pure-Tone threshold averages are measured over a range of frequencies and reported as the average minimum pure-tone sound heard in the better ear without background noise. This threshold increases with age, indicative of hearing loss and expressed in terms of Decibel Hearing Level (dB HL) at a specific frequency. Kiely *et al.* studied changes in hearing acuity over a period of 11 years and their results are summarised in Table 2-5 [40].

Table 2-5: Pure-Tone thresholds hearing level (dB HL) at a range of frequencies. Increases in Pure-Tone thresholds hearing level indicate loss of hearing acuity.

At Frequency (kHz)/Age Group (Males/Females)	Young Normal (20 y M)	55–64 years		65–74 years		75–84 years		85+ Years	
		M	F	M	F	M	F	M	F
0.5	7	10	10	12	15	25	28	30	35
1	5	10	10	15	18	27	28	35	35
2	3	15	12	23	20	35	35	45	45
3	4	29	19	39	28	48	40	60	50
4	5	35	21	42	30	58	45	90	58
6	8	45	35	55	45	70	60	85	72
8	10	45	38	63	55	78	70	93	83

Implications for Interaction with Connected Health Devices

During interaction with Connected Health devices, the loss of audio sensitivity and acuity can lead to difficulties for the older adult when:

- Perceiving beeps or alarms that reside above 2 kHz.
- Perceiving low amplitude beeps or alarms.
- Discriminating acoustic cues that are short in duration.

- Perceiving verbal feedback that is not clear and reasonably paced.
- Trying to localise sounds.

2.3.4 Touch Sensation

A tactile threshold is the point at which an external stimulus registers a response in the user and thus is a critical perception in the user experience. As a person ages, the tactile thresholds of various modalities such as light touch, vibrations sense, spatial acuity and pain are increased [41, 42]. Of particular importance is the tactile threshold at the fingertip. Deterioration of spatial acuity at the tip of the finger has implications for interaction with Connected Health devices. It affects the ability to discriminate tactile gaps and bumps as well as the orientation and direction of lines or surfaces [43]. There is a correlation between decrease in tactile threshold and loss of functional dexterity in the hand [44]. This will be addressed in more detail in Section 3.2.1.

Implications for Interaction with Connected Health Devices

During interaction with Connected Health devices, the loss of sensation and fine motor control can lead to difficulties for the older adult when:

- Attempting to manipulate small interface components such as buttons, knobs, levers and battery compartments.
- Perceiving stimuli such as vibration feedback.
- Distinguishing between tactile gaps, bumps and surfaces.

2.3.5 Psychomotor Performance

Psychomotor performance refers to the performance of cognitive based motor control, particularly finer motor control of the upper limbs such as grip, dexterity, coordination, manipulation and mobility. These psychomotor functions are critically important when using small handheld devices. The decline of psychomotor functionality as a person ages can be measured in terms of loss of muscle power, a decrease in range of motion of joints and an increase in the variability of finer motor movements brought about by motor disorders.

2.3.6 Hand Functionality

The hand is an important functional tool in interacting with a Connected Health device. It is responsible for pushing buttons, sliding switches, turning knobs, manipulating clips and catches and a host of other functions. The ability to easily manipulate and control a device is an absolute necessity for the device to adhere to a high standard of HCD. The device must create appropriate demands on the hand. This management of demands becomes an even more critical issue when the older adult hand is involved. A reliable and valid objective parameter of the functional integrity of the hand is grip strength [45]. There are two types of functional grip, the power grip and the pinch grip. The power grip is employed with the hand is grasped around an object, like holding the handle of a frying pan. The pinch grip is when the tips of the fingers are on one side of the object and the thumb is on the other, like when holding a pen [46]. The change in the strength of these grips as one ages is well documented [47, 48] and is summarised in Table 2-6.

Table 2-6: Mean power grip and pinch grip strength (Kg). D is the dominant hand and ND is the Non-Dominant hand.

Component	30–34 years		55–64 years		65–74 years		75–84 years		85+ years	
	M	F	M	F	M	F	M	F	M	F
Power Grip Strength (D)	55	33.8	50	30	42	27.5	33	22	22.4	16.9
Power Grip Strength (ND)	52.5	32.6	49	29	41	27	32.5	21	23.2	16.7
Pinch Grip (D)	9.9	6.9	10	6.8	8.5	6	7.4	4.8	5.4	3.1
Pinch Grip (ND)	9.3	6.7	9.5	6.5	8.2	5.75	7	4.2	5.5	2.8

A comprehensive analysis of age-induced changes in handgrip and finger-pinch strength, ability to maintain a steady submaximal finger pinch force and pinch posture, speed in relocating small objects with finger grip, and ability to discriminate two identical mechanical stimuli applied to the fingertip was carried out by Ranganathan *et al.* [49]. They compared the functional performance of the hand between a healthy independent young group and an older adult group (See Table 2-7).

Table 2-7: Hand functionality. Comparison between a healthy independent young population and older adult group [45].

Component	Definition	Measured by:	Findings
Grip Strength	Main grasping grip	Hand Dynamometer: 3 trials	Older subjects hand grip was 30% weaker ($p < 0.001$)
Maximum Pinch Strength (MPF)	For picking up and holding items	Load cell which measured forces between 0–50 pounds	Older subjects MPF was 26% lower ($p < 0.05$)
Pinch Force Steadiness	Ability to maintain a sub maximal grip for a prolonged period is important for the manipulation of and interaction with everyday objects	Subjects asked to use the load cell to maintain forces at 5%, 10%, 20% of their MPF for a set time	Older subjects were less able to maintain a steady force and their results showed more fluctuations
Precision Pinch Steadiness	Steadiness of the hand while an object is held in the pinch precision	Holding a probe in holes of various sizes the subject was asked to hold the probe without touching the sides of the hole for 20 s. Errors were recorded	Elderly men made 10 times as many errors as younger men ($p < 0.001$) while elderly women made 22 more errors than younger females. This shows a large decline the ability to hold in place a steady pinch
Hand eye Coordination/Hand Dexterity	The ability to coordinate hand movement and the movement of the individual fingers in the necessary configuration to complete tasks	Using one hand, the subject picks the pegs up off the table and places them into the holes on the board, starting with the top left hand hole and completing the board on a column by column basis. This is timed to completion.	Older subject needed 19% more time to complete the peg test ($p < 0.001$)

Component	Definition	Measured by:	Findings
2 Point Discrimination	The minimal inter-stimulus distance required to perceive two simultaneously applied skin indentations as two distinct stimuli. Important for tactile feedback during interaction.	A 2 point aesthesiometer is placed on the index finger and the subject is asked whether they can feel one or two points. The variable is the minimum distance between the two points at which the subject can discriminate two distinct points.	Older subjects needed twice the distance to discriminate the two points of the aesthesiometer ($p < 0.001$)

As well as these functional components, the loss of flexibility in the joints of the lower arm, particularly the wrist leaves older adults vulnerable to cumulative and repetitive strains. The range of motion (ROM) of the wrist declines steadily as a person ages. For example, a person aged between 70–79 can expect to have a decreased wrist flexion, extension and ulnar deviation of approximately 10%, 30% and 10% respectively compared to people aged 25–30 (Table 2-8) [50]. Vulnerability to repeated movement stress is reinforced by the finding that older adults make more hesitant and less fluid movements than younger people. This increases the number of sub-movements during motion adding to the potential risk of repetitive strain [51].

Table 2-8: Range of motion (measured in Degrees) in different age groups. Lower numbers indicate lesser range of motion in the wrist.

Movement	16–30 Years	60–69 Years	70–79 Years	80–89 Years	90+ Years
Flexion	68.6	61.88	61.25	56.50	48.25
Extension	63.6	44.88	44.66	43.55	40.25
Ulnar Deviation	40	39.88	36.08	35.86	29.50

2.3.7 Arthritis and Hand Anthropometry

Arthritis is the greatest contributor when considering limitation of hand functionality. The prevalence of arthritis among older adults is increasing and it limits performance in a wide range of daily activities [52]. Apart from compounding the decline of functionality which we have already discussed, it can make holding or manipulating

large objects independent of wrist range of motion in one hand uncomfortable. This is particularly relevant for Connected Health devices. Anthropometric data might provide useful guidance for the design of containers for users with arthritis. Deformities in the hand caused by rheumatoid arthritis, an extremely common form of arthritis, will affect the interaction a user has with the device. Table 2-9 shows the maximum grip diameter for individuals with and without dexterity related disabilities such as arthritis [53]. Although the definition of grip diameter used in this study does not completely apply to Connected Health devices, it is interesting to note the difference in values between a normal healthy subject and one who is suffering from dexterity impairment such as arthritis.

Table 2-9: Comparison of Maximum Grip Diameter (mm) with and without dexterity impairments. Maximum grip diameter is defined as the maximum diameter of a cylinder that a person can grasp with contact between the thumb and middle finger.

	Gender	5th Percentile	50th Percentile	95th Percentile
No Dexterity Impairments	Male	45	52	59
	Female	43	48	53
Dexterity Impairments	Male	34	40	47
	Female	34	40	48

Implications for Interaction with Connected Health Devices

During interaction with Connected Health devices, the loss of psychomotor strength, dexterity and sensitivity can lead to difficulties for the older adult when:

- Pressing buttons which require a deal of force that exceeds the capability or comfort of the user.
- Attempting to press buttons which are close together or are small in surface area.
- Gripping heavy or cumbersome objects, particularly in one hand.
- Attempting to reach with the thumb across an interface to manipulate controls when holding a device in one hand.
- Making certain gestures when interacting with touchscreens (*i.e.*, pinches and swipes).

- Attempting to attach a device component with one hand without supervision (*i.e.*, cuff on a blood pressure monitor).

2.3.8 Cognitive Performance

While there is a known association between aging and reduction in cognitive performance, there is naturally some debate as to when this change begins [54, 55]. Cognitive decline has been shown not just to be a function of age but also a function of past experience, environment, social situation and education level [56, 57]. There is little accurate quantification of the true rate and prevalence of cognitive decline [58, 59]. In a longitudinal study, Singh-Manoux *et al.* observed certain cognitive processes of five baseline age groups [60]. Subjects were re-tested 10 years later and their cognitive ability rated as percentage change for their original baseline values. Tests included inductive reasoning, short term memory, phonemic fluency, semantic fluency and vocabulary. They found that average performance in all cognitive domains except vocabulary declined across all age groups (See Table 2-10)

Table 2-10: Percentage change in cognitive ability at 10 year follow-up. Each group was their own baseline at initial testing point. A negative number reflects a percentage drop or decline in cognitive ability in the age cohort from their baseline value 10 years previous. A positive number reflects an improvement or increase in cognitive ability in the age cohort from their baseline value 10 years previous. (Neg refers to a negligible difference)

Cognitive Process\Age Group	45–49		50–54		55–59		60–64		65–70	
	M	F	M	F	M	F	M	F	M	F
Reasoning	-3.6	-3.7	-4.1	-4.3	-5.5	-6	-7	-7	-9	-7
Memory	-2.8	-2.4	-3.5	-3.4	-3.6	-2	-4.2	-4.8	-2.8	-3
Phonemic Fluency	4	4.1	-4.8	-3	-4	-4.3	-4.3	-4.6	-4.5	-4.3
Semantic Fluency	3	3.3	-3	-3.2	-4	-2.5	-4.5	-3.5	-4.5	-5
Vocabulary	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	-1	-1

Implications for Interaction with Connected Health Devices

During interaction with Connected Health devices, the change in cognitive functionality can lead to difficulties for the older adult when:

- The display and interface is cluttered or overly complex.
- Feedback is not presented clearly or intuitively.
- There is no adequate labelling or instructional support.
- Manipulating controls gives unexpected results.
- They are asked to remember difficult or complex operational routines.

2.3.9 Psychosocial Factors

The general population can be classified into five technology use categories; Innovator, Early Adopter, Early Majority, Late Majority, and Laggards [61]. According to this classification, late majority and laggards adopt new ideas after the average members of society. Older adults tend to exhibit the characteristics of the latter two classes, the late majority and the laggard. These classes may be more conservative, sceptical, cautious, less educated, isolated, risk averse, traditional, and suspicious of innovations. Although it is clear that technology has a potential to play an important role in promoting independence and improving quality of life among older adults, negative perceptions to technology often prevent the adoption of new

technology in this population group. Older adults are less likely to use technologies that are perceived to be less beneficial and more difficult to use. When it comes to common technologies such as the internet, it has been found that older adults are more unwilling, unable or afraid to use them than the younger population [62]. The same has also been found for assistive technologies [63].

The connection between emotional factors and technology acceptance for older adults has been studied [64, 65]. Most conclusions are born from qualitative based research which is effective if studied and used properly. An excellent example of a qualitative study of the older adult's emotional response to technology was carried out by Kyung o Kim as part of a doctoral dissertation [66]. The study explored how older adults interact with different technologies and looked to increase understanding of factors influencing their emotional and perceptual responses. Three major themes emerged from the interview based analysis; (1) Simple is Better; (2) Complex Works for Some and (3) Why Do I Need this? Users who follow these themes often share similar characteristics and the study reached some interesting conclusions. Firstly, people with rich networks of support from friends and relatives were more likely to embrace complex technology, while people who were isolated or lacking support preferred simpler technology. The conclusion stressed that the social network of the potential user has a profound effect on their perception of technology. Secondly, compatibility of the technology with one's goals and lifestyle appeared to have a major influence on acceptance. Just because a technology was perceived to be useful or easy to use, did not necessarily translate to the user wanting to use it, especially if it did not fit in with their personal goals. Finally, the term trialability was brought into the discussion, a term originally introduced by Everett Rodgers in his 2003 book *Elements of Diffusion* [67]. Trialability can be defined as the perceived degree to which an innovation may be tried on a limited basis, and is related to acceptance. Many older people may not be exposed to or have access to new technologies to try them out which may explain why overall technology acceptance is less in that population group [68]. The study noted that while many people who enter retirement homes or communities may increase their social network among fellow retirees, their exposure to technology from more tech savvy family and friends will decrease leading to only small windows of trialability and therefore decreased chance of acceptance.

Adoption of information technology has been shown to vary greatly with the specific experience of the individual [69]. Self-actualisation and realising one's potential is also an important factor. The confidence with which one approaches a new technology is greatly influenced by cognitive abilities. More recent research has reported that the older subjects took more time to recover from a failure and get more anxious when the tasks are getting more complex [70]. A technology acceptance model specifically designed for older adults, known as the Senior Technology Acceptance Model (STAM), attempts to show the relationship between these factors and technology acceptance (Figure 2.4) [71].

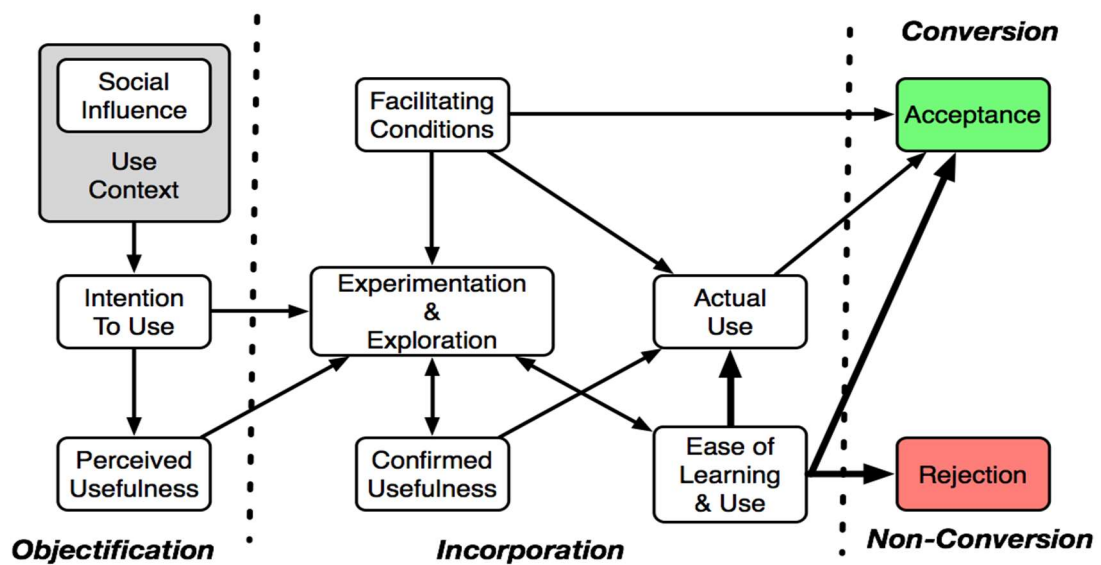


Figure 2.4: Senior Technology Acceptance Model (STAM)

The STAM model consists of three phases; objectification, incorporation, and non-conversion. The objectification phase is influenced by social factors, social and user context and perceived usefulness. The STAM model goes some way to bridging the link between intention to use and actual use by introducing an incorporation phase. The incorporation phase takes experimentation and exploration into account as dynamic factors. Facilitating conditions, confirmed usefulness and perceived “ease of use” are also shown to influence actual use. Facilitating factors, experimentation and exploration show the influence trialability can have on technology acceptance. In the conversion/non-conversion phase, potential users will accept or reject a given technology. The STAM model is meaningful because the model targets older users

who may have unique needs, capabilities, preferences, experiences, and limitations as distinct from young adults.

It is now possible to summarise some of the reasons from a psychosocial aspect, why an older adult may not accept the use of Connected Health devices:

- **Previous Technology Experience:** Lack of familiarity or previous experience with similar devices can cause the older adult to dismiss the device or not be aware of its potential use (no perceived usefulness).
- **Complexity:** Device is perceived to be too complex (no perceived ease of use).
- **Trialability:** Lack of opportunity to use the device experimentally or lack of exposure to new devices in social context.
- **User Context:** The use of the device does not fit in with lifestyle or personal goals.

Social, environmental and emotional factors could play a major part in Connected Health acceptance. Compatibility with personal goals and with current lifestyle may be the most crucial factors. A thorough understanding of older adults' usage and perceptions of Connected Health devices, as discussed here, is essential for maximizing the potential that the devices offer, facilitating independence in the users' everyday life.

2.4 Design Approach and Design Specifications

We have presented the common features of typical Connected Health devices as well as their typical scenarios of use. We have also summarised the perceptual, cognitive, psychomotor and psychosocial traits of the older adult, a key target group for Connected Health devices. Given the information presented on the older users capabilities and normal ageing related decline in many of these capabilities, it is possible to make recommendations both in terms of design approach and design specifications for Connected Health devices.

2.4.1 Design Approach for Connected Health Devices

With such a wide range of technology related capabilities and preferences exhibited by the older adult, it is important that device designers employ an approach which focuses on these characteristics early and often throughout the design process. The best way to achieve this is with early and often user testing. Involving selected end users during the design process is the most effective way of employing design solutions which take into account the capabilities and preferences of the user. These end users can be chosen based on creating profiles of users from activities such as focus groups and ethnography. Table 2-11 describes the general stages in the design lifecycle of consumer products, as per Karowski and Stanton 2011 [72]. The process is most fluid at the start, but as it progresses there are fewer opportunities to make design changes. From a HCD perspective, Stage 1 should identify the high priority user needs which the device must meet e.g., Can the user attach a blood pressure monitor on oneself (one handed) and activate the device to detect, record, and display the reading? In Stages 2 and 3 the needs (from Stage 1) are embodied in functionality of the device through its design. Human factors methods are applied at this Stage 1 and Stage 2, to best fit the user's abilities (perceptual, cognitive, and psychomotor) to the device demand through control and display design (See Figure 2.4) It is preferable to start performing usability testing in Stage 2 using low fidelity prototypes as changes are relatively cheap to make at this point. By Stage 3 there should be comprehensive usability testing.

Table 2-11: Design lifecycle and methods to apply for design of Connected Health devices [72]

Design Stage	Description	Example of approach to use for Connected Health devices
1 Conceptual Design	The concept for the design is proposed with few decisions made about the embodiment of the device	<p>Ethnographic research to observe users in their own environment performing analogous tasks to that of the planned product</p> <p>Focus groups and interviews with users to elicit intelligence about their needs for a planned device.</p> <p>User diaries where they record notes on a daily basis about their current experiences of a medical condition or the treatments/monitors they use</p>

Design Stage	Description	Example of approach to use for Connected Health devices
2 Formalisation of Requirements	The idea becomes more formal with decisions being made on technical features and functionality. The opportunity for design changes reduce considerably.	Heuristic checklists for good design of interfaces for older users Usability tests (e.g., think aloud protocol) with low fidelity prototypes of the device. Participatory design where users give input on their preferences for the device.
3 Design and Prototyping	Virtual prototypes from CAD models are converted to physical prototypes using 3-D printing or other methods for testing. Only critical changes to the design are often accommodated at this point, especially if tooling has been commissioned. The design is finalised and a plan is made for the product development.	Formal usability tests in a lab environment and in the users home Interfaces might be replicated using off-the-shelf technologies.
4 Commissioning	The final design is produced and released on the market.	Few if any features can be changed at this point. It might be possible to change software through online updates.
5 Operation and Maintenance	The device is in use and supported by the manufacturer (if necessary).	Ethnographic testing of the current device to feed into the next generation of the device.

By Stage 4, prototypes, mock-ups and interface card models should be presented to end users. At this point, the window for making major changes to the design is closing and the designers should have already gathered enough information from the testing in previous stages to produce mock-ups that are extremely close to the end solution. By Stages 5 and 6 the final design solution should have been produced and sent to market and only minor changes can be made in the form of software updates, new accessories, adaptable components or instructional updates, with feedback on device usage feeding into next generation devices.

The design life cycle seen in Table 2-11 recognises the role and the input of the user early in the design process. This is the basis of Human-Centered Design (HCD), a

design concept which asks designers to understand the needs and capabilities of the likely users. This implies that the designers can find selected representative users and obtain descriptions of their needs as well as getting them to participate in development teams [30]. The consensus in the HCD community is that there is no way to know in advance which are the particular attributes of a device or service that would make it optimally usable by a target user provided the variety of user profiles and contexts of use. Involving the target users in the product engineering is the optimal approach to assuring that the product will properly meet their needs and fit with their capabilities. HCD represents an alternate methodology to a traditional design approach based on heuristic guidelines and is based on the following four principles:

- **Early Focus on Users:** Designers should have direct contact with intended or actual users via interviews, surveys and participatory design. The aim is to understand users' cognitive, physical, attitudinal, and anthropometric characteristics—and the requirements of the jobs they will be doing.
- **Integrated Design:** All aspects of usability and human factors (e.g., user interface, help system, training plan, and documentation) should evolve in parallel, rather than be defined sequentially, and should be project coordinated.
- **Early And Continual User Testing:** The optimally feasible approach to successful design is an empirical one, requiring observation and measurement of user behaviour, careful evaluation of feedback, insightful solutions to existing problems, and strong motivation to make design changes.
- **Iterative Design:** A system under development must be modified based upon the results of behavioural tests of functions, user interface, help system, documentation and training approach. This process of implementation, testing, feedback, evaluation, and change must be repeated iteratively to improve the system.

The life cycle of HCD, in adherence with the principles outlined above, is shown in Figure 2.5. This is the design process which should be followed for Connected Health devices. To achieve a high level of HCD, a final design solution should not

be considered to have conformed to HCD until at least three iterations have been carried out, as per the cyclical process seen in Figure 2.5.

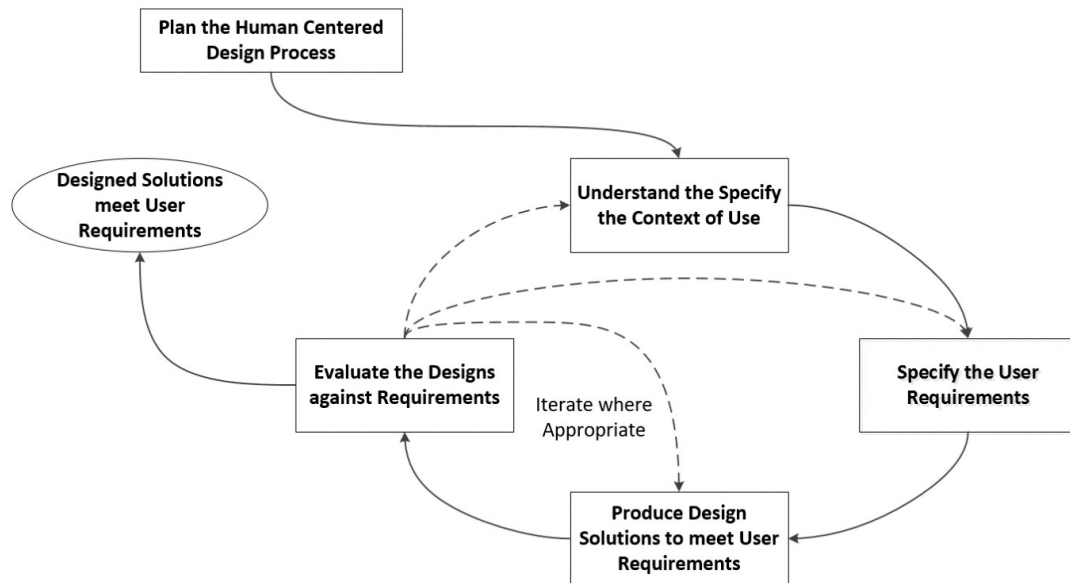


Figure 2.5: The Human-Centered Design Process. The cyclical nature of the process allows for several iterations to take place before a final solution is produced

Companies and organisations should be aware of the HCD process and incorporate as a culture within their business. Iteratively, a variety of policy considerations are involved in the adoption of the proposed HCD process. Policies encouraging or incentivizing the adoption of this approach would accelerate the use. Conversely, development of products with this sort of orientation in turn impact the policy related to the deployment of these technologies.

2.4.2 Design Specifications

Apart from the HCD concepts outlined above, there are also specific steps designers can take to ensure that Connected Health devices conform to a high level of usability and human factors for the older adult. There are a number of general guidelines which should be followed before specific design features are considered.

Display

The display is one of the most important output features on a Connected Health device. In Figure 2.2, we saw how the display is the interface at which device output is perceived so that it can be acted upon. As such, the design and function of displays

will directly contribute to the user experience of the device. We have outlined a range of screen types typically encountered in popular Connected Health devices (Table 2-12).

Table 2-12: Comparison of character sizes and display types for popular Connected Health devices. (Char = Characters)

Device	Display Type	Main Char (h×w)	Approx. Font Size (pt)	Secondary Char (h×w)	Approx. Font Size (pt)	Margin/ Header Chars (h×w)	Approx. Font Size (pt)
Omron MIT Elite (Blood Pressure Monitor)	LCD Black and White	20 × 12	56	12 × 8	34	1 × 2	3
Omron HJ-720ITC Pedometer	LCD	4 × 2	11.3	-	-	-	-
Spirodoc Spirometer	LCD Backlit Touch screen	4 × 4	22	-	-	-	-
Prodigy Autocode Talking Metre	LCD	22 × 7	62	-	-	2 × 1	6
Gentle-Temp from Omron	LCD	8 × 3	22	-	-	-	-
ChoiceMMed Pulse Oximeter MD300C21	Dual colour OLED	7 × 4	20	-	Na	2 × 2	6
HCG-801-E from Omron (ECG Metre)	Graphic LCD high resolution screen with backlight	4 × 2	11.3	-	-	2.5 × 1	7

Connected Health devices are used primarily indoors in the home but may also be used outdoors. For passive LCD screens, common to many devices, lighting levels in the home may often not be adequate for reading comfortably from the screen while

in outdoors environments there are many sources of glare. We know from the information in Table 2-4 that both normal low contrast acuity (LCA) and low contrast acuity in glare (LCAG) will have diminished by a factor of at least 1.5 from the baseline for a typical 70 year old. However from studying the same data we find that high contrast acuity (HCA) will only have diminished by a factor of 1.1. Therefore it is important to incorporate a screen type that not only has low glare and a backlight option but that allows for high contrast between characters and background. The screen should also afford a wide viewing angle. The information on the screen may be read while the user is lying or sitting down with hands by the side. The user should be able to comfortably view and comprehend screen information from a variety of angles. This means that older models of LCD screens should be avoided. Warning information propagated via flashing screen elements or LEDs should be considered to grab user's attention.

Character Size

Even with the increasing use of icons on screen interfaces, much of the critical information of Connected Health devices is presented in text and numerical format. It is clear that text and numerical characters are dominant informational features on Connected Health devices. When it comes to reading characters on a display, there are two important aspects for HCD; legibility and readability. Legibility is more relevant in terms of human factors, in that it determines how easy individual characters are to read. This depends on size, weight and colour among other factors. Readability is defined as how easy it is to read a body of characters, which can depend on layout, justification and colour tone. While optimum character font sizes for the older adult user have not been agreed upon in literature, it is clear that there is some definite size limit below which readability and legibility will become impaired. Darroch *et al.* carried out an experiment where speed and reading accuracy was measured for fonts between 2 and 16 point for both older and younger users [73]. They found that above 6 point font there was little difference in objective performance but subjectively older users preferred a slightly larger font with the optimum and most comfortable range being an 8–12 point font size. Kroehmer *et al.* have also given recommendations for character size when the user is at various distances from the display (Table 2-13) [74].

Table 2-13: Recommendations for display characters from the handbook of occupational ergonomics

Distance of Display from Eye (mm)	Height of Lettering	Approx. Font Size	Width of Lettering
Up to 500	2.5	7	1.875
501–900 (Typical arm length)	5	12–14	3.75
900–1800	9	20–25	6.75

The recommendations in Table 2-13 are particularly relevant to Connected Health devices, given that they are handheld and the user would typically hold them at a comfortable arm's length from the face. The readability of text also depends on contrast and luminance. Table 2-14 shows the relative letter sizes required under different levels of contrast and lighting conditions for two different older age groups [21].

Table 2-13: Recommended minimum optimum text size and weight under different conditions as provided by a Smith-Kettleworth Institute study on older adult vision [21]. There is a sharp difference between optimum character size for a user aged 62 and a user aged 87. Ages are averaged for the two groups studied.

Age	Bright light high contrast	Font Size	Bright light low contrast	Font Size	Dim light low contrast	Font Size	Glaring light low contrast	Font Size
62.5	m	7.5	m	12	m	13.5	m	18
87.5	m	12	m	18	m	24	m	36

Many of the Connected Health devices currently on the market have high contrast LCD screens although many of them are not backlit which may mean readability of characters is dependent on background lighting.

Touchscreens as Displays

The recent evolution of touchscreen means that button size, button layout and font size are customisable. The touchscreen also represents a more intuitive interface as the user is directly interacting with the device controls. However the touchscreen presents its own challenges. For the older adult the touchscreen must have a greater tolerance for error than with a normal user and must not rely on fast or rapid hand movements to carry out functions. The traditional user actions needed to interact with a touchscreen include taps, pinches, swipes and drags. These actions may be problematic for older adult users who suffer from chronic pain or lack of flexibility in the joints of the hand as discussed in Section 3.2. In a study of how the older adult interacts with a touchscreen interface it was found that while older adults are slower than the younger age group they are not much less accurate even when it comes to more complex gestures [75]. Their results showed. They were effectively able to retrace complex patterns accurately, regardless of the three screen sizes presented. Although speed of gesture was slower in the older cohort than the younger cohort, this was not noted as a critical downfall as in some cases it actually prevented errors that the younger cohort were susceptible to.

A similar experiment carried out by Kobayashi *et al.* found that while older adult users improved dragging and pinching performance time by as much as 25% from one week to the next in a two week experiment, tapping small objects was a major problem [76]. Users often tapped outside the target area and introduced error reduction strategies such as exerting more pressure on the screen, carrying out multiple taps to ensure the target was hit or holding their finger on the screen longer than necessary, often confusing the system into initialising a drag or hold command. Sometimes the finger blocked the small target so that the user could not tell if the colour of the target had changed to signify a successful press.

The space between two or more touch sensitive areas is as a factor that could influence user experience. Spacing is a trade-off between button size, desired accuracy, desired reaction time and display size. Jin *et al.* found that using excessive spacing decreased reaction time as users had to spend more time searching the screen [77]. They found the optimum spacing between adjacent elements to be 6.35 mm for older adults. Their findings closely correspond to ISO recommendations, which states that a minimum spacing of 5 mm should be used [78]. Colle *et al.* reported that

1 mm space could be used if the screen has severely limited space [79]. In cases of very limited screen area, 0 mm space can be used without effect responding time although it decreases accuracy and lowers user satisfaction. For capacitive touchscreens, used in most modern smartphones, the need for excessive spacing between elements decreases due to the quality and sharpness of the screen. Big buttons also negate the need for excessive spacing.

Buttons/Switches

Buttons are an almost unavoidable feature of Connected Health devices. Even if a touchscreen is incorporated into the device, buttons may still exist to control volume, locking, on/off, syncing and alarms. Even on most modern smartphones there generally exists a physical on/off button as well as a multipurpose “home” button. Buttons can be considered a weak part of any device. Due to the constant mechanical stress they are often the first part of the interface to breakdown. Poor button design can directly contribute to a negative user experience as we have discussed in Section 2.2 (Common Personal Connected Health Devices, Table 2-2). There are several design specifications than can allow buttons to become a seamless part of the interface. It goes without saying that any kind of button that requires twisting or an uncomfortable level of manipulation should be avoided. Table 2-14 provides a summary of the button size measurements.

Table 2-14: Comparison of the button surface area between the Connected Health devices analysed.

Device	Main Button (h × w mm)	Button Area (mm²)	Secondary Buttons (h × w mm)	Button Area (mm²)
Omron MIT Elite (Blood Pressure Monitor)	16.5 × 41 (power)	676.5	25 × 11 (function)	275
HJ-112 Pedometer	10 × 8 (Mode)	80	8 × 6 (Memo); 4 × 4 (set)	48; 16
Spirodoc Spirometer	27 × 7 (Power)	189	na	na
Prodigy Autocode Talking Metre	10 Diameter (Power)	78.5	na	na

Device	Main Button (h × w mm)	Button Area (mm ²)	Secondary Buttons (h × w mm)	Button Area (mm ²)
Gentle-Temp from Omron	15 × 20 (Power)	300	na	na
ChoiceMMed Pulse Oximeter MD300C21	5 mm Diameter (Power)	19.25	na	na
HCG-801-E from Omron (ECG Metre)	10 Diameter (Power)	78.5	6 × 10 (Side Function)	60

Jin *et al.* found that reaction time decreased with increased button size although it was unclear whether accuracy significantly increased with button size [77]. They found, consistent with other studies, that optimum button sizes resided between 250 mm² and 360 mm². Recommended button sizes, button travel, required press force and distance between buttons were also discussed by Kroehmer *et al.* (Table 2-15) [74]. Buttons are an important feature of many interfaces, Connected Health devices being no exception. Accordingly, the design of Connected Health devices for the older adult should consider issues such as dexterity and repetitive strain.

Table 2-15: Recommended push button characteristics [74].

Button Characteristic	Least Required Value
Surface Area	110–175 mm ²
Surface Area (for an emergency button)	700–1250 mm
Travel (distance button must be pressed to trigger function)	3–10 mm
Spacing Between Buttons	20 mm
Force Required for Operation	2.5–5 N

Audio Feedback

Audio output is primarily used to convey feedback information to the user. The obvious first consideration when designing audio systems on a Connected Health device is to design for adjustability. This specifically refers to volume although it is also a concern that the user may accidentally turn the volume down too low or off altogether, thereby negating the usefulness of reminders, notifications and alarms. Audio feedback can be combined with tactile feedback like vibration and a flashing

screen to ensure that feedback is not exclusively dependent on volume and frequency of audio signals.

From our analysis of the older adult user's auditory response thresholds, it is clear that frequencies above 3–4 kHz cannot be as easily picked up by the older adult ear. Therefore it is recommended that important auditory feedback reside in the range of 500–1000 Hz with an adjustable volume setting. If voice feedback is used, similar sounding terms should be avoided.

Module Size

An important consideration for hand held devices is the size of the device itself in relation to the hand which will be holding it. This becomes especially important for devices that have buttons and switches that may need to be manipulated with the holding hand while the other hand is engaged in another task. This characteristic of a hand held interface is known as reachability. The issue of reachability has come into focus recently with the release of the iPhone 5, which has a screen size of 4 inches compared to the 3.5 inches of the iPhone 4. Apple has said that this increase is possible due to a 20% reduction in the phone thickness, thereby still affording the same grip diameter as the previous model.

It is interesting to compare these data with information in Table 2-8 and Table 2-9 and how the dimensions and weights might affect the reachability of users suffering from conditions which affect the anthropometry of the hand. The care which Apple takes in assuring that the iPhone is completely useable in one hand is an example which should be followed in the design of Connected Health devices. Table 2-16 shows the varying dimensions and weights of common Connected Health devices.

Table 2-16: Size and weight of common Connected Health devices

Device	Module Size (hXwXd)	Weight (g)
Omron MIT Elite (Blood Pressure Monitor)	157 × 74 × 34	270
Blood Glucose Monitor	96 × 52 × 22	55
Pulse Oximeter	58 × 32 × 34	28
Pedometer	73 × 47 × 17	35

Device	Module Size (hXwXd)	Weight (g)
Spirodoc Spirometer	73 × 53 × 16	116
Weighing Scales	101 × 48 × 16	2870
GentleTemp	94 × 45 × 58	50
HCG-801-E from Omron (ECG)	121 × 67 × 24	130
iPhone 6 (As a reference)	138 x 67 x 7	129

2.5 Design Recommendation Summary

In Section 2.4 we have detailed the key common feature sets (display, character size, buttons/switches, audio feedback and module size) of many Connected Health devices in the context of the capabilities of the older user. It is now possible to make some standard recommendations for the design of Connected Health devices for the older adult. The specifications presented in Table 2-17 should be where the design specification standard for Connected Health devices for the older adult begins. Naturally during the design process, user testing will give the designer the opportunity to customize and optimize these specifications based on the feedback received.

Table 2-17: Design Recommendations for common feature component of Connected Health devices.

Feature	Recommendation	References
Screen Type and Screen Lighting	Low quality LCD screens will often display dull tones and have extremely narrow viewing angles, making it hard for a user to see details on the screen if they are looking at them off centre. This can be avoided by either increasing the screen size or installing higher quality LCD and OLED screens in devices, allowing sharper detail and wider viewing angles.	[21]
Colour	The effects of ageing on colour vision perception may significantly diminish the visual effectiveness of certain colour combinations. Make critical elements larger and ensure that they have high luminance contrast with their surroundings. Warnings should not be solely dependent on colour, but also on visual cues such as flashing, labelling and positioning.	[21]

Feature	Recommendation	References
Character Size	With the advent of touchscreens, adjustable text size will become the norm. Our recommendation is that character size should not go below 12 pt on a High Contrast screen interface.	[21,71,72]
Button Surface Area	Designers should aim for button sizes which allow for easy visibility and easy manipulation. Button surface area should typically reside above 150 mm ²	[72,75,78]
Required Button Press Force	<ul style="list-style-type: none"> - Required push force should not exceed 5 N, and should reside between 2.5–5 N. - This is consistent with the AMMI Medical Device Standard, which states that the required press force should not exceed 5 N. 	[5,72,75]
Touchscreen	Touchscreen are a more intuitive way of interacting with a display, but poor quality touchscreens are no substitute for good buttons and as such designers should be wary of introducing a touchscreen just for novelty sake. The touchscreen has to be of good quality in order to prevent user frustration and has to have a big enough screen size so as to allow for adequate spacing between elements. It has been shown that older adults can interact effectively with touchscreen interfaces.	[73,74]

2.6 Conclusion

In this paper, we have discussed and presented a review of the terminology associated with usability, human factors and user experience and how they relate to interaction with everyday devices. We then reviewed some current market Connected Health devices, how they are used and what kind of interface features they have in common. We have also specified the user characteristics of the biggest user group of Connected Health devices, the older adult. We have characterised the older adult user in terms of perceptual, psychomotor and cognitive ability. We have established the common features of Connected Health devices that may present problems for the older adult user given the older adult populations limited abilities and provided our own design recommendations in terms of design approach and design specifications. In carrying out this analysis, we have effectively met, from a theoretical standpoint, the first two guidelines of Human-Centered Design as per the guidelines in ISO 9241-210. The guidelines are as follows:

- (a) Understand and specify the context of use: We have specified a user group and analysed the context in which devices are used and how they are used.

Having specified the user group, we have analysed their requirements based on quantitative data on their perceptual, psychomotor and cognitive capabilities.

- (b) Specify the user requirements: From this data, we produced a set of specific requirements which the design must meet in order to create a degree of fit between device and user; (an example of this is seen in Table 2-17 of Section 2.5)
- (c) Produce design solutions: The next step is to produce design prototypes based on these specifications and present them to the user in the form of user testing.
- (d) Evaluate: Once feedback has been received, the process begins again until all user requirements have been met.

The benefits of adhering to these guidelines are that it provides a comprehensive structure for the role of usability, human factors and user experience as part of product quality. The broader concept of quality in use as an ISO standard increases the business relevance of Human-Centered Design. Companies and organisations should be aware of the HCD process and incorporate it as a culture within their business [6]. Iteratively, a variety of policy considerations are involved in the adoption of a HCD process such as this. Policy encouraging or incentivizing the adoption of this design approach would accelerate the use of it, while creating a product that follows this approach will have a profound and positive effect on future development.

This paper argues that optimal design for the older adult user group can be achieved by following the HCD process and we propose a design methodology for enhanced usability. Figure 2.6 illustrates a suggested methodology, which consists of three distinct phases. In the first phase, the main objective is to gather user requirements, which includes establishing who the users are and in what context the device or system would be used in the form of a Use Case. Once a design solution, which at this point could be in the form of mock-up, has been developed as a result of these user requirements, it is put forward for usability inspection by a group of experts (Phase 2). If the device or system has been found to meet the user requirements it goes forward to phase 3, where it is tested with end users. The whole methodology or individual phases can be repeated as necessary. The number of experts or end

users required required during the test phases (2 and 3) can vary depending on what is being tested, although several publications, including IEC-62366-1 have recommended that at least 10 testers are required for each usability test to uncover at least 95% of usability problems. This methodology and its associated benefits and possible limitations are discussed in upcoming chapters.

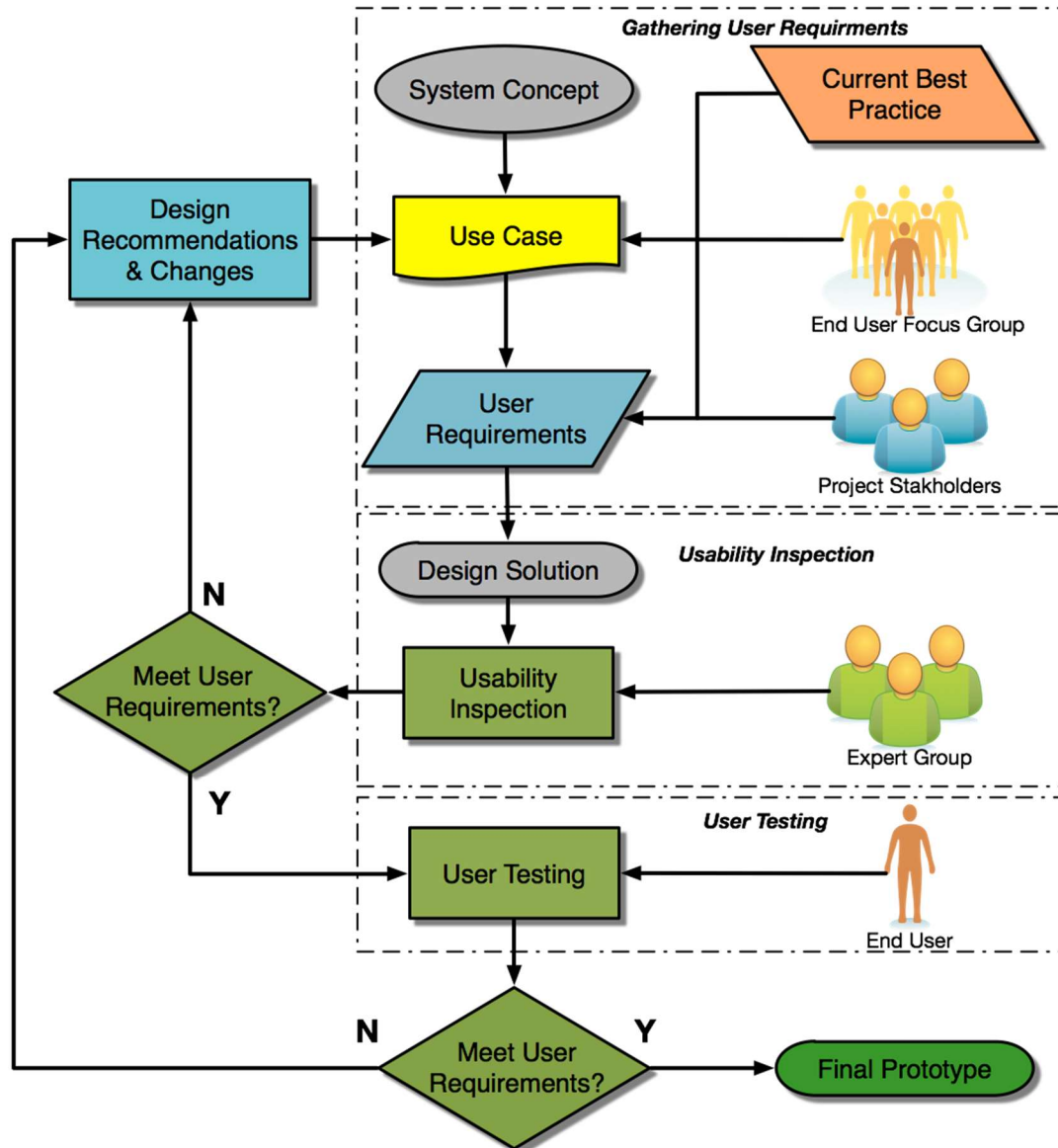


Figure 2.6: Our Design Methodology for enhanced Usability. In this process we utilise Use Cases to document and present user requirements, the usability inspection to allow expert stakeholders to assess design solutions and finally user testing to further validate prototypes

From our review of the Connected Health devices in this paper, it is reasonable to assume that some older adults may struggle with some aspect of their use. Issues with character size, button size, button layout, interface presentation or audio

feedback may be just some of the issues they could encounter. From our review of psychosocial characteristics of the older adult, it is also apparent that this user group may be less likely to have adequate support structures in place to help them operate and maintain these devices. The goal for designers should be to produce devices that need as minimal introduction, maintenance and instructional support as possible. Apart from the design concepts and approaches outlined in this chapter, the starting point for design solutions should rest on the basics of human factors and usability, which we have established are the main components of user experience. Character size, audio volume, colour tones and button size may seem old fashioned and clichéd, but these are the simple interface characteristics which can greatly influence user experience. We have presented some simple guidelines and specifications which designers should regard as a first approximation to the preferences of the majority of older adult users.

The task for organisations which design Connected Health devices is clear. They should strive for the implementation of a Human-Centered Design approach, similar to that shown in Figure 2.6, with explicit involvement of users through the design process. This approach should be embedded in the corporate make-up of medical device organisations. With the number of older adult users increasing, the HCD approach which designs for the vast range of capabilities exhibited by this user group is the most effective and viable way of creating highly acceptable devices.

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Conflicts of Interest

The authors declare no conflict of interest.

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**Chapter 3 – Supplemental Review
Relating to User-Centered and Human-
Centered Design Methodologies**

In Chapter 2, it was established that the older adult user group may struggle with some aspects of the use of Connected Health devices and systems due to an incongruent degree of fit between device/system demands and user capabilities. At the end of the chapter an outline of a design methodology was proposed, which could be utilised to ensure that Connected Health devices achieve high standards of usability, human factors and user experience. However, before elaborating on this methodology, it is necessary to explore the literature to become familiar with current practices such that our methodology can be informed by them. This review will focus on the user-centered and human-centered design approaches which have been applied to the design of Connected Health devices and systems.

3.1 Introduction

The aim of this chapter was to review the work which has already been conducted in the field of Human-Centered Design (HCD) and User-Centered Design (UCD) in the context of designing devices for use within a Connected Health, e-health or telemedicine domain. The review reports on the methodologies which have been used to inform the design of Connected Health devices and systems, and explores the techniques which have been utilised to test and evaluate their usability, human factors and user experience. A structured approach will be used to search the literature.

Within the design process, for an interactive device or system, taking account of usability, ergonomics and user experience, as defined in Chapter 2, is important such that the design solution meets the specific requirements of the user and creates a degree of fit between the user's physical, cognitive and perceptual capabilities and the demands of the device. The importance of optimising this degree of fit has been recognised in various fields since the commercialisation of computers, with System Ergonomics [1] and Cognitive Ergonomics [2] being examples of processes which have sought to take account of user requirements when designing interactive systems. The cost benefits and social benefits of taking a formal user-centered approach to design started to be more widely recognised in the mid-1980s [3, 4]. In 1985, Donald A. Norman provided the first description of User-Centered Design (UCD) and put forward guidelines which designers could follow in order for their

interfaces to achieve good usability outcomes [3]. In 1999, the standard ISO 13407 provided guidance on how to achieve effective usability in the design process by utilising what was termed ‘Human-Centered Design (HCD) [5]. HCD has four defined activity phases; 1) Identify the User and Specify the Context of Use 2) Specify the User Requirements, 3) Produce Design Solutions 4) Evaluate Design Solutions against Requirements. The process model of HCD is illustrated in Figure 3.1.

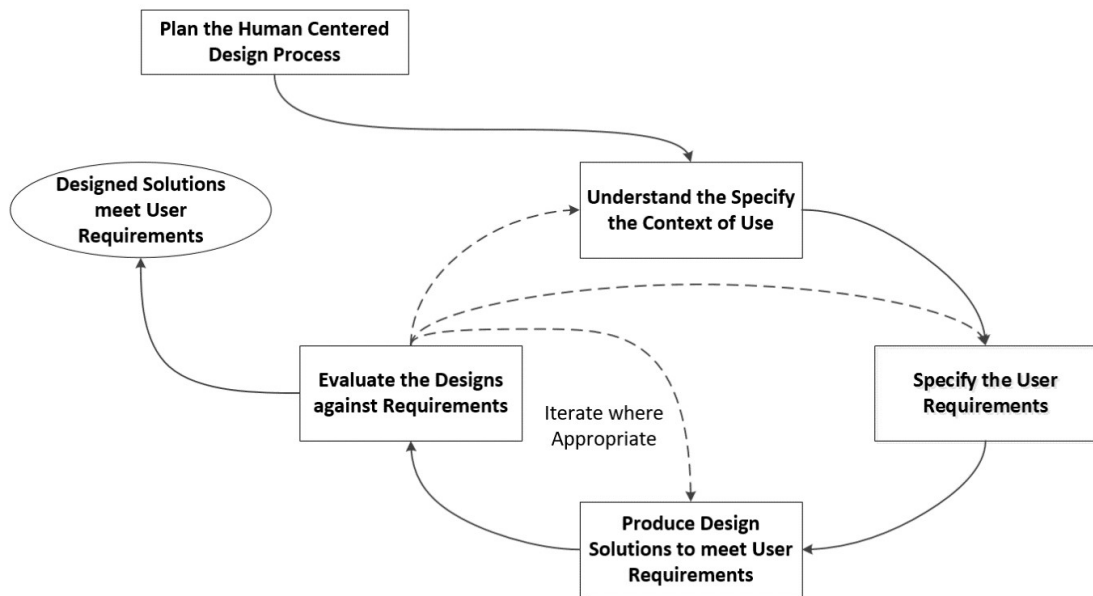


Figure 3.1: HCD has four main activity phases; 1) Specify the User and the Context of Use 2) Specify the Users Requirements, 3) Produce Design Solutions 4) Evaluate Designs against Requirements.

HCD was again formally defined and described in the updated standard, ISO 9421-210 in 2010 [6], replacing ISO 13407. HCD draws on multiple sources of knowledge to support design solutions that are based on the end users’ capabilities and needs. HCD focuses on contexts, people, and tasks that characterize different situations and settings in which the end user will use the device or system [7]. From the field of UCD and HCD emerged new terms and sub-fields, such as Human Computer Interaction (HCI) [8], Interaction Design [9] and User Experience (UX) Design [10].

In Chapter 2 of this thesis, the importance of designing for optimum usability, human factors and user experience was discussed, particularly for healthcare technologies where ‘normal use’ [11] can cause a potential problems for the user if

the demands of the device do not match the capabilities, experience or expectations of the user [12]. Potential hazards linked to usability problems have been documented in a range of healthcare devices and systems, such as common defibrillators [13, 14] and medical infusion pumps [15, 16]. These and other examples [17, 18], show clear links between usability problems and use hazards for the user. It has also previously been reported that many healthcare products fail due to a lack of a systematic considerations of human and other non-technology issues in the design and implementation processes rather than due to flawed technology [19].

The goal of this review was to explore what particular methodologies have been employed in the literature to influence and enhance the usability, human factors and UX of Connected Health devices and systems under the banner of a HCD or UCD process. What kinds of activities are being used? At what point in the methodology are they being used and for what reason? Is there a standard approach being employed or is there a great deal of variation? Are any standard guidelines being referenced or followed? How is the end user being incorporated into the design process? These questions will be answered in the following sections. A secondary objective of the review is to pay close attention to methodologies which have been employed in the design of devices or systems for older adults.

3.2 Methodology

A scoping exercise was carried out, which involved searching Scopus, Science Direct, PubMed and Google Scholar using keywords associated with the subject area. From this exercise, a list of search terms were generated. These search terms were put forward for consideration and discussed by the research team. Table 3-1 shows which search terms were eventually chosen and in what combination they were placed into the databases. The following databases were searched, Scopus, Pubmed, Embase, Science Direct, Web of Science and IEEE Explore.

Table 3-1: Search Criteria for Systematic Review

Search	Operator	Terms
All fields	-	usability OR “human factors” OR “user experience”
All fields	AND	mobile OR wearable OR portable OR “cell phone” OR “smartphone”
All fields	AND	“human-cent??ed design” OR “human cent??ed design” OR “user-cent??ed design” OR “user cent??ed design” (to account for difference in UK and US spelling of centered and to account for the fact that some authors do not hyphenate ‘user-centered / human-centered’)
All fields	AND	mhealth OR telemedicine OR telehealth OR “Connected Health”
Limit	Time	2000 - 2015
Limit	Language	English
Limit	Source	Journals
Limit	Doc Type	Article

Table 3-2 (Initial Search column) shows the number of results returned in each database by using the search combinations in Table 3-1. The abstract for each of these articles was read. If no reference was made to either a UCD, HCD or some form of ‘user-centered’ design and evaluation methodology, or if no reference was made to a health device or system, the article was removed from further analysis (Abstract Analysis).

Table 3-2: Results of Systematic Search

Database	Initial Search	After Abstract Analysis
Scopus	81	37
PubMed	2	2
Science Direct	7	4
Embase	4	4
Web of Science	4	4
IEE Explore	4	0
Total Excluding Duplicates	87	30

3.3 Results

30 articles were reviewed. Of these 30 articles, 16 referenced UCD or HCD but did not describe a methodology. 14 articles described a design methodology with each of the steps outlined in detail. The purpose of this review is to review design methodologies, therefore the 14 articles which describe a design methodology will now be summarised.

Van Osch et al. described a four phase user-centered methodology to design iVitality, an online research platform for home-based health monitoring [20]. In Phase 1, semi-structured interviews were carried out with end users to provide insight into their motivation for and their potential acceptance of using iVitality. In Phase 2, a focus group with six participants elaborated on expectations and preferences regarding iVitality. Findings from Phase 1 and Phase 2 were combined in two semi-structured interviews in Phase 3. In Phase 4, four participants assessed the usability of the smartphone application using a think aloud procedure and a Likert type questionnaire measuring ease and efficiency of use.

Sanchez et al. described the design of a multimodal tool for tele-monitoring patients with COPD (Chronic Obstructive Pulmonary Disease). They utilised an iterative UCD methodology to implement a prototype that satisfied users' requirements [21]. Five distinct phases were described. Phase 1 was a planning and requirements gathering phase and included a field study to study the needs of COPD patients. In Phase 2, input was gathered from experts in the relevant field. In Phase 3, using concrete requirements gathered in Phase 1 and 2, paper prototypes were iteratively used by software designers to create a functioning high-fidelity prototype. This high-fidelity prototype was then exposed to usability testing in Phase 4. Nine subjects were divided into groups of 4 and 5 and two types of sessions (focus group and individual) were conducted. The participants completed tasks with the prototype using a think-aloud protocol and filled out questionnaires to measure satisfaction. They then participated in a semi-structured interview at the end of the testing session. The results from Phase 4 were communicated to the designers to finalise the prototype for release in Phase 5.

Trianafyllidis et al. described a design refinement methodology for a mobile heart failure monitoring system for use in the home by older adults [22]. The authors described an iterative approach for refining an existing system which was informed by ‘Action Research’[23] and ‘Agile Development’[24]. The initial design of the system was based on a two stage process. In the first stage, requirements and specifications were outlined by a group of six experts (two clinicians, one social scientist and three engineers), then in the second stage workshops were carried out with end users who were exposed to mock-up prototypes before a functioning prototype was built. The refinement methodology consisted of four overlapping and complementary phases. In Phase 1, the needs of users were analysed by carrying out interviews and asking patient users for feedback during their routine clinical visits or during home visits by a researcher. In total 26 users were consulted. In Phase 2, using the feedback from Phase 1, new features were designed and coded for the system. In Phase 3, the newly updated system was introduced to the 26 users. In Phase 4, a usability evaluation was carried out using interviews, logging task completion times and gathering satisfaction ratings from the 26 users.

Peischl 2015 described a UCD testing methodology for a mobile medical App [25]. The article emphasised the importance of early end user involvement, particularly within a fast-paced and innovation-driven setting, when there are ‘rather fuzzy requirements’. The early feedback of potential users was seen as a way to considerably improve the quality of the resulting product. The process consisted of two phases. In Phase 1, questionnaires and interviews were conducted with eight end users (three nurses, three physiotherapists and 2 doctors), while in Phase 2, an evaluation of the user interface of the App was conducted with the same eight end users. The usability evaluation consisted of a task-based analysis of the mobile interface, where metrics such as task completion rate were recorded.

Gkatzidou developed a mobile App for sexual health interventions for young people [26]. Their methodology had three phases. In Phase 1, a prototype was developed in response to feedback gathered from preliminary qualitative interviews with end users (n=25) and cross disciplinary reviews by experts in the field. This prototype was then exposed to end users in a series of focus groups (nine focus groups involving 49 target end users). These sessions were used to further identify and enhance the range

of preferences for user interface design features for the App. The feedback from the focus groups was used to update the prototypes in Phase 3.

Nicolas-Rocca et al. utilised a three phase design methodology to develop an e-health system to improve patient understanding of their condition and care at discharge [27]. In a preliminary phase, the authors identified challenges with patient education prior to or at the time of discharge using a satisfaction measuring survey which was distributed to 986 patients who had just been discharged from an emergency room. Likert scales were used to measure satisfaction. Three phases of design were then carried out to develop the system. In Phase 1, a visual aid system (a paper prototype) was developed and was introduced to patients. During this intervention period, patients were again surveyed (n=1043) and physicians were also interviewed to gain feedback on their use of the new visual aid system. In Phase 2, a web-based form of the first paper prototype was created based on the feedback from Phase 1 and this prototype was evaluated in a series of focus groups (n=49). In Phase 3, the design was then modified based on the focus group feedback.

LeRouge et al. suggested a five phase design methodology for the design of general Consumer Health Technologies (CHT) for older adults [28]. This article emphasised the importance of creating user profiles. These profiles can be used to describe the characteristics of the user in order to generate user requirements. The authors described the first two phases in detail and recommended that the findings can be used to drive the final three phases of the methodology (which was not described). In Phase 1, user requirements were gathered using focus groups, interviews, field observations and surveys. Direct observations were carried out of the target end users during recreation activities and during visits to clinics where diabetes patients were being treated. Semi-structured interviews were carried out with medical care professionals who directly serve the end user. From this feedback, Phase 2 saw the development of user profiles to illicit specific requirements for different user groups. In Phase 3, prototypes would be developed and then in Phase 4 the prototype would be evaluated using user testing. In Phase 5, the updated prototype would be implemented.

Vermeulen et al. applied a five phase iterative user-centered development methodology to design an monitoring App which provided feedback about changes in physical functioning and was targeted at older adults [29]. In Phase 1, three ‘user representatives’ were selected to form part of the design team (these were older adult end users). In Phase 2, a geriatrician, a geriatric nurse, a geriatric physiotherapist, a nursing home physician and a social gerontologist were selected to advise the development team during four discussion meetings regarding important characteristics of potential users of the App. In Phase 3, group meetings were organised with the representatives from Phase 1, and requirements were discussed and prioritised. A workshop was then organised for 24 additional end users where they discussed these requirements, with additional requirements added if required. In Phase 4, a prototype interface was developed using the requirements gathered in Phase 3. Finally, in Phase 5, this prototype was evaluated using a two part usability evaluation. First, a group of eight inspectors (three system developers and five non-experts) carried out a heuristic evaluation of the interface using Nielsen’s ten heuristics. Secondly, the group of older adult end users, who participated in the Phase 3 workshop, participated in a task based usability test of the updated prototype, utilising a think aloud procedure and completing satisfaction questionnaires.

Taylor et al. described an eleven phase UCD methodology which was applied to Digi-Switch, a web-based health information database [30], In Phase 1, a web based questionnaire (n=300) was circulated to gather requirements. In Phase 2, a comparative analysis was carried out of three similar websites, examining functionality, navigation and usability. A prototype was then created in Phase 3. In Phase 4, a cognitive walkthrough was carried out of the prototype followed by Phase 5 which consisted of a heuristic evaluation based on Nielsen’s heuristics. Usability testing with 20 end users was carried out in Phase 6, where metrics such as task completion rate and satisfaction (using Likert type questionnaires) were measured. The feedback from that series of evaluations was used in Phase 7 to modify the prototype. A content test was carried out in Phase 8 to assess the readability of the website. Expert testing of the prototype with nine members of the organization’s management team was carried out in Phase 9. A final evaluation with a usability

expert to evaluate the site's compatibility with certain guidelines was carried out in Phase 10. Final modifications to the prototype were then implemented in Phase 11.

Ross et al. described the design of a personal medical management App for a tablet interface for older adults [31]. Their methodology consisted of two phases, a Design Phase and a Prototyping Phase. In the design phase, 29 individual interviews were carried out with potential end user (12 with primary users in a home setting, 15 with primary end user in a hospital setting and two with family caregivers). Four group interviews were also carried out with 27 primary users. Storyboards and prototypes were developed from the feedback gathered in the Design Phase. In the Prototyping Phase, seven participants (five older adults from the target user group and two caregivers) participated in an individual prototype evaluation exercise. Two group evaluation sessions were also conducted with nine older adults from the target user group and three caregivers. Six further rapid iterative testing and evaluation sessions with a total of 22 primary users and nine caregivers were also carried out. The format or procedures used for these sessions was not described.

Govercin et al. described a user-centered development process to develop a wearable, optical fall prediction and fall detection devices for home use by older adults [32]. The first phase consisted of semi-structured interviews during three focus group discussions with 22 participants. This was used to illicit user requirements for fall detection devices for older adults. The purpose of this article was to just to describe the elicitation of the user requirements for the system and no further design phases were described.

Fonda et al. described the development of a Personal Health Application (PHA) for diabetes self-management [33]. The design process consisted of four phases. In Phase 1, focus groups were carried out with people with diabetes (n=21) to ascertain their needs for a PHA. A prototype was then developed in response to these needs in Phase 2. In Phase 3, through additional focus groups and step-by-step demonstrations with people with diabetes as well as with healthcare providers, feedback was obtained about the prototype. In Phase 4, the feedback from Phase 3 led to changes in the PHA's presentation and function.

Arsand et al. developed a mobile phone-based self-management tools for type 2 diabetes [34]. A design methodology based on ISO 92410-210 (then ISO 13407) was utilised which consisted of five phases and was based on a methodology from a previous publication [35]. Overall the total design process lasted just over one year and the same twelve participants were involved in each phase. In Phase 1, focus groups were carried out to identify user needs. In Phase 2, the context of use was analysed and paper prototypes were evaluated in focus group and workshops. In Phase 3, patient requirements were specified through the use of scenarios and storytelling. In Phase 4, a design solution was produced. In Phase 5, the solutions were evaluated in user testing (with the same 12 participants), with the System Usability Scale (SUS) [36] utilised to measure the usability of the system.

Johnston et al. developed a web-based interface for self-monitoring of exercise and symptoms for older adults with COPD [37]. UCD principles guided the four phase development process of a set of integrated tools for symptom self-management. In Phase 1, individual semi-structured interviews were conducted with participants who had completed a 6-month study on Internet-based dyspnoea self-management. In Phase 2, a targeted review of publicly available self-monitoring tools was conducted and paper prototypes were developed. Usability testing of the prototypes was carried out with three end users. Phase 3 was dedicated to full-time software development of a functional prototype. This was then tested in Phase 4 using field usability testing with three end users. This was a task-based analysis which followed a think aloud procedure. Results of Phase 4 were analysed in the context of Nielsen's Heuristics and satisfaction was measured using Likert scales.

Of the 14 articles discussed in this section, nine explicitly used the term User-Centered Design or Human-Centered Design. Others used terms like user-centered development [32] or user-centered methods [34]. One referenced the standard ISO 9241-210 [34]. Four out of the 14 papers described devices or systems which were specifically aimed at older adult users, which included a mobile monitoring tool for heart failure [22], an activity monitoring system [29], a medication management App [31] and a fall detection device [32]. The main features of each of the 14 described methodologies are presented in Table 3-3.

Table 3-3: An ✓ indicates that this activity was carried out within the methodology. Where applicable the number of participants or nature of the activity are also indicated under the ✓. An X indicates that there is no record of this activity being carried out in this methodology.

Author / Year	# of Phases	Interviews with end users	Ethnography (field studies)	Focus Groups / workshop	Use Case /Storyboards / Use Scenarios / User Profiles	Quest... / Survey	Usability Reviews/ Inspections with experts	User Testing with end users	Prototypes (Type)
Van Osch et al. 2015	4	✓ Phase 1, n=6. Phase 3, n=2	X	✓ n=6	X	✓ In user testing to measure efficiency and ease of use with Likert scales	X	✓ n=4 think aloud	✓ Functional
Sanchez et al. 2015	5	X	✓ unspecified length	X	X	X	✓	✓ n=9 think aloud	✓ Paper and functional
Trianafyllidis et al. 2015	4	✓ n=26	X	X	X	✓ satisfaction ratings from Likert items during user testing)	✓ n=6	✓ n=26	✓ Mock-up screens

Table 3-3 cont...

Author / Year	# of Phases	Interviews with end users	Ethnography (field studies)	Focus Groups / workshop	Use Case /Storyboards / Use Scenarios / User Profiles	Quest... / Survey	Usability Reviews/ Inspections with experts	User Testing with end users	Prototypes (Type)
Peisch et al. 2015	2	✓ n=8	X	X	X	✓ one-on-one n=8	X	✓ n=8 think aloud	X
Gkatzidou et al. 2015	3	✓ n=25	X	✓ focus group n=49	X	X	✓ n=?	X	✓ Axure™ Software
Nicolas Rocca et al. 2014	3 (1 prelim phase)	X	X	✓ focus group n=39	X	✓ survey in Phase 1, n=986, repeated in Phase 2, n=1086	X	X	✓ Phase 1, Paper Phase 2, Electronic

Table 3-3 cont...

Author / Year	# of Phases	Interview	Ethnograph.	Focus Group / workshop	Use...	Quest... / Survey	Reviews/ Inspections	User Testing	Prototype
Vermeulen et al. 2013	5	✓ n=3	X	✓ workshops n = 24	✓ User Profiles	Post-Study System Usability Questionnaire (PSSUQ)	✓ review of requirements n=5 Heuristic eval. n=8	✓ n=24 think aloud	X
LeRouge et al. 2013	5	✓ n=30	✓ 40 hours of observations	✓ Focus groups n=54	✓ user profiles of older adults with diabetes	X	X	✓ n=?	✓ Unspec.
Taylor et al. 2011	11	X	X	X	X	✓ web based questionnaire n=300 (15 responses) Computer-SUS during user testing	✓ Group Reviews Phase 9, n = 9 Phase 10, n=1 Heuristic eval. n=? Cog. Walk. n=?	✓ n=20	✓ Funct.
Ross et al. 2011	2	✓ n=29	X	✓ Focus groups n=27	✓ storyboards	X	X	✓ n=41	✓ Unspec.

Table 3-3 cont...

Author / Year	# of Phases	Interviews	Ethnography (field studies)	Focus Group / workshop	Use Case /Storyboard /Scenarios / User Profiles	Ques / Survey	Usability Reviews/ Inspections with experts	User Testing with end users	Prototypes
Govercin et al. 2010	n/a	✓ n=22	X	✓ Focus groups n=22	X	X	X	X	X
Fonda et al. 2010	4	X	X	✓ workshop n=21	X	X	X	X	✓ Funct.
Arsand et al. 2010	5	✓ n=12	X	✓ Focus groups n=12	✓ Storytelling and use scenario definitions	✓ SUS used during user testing	X	✓ n=12	✓ Paper and functional
Johnston et al. 2009	4	✓ n=8 interviews also conducted after user testing	X	X	X	✓ Likert scales during user testing	X	✓ n=3 think aloud	✓ Paper and funct.

3.4 Discussion

The results of this structured review has summarised the various design approaches which are being employed in the recent literature to inform the design of Connected Health, telehealth, e-health and telemedicine devices and systems. While, there is some degree of variability in the methodologies, particularly in terms of how many phases are implemented and in terms of what kind of activities are carried out (see Table 3-3), there is also a large degree of commonality. In general, the methodologies are usually organised into an early phase where user requirements are gathered through the use of interviews, focus groups and field studies, an intermediate phase(s) where low fidelity prototypes are tested in some format such as expert reviews, usability inspections or focus groups and an advanced phase(s) where high fidelity prototypes are tested with end users in user testing. All of the methodologies, strived to include the end user in the process. They also strived for an iterative approach where prototypes are updated after certain phases within the methodology. Many also tried to incorporate the input of multi-disciplinary teams [22, 29].

3.4.1 Design and Testing Activities

There was a range of activities (Table 3-3) which were utilised within the design methodologies. These activities can be split into five distinct categories.

Understanding the User and Context of Use (Interviews, Focus Groups and Observations): These activities are usually carried out in the early phases of the methodology. Discussing preferences, requirements and experiences with the end user in the form of interviews or focus groups is usually the first activity in a design methodology and was utilised as an early activity in 13 of the 14 articles. Structured/open-ended interviews and focus groups can allow the user to voice their needs and goals for the system [38, 39]. The use of ethnography [40, 41], which entails becoming immersed in the lives and behaviour of the target end user to better understand their user requirements was utilised effectively by Sanchez et al. for their COPD App [21], and by LeRouge for the design of CHTs for older adults [28]. These activities can illicit rich seams of data, which can be used to generate

requirements. Surveys can also be used to reach a wide number of people in a quick manner and were utilised by Nicolas-Rocca et al. [27] and Taylor et al. [30].

Generating, Analysing and Prioritising User Requirements: After gathering initial user data, requirements need to be generated and analysed to develop design solutions. Constructing Use Cases and User stories are common activities to analyse and prioritise user requirements and user preferences [42, 43], and were used effectively by Arsand et al. [34] and Vermeulen et al [29], while LaRouge et al. constructed User Profiles to analyse requirements [28]. Storyboards were utilised by Ross et al. to define scenarios of use for their tablet interface for older adults [31].

Producing Prototypes and Mock-Ups: In the early phases of the design process there may be many different possible solutions and concepts that designers could pursue. An easy way to test the user response to these solutions is through the use of paper prototypes and mock-ups. Paper prototypes were utilised by Sanchez et al. [21], Nicolas Rocca et al. [27], Arsand et al.[34], Trianafyllidis et al. [22] and Johnson et al. [37] as a way to quickly develop and evaluate interface solutions. Prototyping software such as AxureTM can also be used to quickly generate and test solutions and was utilised by Gkatzidou et al. [26].

Evaluation and Inspection Methods: Usability inspection, involves a multi-disciplinary expert group inspecting the interface and attempting to identify usability and human factors problems [44]. This can be in the form of a heuristic evaluation where the interface is compared to set of predefined design guidelines [45, 46] or a cognitive walkthrough [47, 48], where the expert group carry out a task by task analysis of the interface while focusing on cognitive processes which the task requires, documenting where they encounter problems [49]. Usability inspections are seen as a low cost and easily implementable techniques than can garner quick and concise feedback [50]. Heuristic analyses (using Nielsen's Heuristics) and cognitive walkthroughs were utilised by Taylor et al. [30] and by Vermeulen et al.[29]. In both of these cases, usability inspection was used as a precursor to user testing.

User Testing: User testing has been greatly described in literature [51-53] and involves monitoring the user while they interact with the system interface. This

monitoring can be carried out in different environments, with laboratory sessions allowing for more control over the experiment and more robust data albeit with the loss of real-world fidelity, while observing users in a more natural use environments can lead to richer data but the data can be harder to quantify effectively. In user testing, the administrator will often ask the subject to think-aloud, allowing the observer to gain an insight into the usability problems a user is encountering, and this technique was applied by Van Osch et al. [20], Peisch et al. [25], and Johnston et al. [37]. Cameras, audio recorders and note taking are used to record the testing, and Likert type scales can be used to measure satisfaction or perceived usability, for example the System Usability Scale utilised by Arsand et al. [34] or the Post-Study System Usability Questionnaire (PSSUQ) utilised by Vermeulen et al. [29]. Efficiency and effectiveness can be measured by recording time taken to complete tasks [22] and error and completion rates [25].

3.4.2 Older Adults in the Design Process

This review did not return a large amount of findings on devices or systems specifically design for older adults within the HCD domain (4 articles). From the articles reviewed, it was found that the designers did make attempts to include the older adult end user in early stage development and this is an approach which will be adopted in this thesis. For example, Ross et al. systematically utilised focus groups and interviews with older adult end users to discuss requirements and present prototype solutions for evaluation and feedback [31], while Vermeulen et al. employed older adult end user representatives in the first phase of their methodology so feedback could be gathered on typical user characteristics and preferences [29]. In a recent review of the involvement of older adults in the development of fall detection system, it was found that until very recently the involvement of older adults in the design process has focused mainly on technical aspects of the systems and that little attention has been given to the specific needs and views of older people in the context of fall detection system development and usage [54]. From the findings in this review it is clear that designers are now making considerable efforts to incorporate older adult requirements into their design solutions.

3.5 Conclusion

This review, even in its relatively narrow scope has shown that there are many different methodologies being employed to inform the design of Connected Health devices and systems in the context of usability, human factors and user experience. The methodologies described in this chapter were all reported as being effective and as such should be considered best practice in the field of UCD and HCD for Connected Health devices and systems. Of course, a design methodology should be tailored to fit the type of device or system being designed and the particular purpose it is being designed for. This might explain the variations in approaches. Thus, in the next chapter, a design methodology will be derived based on the best practices uncovered in this review and which is tailored to meet the design considerations of Connected Health devices and systems and the requirements of older adults.

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Chapter 4 – A HCD Methodology to Enhance the Usability, Human Factors and User Experience of Connected Health Systems

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Having reviewed the relevant literature and studied the characteristics of the target devices and target end users, it is now possible to derive a structured methodology which follows the principles of Human-Centered Design, such that the needs of the user are taken into account throughout the design process, while maintaining a rapid pace of development. In this paper we present the methodology and its rationale, before outlining how it was applied to the design of a Connected Health system. We derived a three phase methodology. In Phase 1 we emphasised the construction of a Use Case document which can be used to detail the context of use of the system by utilising storyboarding, paper prototypes and mock-ups in conjunction with user interviews to gather insightful user feedback on different proposed concepts. In Phase 2 we emphasised the use of expert usability inspections such as heuristic evaluations and cognitive walkthroughs with small multi-disciplinary groups to review the prototypes born out of the Phase 1 feedback. Finally in Phase 3 we emphasised classical user testing with target end users, using various metrics to measure the user experience and improve the final prototypes

4.1 Introduction

Connected Health is a term used to encompass healthcare concepts such as eHealth, telehealth, telemedicine and mHealth, and refers to the use of health technology to deliver healthcare to patients remotely [1-3]. An increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the Connected Healthcare market. In a study by Geisenger Health Plan it was found that using Connected Health monitoring, post-discharge for heart patients, reduced re-admission to hospital by 44% [4], while a similar study by Agboola et. al. reported similar decreases in Heart failure related readmissions of 48% in first 30 days post-discharge [5].

Many Connected Health devices share common features; they are typically compact, electronic modules that carry out at least one specific healthcare function. They generally have buttons, switches, screens (touch or non-touch), speakers and wearable clips/belts and are designed to measure some aspect of a person's health status [6]. Connected Health devices such as wearable heartrate or blood pressure

monitors, can be synced to smartphones with the smartphone acting as a data storage, data transmission and interaction platform.

Connected Health devices have various characteristics which make them unique compared to other health or medical devices, which may be utilised in hospital, clinical or surgical settings [7]. Connected Health devices are designed to be used in an unsupervised manner in the home by users, who may not be specialists in healthcare. Connected Health devices have User Interfaces (UI) which require some level of Human-Computer Interaction (HCI) and they comprise software and hardware elements. Due to the likely use of these devices by disabled, elderly or infirm users, Connected Health devices require UIs with good usability characteristics. There may be different levels of interaction required, both in terms of complexity and regularity, across a range of devices.

So far, we have discussed the increasingly important role of Connected Health devices in healthcare globally [8]. We have established that various Connected Health devices have interface characteristics which could cause problems for older adult users or users with disabilities [6] and we have established that as medical devices, Connected Health devices and systems are unique in terms of context of use and UI requirements [7]. Finally, we have outlined the technical aspects and requirements of HCD. This leads us to the question, “why is all this important for Connected Health system design?” In the context of what has just been discussed, we think there is a need for a customised HCD methodology for Connected Health devices design and now we will further explore why we think this is necessary, by highlighting three specific needs.

4.1.1 The Need for Descriptive Detail and Standardised Structure for Human-Centered Design Methodologies within Medical Literature

We must make it clear that various HCD approaches to the design of healthcare technology have been described in the literature. For example, Vermeulen et al. described a multi-phase HCD methodology for the design of an older adult activity monitor, with the phases including; analysis of users and their context, identification of user requirements, development of the interface and evaluation of the interface in the lab [9]. Schaeffer et al. employed a HCD methodology where they used surveys

and focus groups to gather user requirements and create interface prototypes for an insulin pump [10]. Castilla et al. described a HCD process for a tele-psychology app, where they presented end users with icon and interface concepts in the first step of their design process, before moving onto a cognitive walkthrough methodology to evaluate the navigation of the interface. These, and many other examples like them [11-13], show the wide variance in the application of HCD to health devices and systems. It also exhibits the broad range of usability and human factors testing activities available to engineers and designers to gather feedback. Many of these activities are not new, much of the most well-known testing and evaluation techniques had been developed by the late 1980's [14-17]. However, as seen in Chapter 3, sometimes there is a lack of descriptive detail of the activities carried out within the design process and a lack of reporting on how successful or unsuccessful these activities were.

4.1.2 The Need for a Methodology which allows for Rapid Development Cycles

Additionally, the Connected Health industry is seen as a fast moving highly competitive industry [18], highlighting a need not only for devices that achieve adequate levels of usability, but also for devices which can have rapid development cycles associated with them. This need is punctuated by the association of Connected Health technology with mobile devices, such as smartphones. The phones themselves, typically act as collection, transmission and storage platforms for the health data, while the Smartphone Apps provide users with an interface to their data or to an external device. In 2015 over 100,000 mobile health Apps were available for download between the Google Play Store and the Apple App store [19]. By 2016 over 500 million people are expected to be utilising mobile health Apps to some degree [20]. This proliferation of mobile health devices and Apps, means that these devices and their Apps can become relatively obsolete in a short period of time [21], with a consequent need for shorter and shorter product lifecycles as was previously experienced in software industry. This can mean that companies may not be able to incorporate a full Human-Centred Design methodology into their product development cycle. In light of this observation, it is the authors' opinion that presenting a detailed, comprehensive description of a Human-Centered Design Methodology, which is in line with ISO 9241-210 and is optimised for use with

Connected Health device through the streamlining of the different steps in the HCD process, is warranted.

4.1.3 The Need for a Guided Approach which Emphasises Planning and Documentation

It has been previously observed that developers of Connected Health solutions are in many cases more engaged with the technical innovation in these systems rather than with their usability [7, 22]. More recently it was identified that there is a need for guidelines on how to conduct the design and development process for Connected Health devices in terms of usability [23]. Finally, in the development of medical devices, appropriate documentation of the design process is critical, particularly if the device is to adhere to a standard such as IEC-62366-1.

Therefore as well ensuring our methodology adheres to the 6 guiding principles of Human-Centered Design as outlined in ISO 9241-210 (see Requirements 1-6 in Section 4.2), we will add three more requirements that our methodology must meet. We will refer to these three new requirements as Requirements 7 – 9:

7. Details of suggested activities and their expected outcomes within each phase will be embedded within our methodology.
8. Our methodology will utilize activities which allow for rapid prototyping, testing and development
9. Our methodology will emphasise planning activities in advance and generating the appropriate documentation

In this paper, we will describe a three phase methodology which follows the same process as outlined in ISO 9241-210 (Figure 3.1), which adheres to the 6 requirements it outlines as well as the three additional requirements we have just derived. In the following section, we will provide a detailed description of our activities and the justification for them. An example of the application of the methodology to a Connected Health system will also be provided, the results of which will be described in Chapter 5 of this thesis.

4.2 Methodology

The methodology which will be described in this section now has 9 requirements which must be fulfilled. These are listed below with an appropriate elaboration:

1. The design is based upon an explicit understanding of users, tasks and environments: In the first phase of our methodology we will establish context of use, user requirements and user profiles
2. Users are involved throughout design and development: We will involve end users and expert users in each phase
3. The design is driven and refined by user-centered evaluation: We will use evaluation techniques at each phase to achieve measurable results
4. The process is iterative: We will have multiple phases where design changes can be made after each phase, the process can revert back to a previous phase if necessary
5. The design addresses the whole user experience: Use Case(s) developed in the first phase will address all aspects of use and will be used as a reference point before and after each phase
6. The design team includes multidisciplinary skills and perspectives: We will incorporate multiple perspectives from disciplines within the design team, from stakeholders and from experts. Here we define stakeholders as any person involved in the project who is affected by the activities or outcomes related to the product in question, while an expert is defined as any person with an expert knowledge of the product, the end user or of usability and human factors.
7. Provide explicit details of suggested design and testing activities and their expected outcomes within each phase.
8. Rapid Development and Testing while maintaining clear structure: The early phases of our methodology will describe activities which allow for rapid prototyping and evaluation.
9. Well Planned with all activities, outcomes and design changes properly documented: Our methodology will seek to embed the documentation of all activities, design and developments.

Based on these requirements, we will now describe a three phase methodology which will fulfil these requirements. These three phases are as follows:

- Phase 1: Establishing Context of Use and User Requirements
- Phase 2: Expert Inspections and Walkthroughs
- Phase 3: Usability Testing with End Users

The full methodology is illustrated in Figure 4.1 and then described in further detail below the figure.

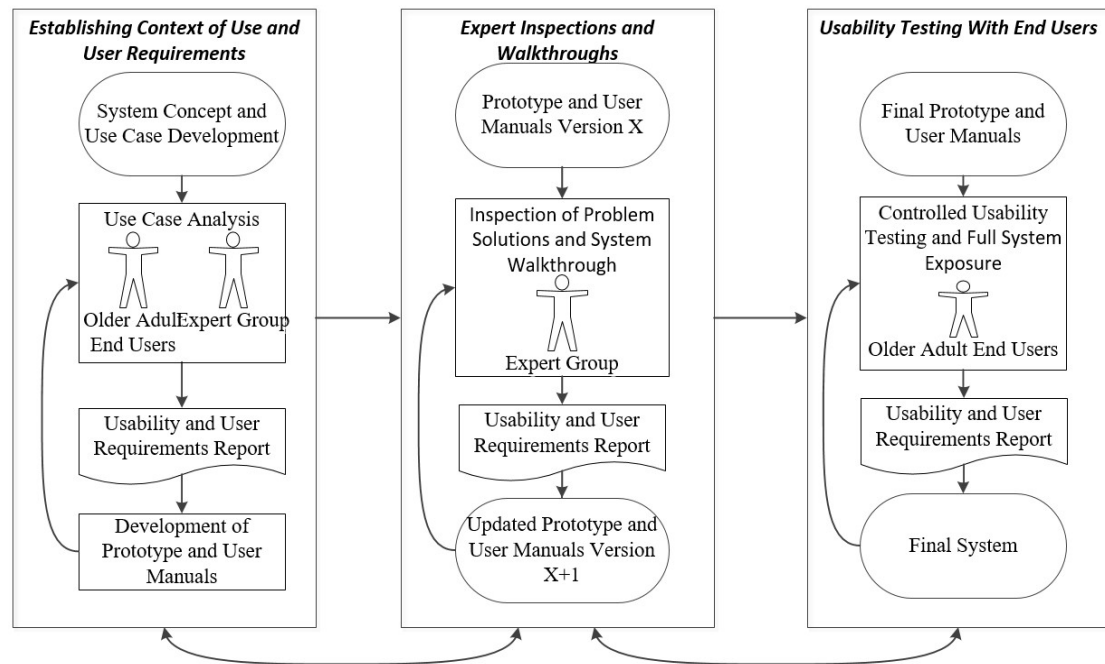


Figure 4.1: Our HCD Approach to a Connected Health Application

4.2.1 Phase 1: Establish Context of Use and User Requirements

Overview

This phase establishes the context of use of the device and the requirements and needs of the target end user. Usually in early phase testing, to understand the needs of the user, activities such as interviews [24], surveys and ethnographic observations are carried out [25, 26]. This can be resource intensive and difficult to document properly. This phase seeks to gain an explicit understanding of users, tasks and environments (Requirement 1) through the immediate construction of a Use Case document. Constructing use cases is a commonly used method to analyse user requirements and user preferences [11, 27, 28]. Traditional Use Cases are made up of

a series of diagrams known as Universal Modelling Language (UML) although in our case, the Use Case Document is made up of flow diagrams, storyboards, screenshots, interface mock-ups, paper prototypes and descriptive end user profiles, starting with the System Concept as a reference point,. The document is designed to be interactive, descriptive and to provide a common platform for project stakeholders to communicate their vision for each component's and user's role within the system and the interactions they have with each other, thereby attempting to address the whole user experience (Requirement 5). User profiles should be drawn up within the Use Case document of potential users, describing capabilities, requirements and preferences.

Suggested Activities

These Use Cases can be exposed to a groups of experts with knowledge of the system and/or usability (Requirement 6) and to a group of end user representatives (Requirement 2) [29]. At various points in the document, questions can be put to the reader or they can share their insights, in this way the Use Case analysis acts like an interview, survey and ethnographic exercise all in one, allowing for more rapid turn-around of information related to user requirements (Requirement 8). In the early phase of the design process there may be many different possible solutions and concepts that designers could pursue. Within the Use Case, or as an accompaniment to it, paper prototypes, wireframes (essentially a skeletal framework of an interface, usually a website) and mock-ups should be exposed to the users [30-33]. Likert-type scales can be used to query the reader's agreement with aspects of the prototypes (Requirement 3). An example of a Likert item might be 'I can read the text on the screen without any difficulty', with a scale of 1-5 allowing the user to strongly disagree or agree.

Outcomes

A usability report and a list of user requirements, backed up by quantitative and qualitative data, is produced (Requirement 3, 9). Semi-functioning prototypes or mock-ups which fulfil as many of the uncovered requirements as possible should now be built and made available for testing in Phase 2. The first user manuals, if

required, should also be ready for inspection in phase 2. This phase fulfils requirements 1, 2, 3, 5, 6, 7, 8 and 9.

4.2.2 Phase 2: Expert Inspections and Walkthroughs

Overview

The testable prototype should now be exposed to a controlled formative test which takes into account usability, human factors and overall user experience characteristics, as well as testing the overall functionality of the prototype (Requirement 3, 5, 6). This can be done using so-called discount usability techniques, such as usability inspections and heuristic inspections as suggested by Norman, so as to ease burden on time resources and to forgo expensive recruitment of end users (Requirement 8). The testing is carried out with reference to the Use Case and the requirements generated from Phase 1. Problems uncovered by the tests need to be prioritised and addressed in turn by the development team, with testing repeated if necessary (Requirement 4).

Suggested Activities

Evaluation and Inspection Methods: Usability inspection, involves a multi-disciplinary expert group (Requirement 6) inspecting the interface and attempting to identify usability and human factors problems [11]. This can be in the form of a heuristic evaluation where the interface is compared to a set of predefined design guidelines [33, 34] or a cognitive walkthrough [35,36], where the expert group carry out a task by task analysis of the interface while focusing on cognitive processes which the task requires, documenting where they encounter problems. Usability inspections are commonly used as a precursor to formal end user testing [37-39] because they are seen as low cost and easily implementable techniques than can garner quick and concise feedback [40]. Their flexibility and quick feedback lend themselves well to the evaluation of almost any type of system or device and have been used to assess the usability of electronic health record systems [41], web-based interfaces for telemedicine applications [42], online educational websites [43], infusion pumps [44], pacemaker programmers [45], instrumented insoles [39] and smart-phone applications [46].

Outcomes

An updated usability report is produced (Requirement 9). A now advanced prototype with almost full functionality with accompanying user manuals should now be ready for testing with end users. This phase fulfils requirements 1, 3, 4, 5, 6, 7, 8 and 9.

4.2.3 Phase 3: Usability Testing with End Users

Overview

The now advanced prototypes(s) are exposed to end users in summative user testing (Requirement 2). The test can be carried out in controlled settings like a lab but it is more useful to carry out field testing with end users, such as in their home. Problems uncovered by the tests need to be prioritised and addressed in turn by the development team, with testing repeated if necessary (Requirement 4). Test cycles should be kept short with at least 10 participants in each cycle if possible.

Suggested Activities

User Testing: User testing has been greatly described in literature [47-49] and involves monitoring the user while they interact with the system interface. This monitoring can be carried out in different environments, with laboratory sessions allowing for more control over the experiment and more robust data albeit with the loss of real-world fidelity, while observing users in a more natural use environments can lead to richer data but the data can be harder to quantify effectively. In early instances of user testing, the administrator will often ask the subject to think-aloud, allowing the observer to gain an insight into the train of thought the user is employing as they encounter and attempt to overcome usability and human factors problems [50,51] (Requirement 1, 5). Cameras, audio recorders and note taking are employed to record the user behaviour, and scales such as the QUEST, System Usability Scale (SUS), After Scenario Questionnaire (ASQ), NASA Task Load Index (TLX), Visual Analogue Scale (VAS) and 5 point Likert items [52] are utilised to record and quantify user satisfaction (Requirement 3). Efficiency and effectiveness are measured by recording time taken to complete tasks and error and completion rates [53].

Outcomes

A very advanced prototype which can be subjected to further user testing or expert inspection if required. This phase fulfils requirements 1, 2, 3, 4, 5, 7, 8 and 9.

Within each phase, activities can and should be repeated if necessary (Requirement 4). After each phase, all problems are recorded and documented in structured usability and human factors reports (or other form of presentation) so that all stakeholders are aware of the problems and all problems and changes are documented (Requirements 9) [54].

4.3 Application of Methodology to a Connected Health System

This methodology was applied to assess and enhance the usability, human factors and user experience of a Connected Health system known as WIISEL (Wireless Insole for Independent and Safe Elderly Living) (wiisel.eu) system, a system designed to continuously assess fall risk by measuring gait and balance parameters associated with fall risk [55]. The system is also designed to detect falls. The architecture of the system is illustrated in Figure 4.2 and it is described in further detail below.

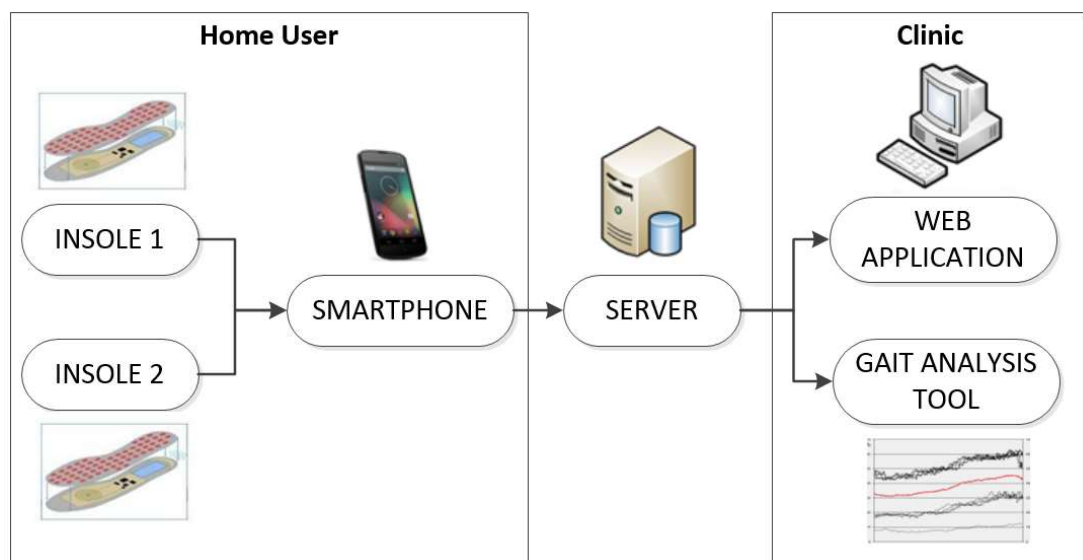


Figure 4.2: The WIISEL System

It is proposed that the system can be used in the home by a user for a period of time in order to identify specific gait and balance patterns that may be affecting a user's fall risk. The system is targeted at older adults who represent a high fall risk group. The system consists of a pair of instrumented insoles worn by the user and a smartphone carried by the user. Data collected by embedded sensors in the insoles are sent to the smartphone, where they are then uploaded to a server in a clinic for processing and analysis. The smartphone represents a major interface in the system as this is how the home user will primarily interact with the WIISEL system with the WIISEL App allowing the user to check the system status, sync with the insoles, send data to their local clinic and monitor their daily activity.

4.3.1 Phase 1 Activities

The process of Phase 1 is summarised and illustrated in Figure 4.3.

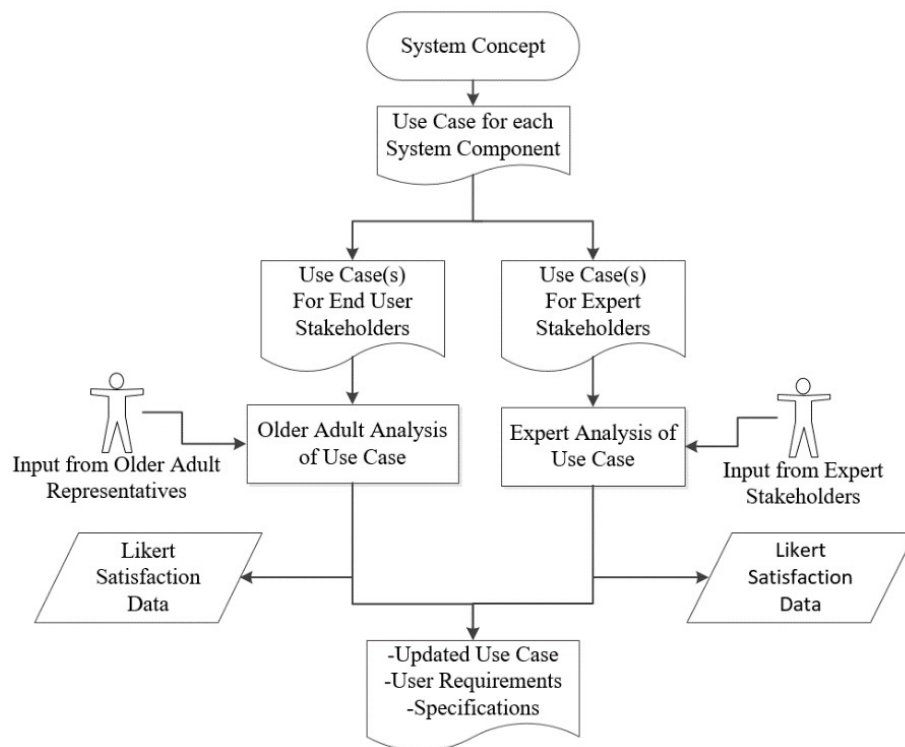


Figure 4.3: Phase 1 Activity Flow

Use Case Creation

The Use Case document was constructed with inputs from all WIISEL project stakeholders, which included engineers, developers and clinicians, who were able to

share their opinions on how the system would work and what it would be used for. Scenarios were described in the document which identified the tasks the user must carry out with the system, the order the tasks were carried out and the context in which the tasks were carried out. Potential risks which the user might encounter through their interaction with the system were also identified (using IEC-62366 as reference guide). Examples of the information included in the WIISEL Use Case are illustrated in Figure 4.4.

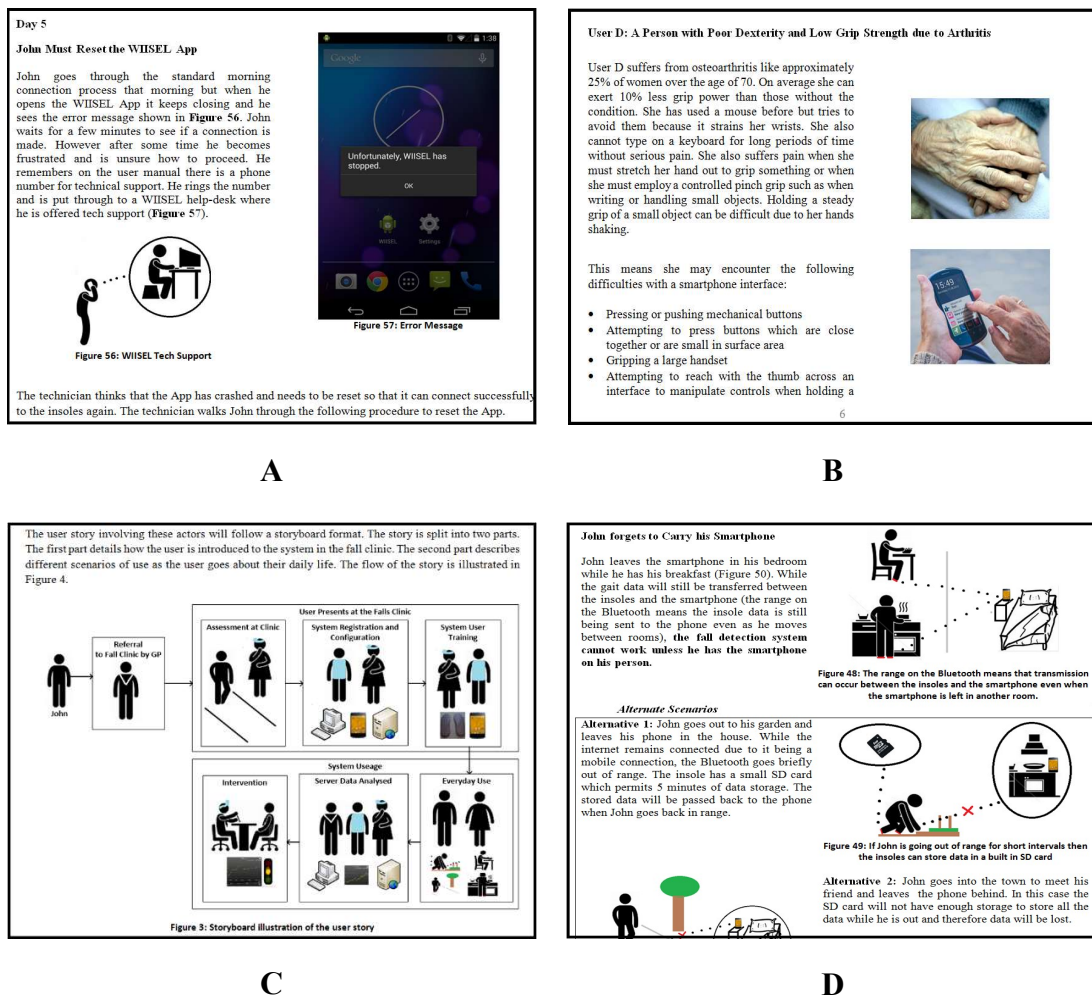


Figure 4.4: A) A scenario presented in the Use Case where the User, John, must carry out a troubleshooting sequence with the App, a life-size colour screenshot of the smartphone interface is shown B) A section of the Use Case which profiles typical physical capabilities of the target user and how it might affect their interaction with the smartphone C) A storyboard at the beginning of the document summarising the whole process, from when the user is prescribed the system to when they return to the clinic having used it for a period of time D) A scenario in the Use Case where it describes what might happen to the phone while the user is doing daily home chores

Use Case Analysis

The Use Case(s) were examined by a series of stakeholders (n=20), which included 10 older adult end users and 10 experts. The expert group included health professionals who could potentially be end users and people with relevant expertise who may not necessarily be end users but have experience in the design and usability of similar systems. The reader examined the scenarios one after another. After each scenario of the Use Case, the reader was interrogated on their thoughts on what they had seen using tick-box Likert scales which were embedded in the document. For example, in the case of the Use Case describing the use of the WIISEL smartphone, the user filled out Likert scales which queries their opinion on colour schemes, text size, button size and screen navigation flows (as observed from High Definition colour screen shots). An example of an end user interrogating a Use Case and filling out the appropriate scales is shown in Figure 4.5.



Figure 4.5: Older Adult Participants analysing and providing feedback on the Use cases

Apart from the set scales the reader filled out, the think aloud protocol was also employed by the reader so that they could elaborate on any potential problems and digress if necessary to related problems not explicitly presented in the Use Case.

Problem Classification

There are a number of methods to classify usability problems [56-58]. Many of these methods, such as Clustering, Heuristic Evaluation and Nielsen's Classifications, prove effective in identifying how likely an identified problem is to affect the user's interaction with the system. As the Use Case is not representative of the fully

interactive system (i.e. for example the user cannot push the buttons physically), it is not possible to carry out a traditional classification by observation and evaluation, but rather we used the transcripts and the scoring from the Likert scales to predict potential problems. A three step process was employed:

1. *Clustering Identified Problems*: Using the compiled transcripts from the think aloud protocol, we grouped explicit identification of problems on a scenario by scenario basis. Problems can be grouped according to a set of heuristics, making the problems easier to classify and track throughout the design cycle. In the case of the WIISEL smartphone Use Case, the following set of heuristics (a-e) was used [58]:
 - a. *Consistency/Clarity of Task Structure*: The flow of the task or the interface may cause confusion or may be hard for a typical user to follow
 - b. *Completeness and Sufficiency of Task Meaning*: Feedback when the user carried out an action or was required to carry out an action was unclear or may cause confusion
 - c. *Noticeability*: An element on the interface that is important to the completion of the task is difficult to notice
 - d. *Discernibility*: Physical interface characteristics such as text size, button size and colour scheme (each of which is a sub-category) may make it difficult for the user to complete the task.
 - e. *Cognitive Directness*: The user was required to carry out an action which did not result in the expected outcome.
2. *Relate Problem to Likert Item*: The identified problems were related to one of the Likert Items put to the participants at the end of each Use Case scenario. The Likert items are related to each of the categories above.
3. *Calculate Severity Rating*: The median score was calculated for the Likert item (adjusted range 0-4, with 0 considered a perfect score and 4 considered the most severe). This provided a Problem Rating for the problem.

The methodology is illustrated in Figure 4.6. This methodology is sometimes referred to as bottom up clustering because it groups together similar problem descriptions from first principles.

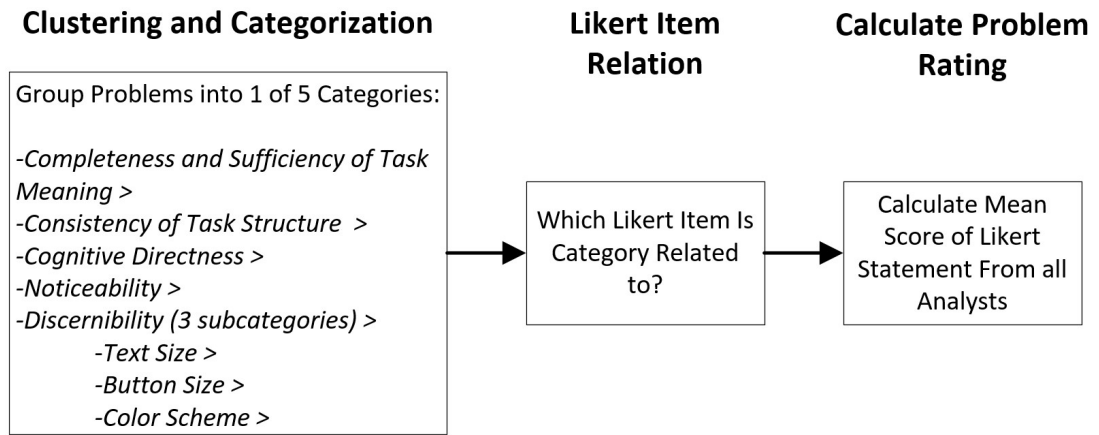


Figure 4.6: Structured Process for Prioritising Usability Problems

This list of problems can be dealt with straight away, as most of them will be aesthetic and superficial problems, while more complex problems such as ones related to concepts and flow can be further explored in functioning prototypes.

4.3.2 Phase 2 Activities

The phase 2 activity flow is illustrated in Figure 4.7.

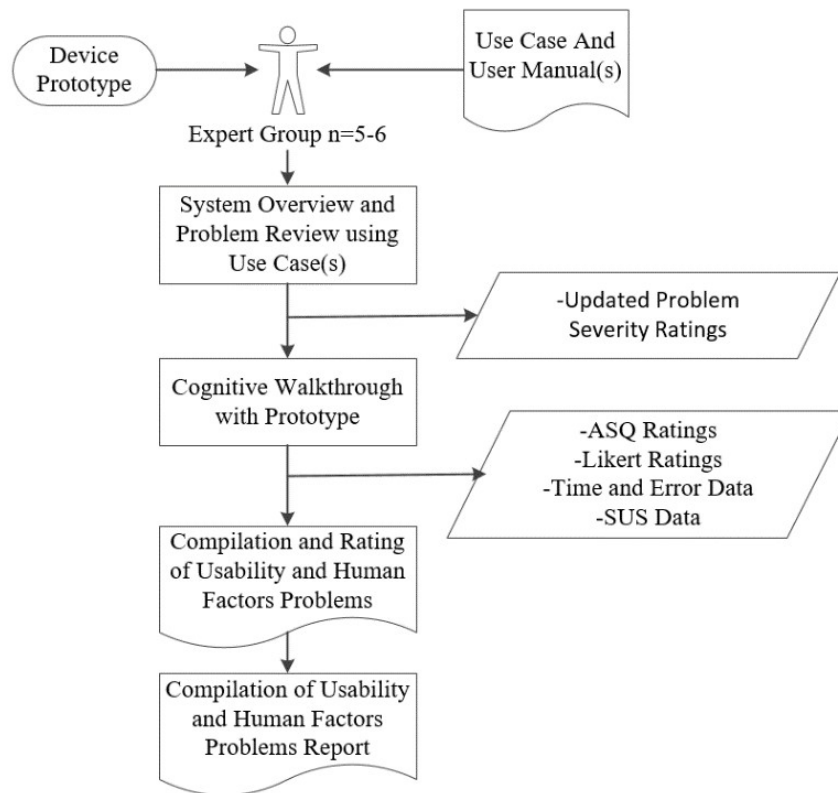


Figure 4.7: Phase 2 Activity Flow

Inspection of Updated Use Case

In response to this feedback from Phase 1, a semi-functioning WIISEL Smartphone App prototype was also developed with accompanying user manuals (Working Prototype Version 1) and made available for expert walkthrough. An updated Use Case was also created to accompany the inspection (Paper Prototype Version 2). The original experts from Phase 1 carried out a two part usability inspection. Firstly, the experts inspected the solutions to the problems they had identified in Phase 1 using the new version of the Use Case (Paper Prototype Version 2) as a guide. This Use Case only presented the problems which the experts identified in their original analysis and showed how the problems had been addressed. Secondly, they inspected the physical App (Working Prototype Version 1) utilising a walkthrough methodology.

The Use Case inspection consisted of 4 steps:

1. The expert was presented with the original Use Case scenario (Paper Prototype Version 1) in which they originally identified the problem. This provided the problem context.
2. The expert was presented with a description of the problem they identified within the scenario with, where possible, an annotated screenshot of the interface outlining where exactly the problem was identified
3. The updated interface (Paper Prototype Version 2) was presented to the expert which has sought to address the problem
4. Ask the expert to mark the relevant Likert item for the purpose of calculating a new Problem Rating

The expert was notified before proceeding that they could still reject any changes to the interface as being either inadequate or not being what they had suggested. The new Problem Ratings calculated from the Likert items filled out in Step 4 were then compared to original ratings.

Cognitive Walkthrough with Manuals

In order to give the expert a chance to fully analyse the physical App and transition from a high-fidelity paper prototype to a functioning physical prototype, the App

was presented to the expert following a cognitive walkthrough methodology. The cognitive walkthrough method is employed as a means of identifying usability problems in interactive systems, with a primary focus on determining how quickly and accurately new users would be able to complete task with a system. A lightweight overhead camera (Microsoft Life™ HD+Mic) was attached using a wire cradle to the phone handset which captured all interactions with the phone screen interface Figure 4.8.

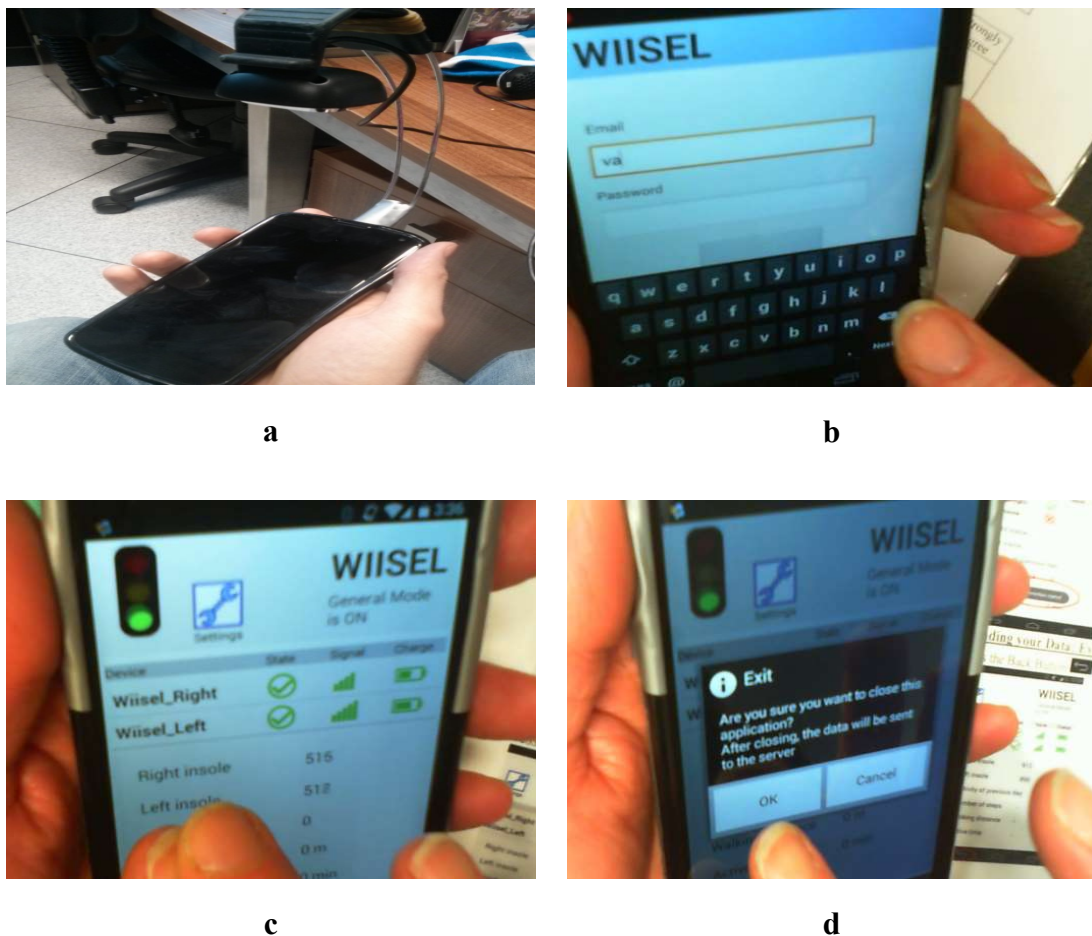


Figure 4.8: a) The Experts walked through each scenario in the User Manuals with the phone, the Cradle Camera captured all of their interactions with the smartphone; b) An Expert attempts to login to the smartphone App; c) An expert following the connection sequence from the user manual; d) An expert carrying out the data upload sequence

The experts were walked through the user manuals and the App by the researcher as if they were a first time user and were then asked to carry out a number of scenarios. They could consult the User Manual at any time but were not prompted by the administrator. They were encouraged to think aloud as they carry out each task. A

number of usability metrics such as time taken to complete task, errors made and completion rate were recorded during the walkthrough (captured using the overhead camera). The After-Scenario Questionnaire (ASQ) was employed after each scenario. The ASQ is a 7 point scale where a score of 7 indicates strong disagreement and 1 indicates strong agreement (a lower score indicates increased satisfaction with the interface). It seeks the user's agreement on 3 statements related to key usability metrics; Overall I am satisfied with the ease of completing this task, overall I am satisfied with the amount of time it took to complete this task, overall I am satisfied with the support information (on-line help, messages, documentation) when completing this task. All observed problems were again recorded and compiled in a usability and human factors report.

4.3.3 Phase 3 Activities

The process of Phase 3 is summarised and illustrated in Figure 4.9.

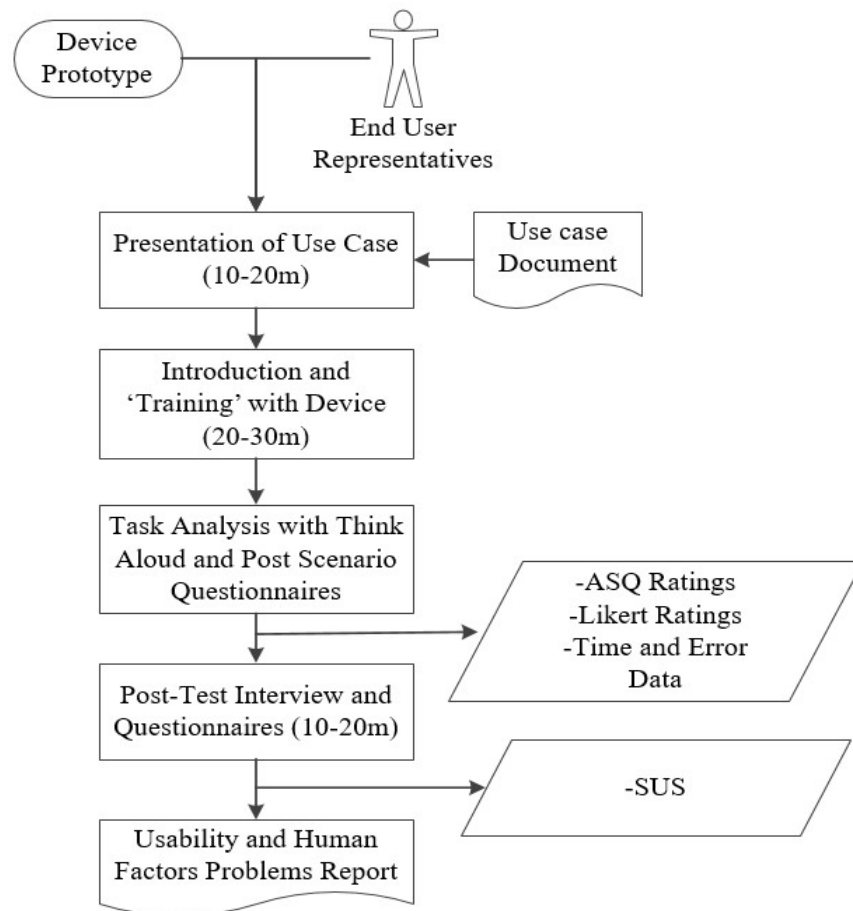


Figure 4.9: An example of Phase 3 Activities

User Testing

In this phase, a now advanced functioning prototype, complete with user manuals where necessary, was exposed to end users in controlled summative user testing. Any major problems with the system identified in the expert inspection should have been addressed by this time, particularly any problems which could adversely affect the health of the end user. The new manuals and updated interface (Working Prototype Version 2) were exposed to 10 older adults who had previously analysed the Use Case. The testing was carried out in the home of the participant. The procedure was as follows:

- The participant was asked to complete all tasks defined in the original Use Case
- Each task was carried out three times.
- Before the testing began, the participants were guided through the task by the researcher using the user manuals. Allowing to the participant to become familiar with the interface is important to separate genuine usability problems from mistakes due to unfamiliarity with the interface or device.
- The overhead camera was attached and the screen interaction was recorded. No prompts were given to the participant, who were expected to complete the task using only the user manual as a guide (See Figure 4.10).



Figure 4.10: Older Adult Users Carrying out Tasks using the User Manual as a guide during the User Testing Phase

The same usability metrics were captured as in Phase 2 and the users were also interviewed post-test to get their general feelings on the device and interface. The feedback from user testing was used to generate the first working system complete with user manuals. Another usability report was compiled for the consumption of all stakeholders.

4.3.4 Method Overview

The complete methodology, with a breakdown of each phase, is illustrated in Figure 4.11.

<u>Phase</u>	<u>Activities</u>	<u>Objectives</u>	<u>Data</u>	<u>Characteristics</u>
Phase 1: Establish Context of Use, User Profiles, User Requirements and Interface Concepts	<ul style="list-style-type: none"> -Use case construction -User and expert interviews with use case -Updated use case(s) -Usability and human factors report 	<ul style="list-style-type: none"> -To define interface concepts -To define task flows -To define user profiles -To define contexts of use -Aesthetic design -To produce semifunctioning prototypes 	<ul style="list-style-type: none"> -Likert satisfaction scores on interface elements and task flows -Qualitative data from interview transcripts 	<ul style="list-style-type: none"> -Phase can be carried out quickly and at relatively low cost, Agile flow -Use case can receive input from all project stakeholders before exposure to end users -Data is easily readable and can be used to justify changes
Phase 2: Experts Inspections and Walkthroughs	<ul style="list-style-type: none"> -Inspection of updated use case and comparison to original use case -Cognitive walkthrough and heuristic evaluation of functioning or semifunctioning prototypes -Usability and human factors report 	<ul style="list-style-type: none"> -To check if user requirements have been met and that the system(s) adheres to basic usability and human factors principles -To give the system the greenlight for end user testing -To produce fully functioning prototypes 	<ul style="list-style-type: none"> -Likert satisfaction scores on interface elements and task flows -ASQ scores for each scenario -Task times and error rates -System Usability Scale global score -Qualitative data from Think-Aloud Protocol 	<ul style="list-style-type: none"> -Phase does not require many participants, as little as 4-6 experts or stakeholders -Phase can be carried out quickly and at relatively low cost -Data is easily readable and can be used to justify changes
Phase 3: Usability Testing With End Users	<ul style="list-style-type: none"> - User testing with the target end users -Task and scenario-based testing following the structure of the use case(s) 	<ul style="list-style-type: none"> -To validate prototype solutions with the target end user in the lab is necessary or in the end users own environment if possible -To create final prototypes 	<ul style="list-style-type: none"> -Likert satisfaction scores on interface elements -ASQ scores for each scenario -Task times and error rates -System Usability Scale global score -NASA TLX -Qualitative data from Think-Aloud Protocol 	<ul style="list-style-type: none"> - The most expensive phase of testing -This testing can be repeated multiple times in different environments where necessary -Data is easily readable and can be used to justify changes

Figure 4.11: An overview of the complete methodology and all the suggested activities in each phase as applied to the WISEL systemDiscussion

A sensible and robust HCD approach to designing Connected Health devices has been presented. The proposed methodology and its example application to the WIISEL system will not be reviewed by comparing the outcome to the 9 requirements which were originally derived.

4.3.5 Did Our Methodology Meet Our Requirements?

In terms of the first 6 requirements, we implemented a three phase methodology which followed the flow of ISO-9241-210. The 3 phases allow for design iteration and can be repeated if necessary. The phases where iteration are most likely to occur are Phase 2 and Phase 3 [59], as these are the major testing phases with measurable outcomes, where outcome metrics can be compared when tests are repeated after prototypes have been updated. Comparison of metrics between phases is important to exhibit improvement in design, particularly when communicating design changes to stakeholders or regulators. The methodology began with a phase which sought to gain an explicit understanding of users, tasks, environments and tried to address the whole user experience by constructing a use case. This use case allowed for end users and multi-disciplinary experts to become involved and evaluate the system concept, prototype screens and the user task flow. The Use Case we developed for WIISEL contains information regarding the typical capabilities of the user, possible risks a user may encounter (using IEC 62366 or ISO 14971 as a reference for example), what might happen if an error arises and how often they would be expected to interact with the system. These aspects of system use were then explored in more detail in Phase 2 and 3, using the original Use Case as a reference point. The target end user was involved in Phase 1 and Phase 3. The end users in Phase 1 were able to provide accurate feedback on their user profiles, the context of use in which they would use the system and provide early feedback on interface concepts and task flows. In Phase 3 we were able to closely observe them performing the system tasks which had been carefully designed in the previous two phases. In total 22 end users were involved in our process. We successfully integrated multi-disciplinary inputs into our design utilising experts from various backgrounds such as computer science, medicine, nursing, gerontology, psychology and design (See Table 5-1 in Section 5.2.1 for further details of these experts). The experts should be chosen based on the type of system being designed and who the target end user is. In our case the input of

gerontologists and nurse's with experience in technology for older adults was invaluable. If the necessary experts are not available, then specifically trained generic inspectors should inspect the prototype using pre-established and carefully selected heuristics. Again, the output of this activity will depend on the quality of the inspections and differences in outcomes may arise i.e. problems missed, if inspectors are not appropriately trained.

In terms of the 3 further requirements that were derived to add to the original 6, ISO-9241-210 was used as a guiding source by both following the principles and steps outlined within it to fulfil Requirement 7. To fulfil Requirement 9, before the process began we set out exactly what testing and design activities we were going to carry out. While there are many activities usability engineers can employ to test products it is never necessary to try to use all of them in the same project. We felt it was best to choose what activities would best suit our particular device and project. It is important to plan and document the activities in a design file, particularly if the device is to adhere to a standard such as IEC 62366-1. Regular meetings were carried out among stakeholders and developers to discuss upcoming activities and design changes. After each activity, all results and findings were placed into presentable formats, such as PowerPoint slides, so they could be disseminated among team members and stakeholders. Methodologies for activities were also disseminated such that changes could be made before activities took place. To fulfil Requirement 8, in Phase 1 we carried out a well-planned and choreographed Use Case Analysis activity which was designed to allow for rapid idea and concept exchange. The Use Case analysis acted like an interview, survey and ethnographic exercise all in one because it was addressing the whole user experience and allowed end users, experts and stakeholders to participate in the formation and analysis of concepts and ideas, as well as providing validation on user profiles and context of use. We extensively utilised paper prototypes in Phase 1 and usability inspections with small expert teams in Phase 2. This use of so-called discount usability engineering methods again allows for rapid turn-around times on prototypes and quick feedback to be sent to the design team. The Use Case(s) can be constructed in a matter of days, while a full Use Case analysis can be carried out with an end user or expert in an hour. The data is manageable and concise because all the data, the

Likert data and think-aloud transcripts, are available from a single activity and are relatable directly to the end user and the context of use.

4.3.6 Final Comments and Limitations

We can say on a preliminary basis that all the objectives we originally outlined for this methodology have been successfully met. We feel that our proposed methodology, and the examples of its implementation in this paper, will provide prospective designers with a methodological blueprint to follow a HCD process which adheres to a standardised structure but also allows for rapid development cycles.

We have also recognised some possible limitations in our methodology which need to be addressed. While acknowledging the importance of involving end users throughout the design process, in phase 2 we only tested the prototypes with experts from various disciplines. There are a number of reasons for this. Firstly, as a matter of principle in terms of ergonomic quality control and safety, we feel it is important to not expose a prototype to a potentially vulnerable user group, such as in this case older adults, until it has been fully inspected and walked through by experts. While for the example of a smartphone App, it may not seem necessary to have this level of caution, we want this methodology to be applicable to all kinds of Connected Health devices, some which may have greater levels of risk than others. Secondly, the expert input in Phase 2 allowed for a fresh third party perspective on the system and brought a level of expertise in areas of usability, human factors and interface design, something which the target end user themselves may not have experience in. Finally, the expense of recruiting end user may be a burden on start-ups, research groups or enterprises with limited resources, therefore Phase 2 acts as a way to remove many of the usability problems, however simple or complex they may be, before the prototype reaches end users. Experts may also be expensive to hire or recruit, however within a research group or enterprise, usability inspection groups can be formed from stakeholders, designers and developers who may already be involved in a project or related projects.

One of the requirements of methodology was to create an emphasis on rapid prototyping and evaluation, which is made possible in the methodology by

introducing a paper prototyping activities in Phase 1 and so-called discount usability engineering techniques in Phase 2. This emphasis on rapidity may lead to a depreciation in quality. However our methodology emphasises the need for documentation and review after each phase. This will ensure that changes which have been recommended are disseminated, prioritised and implemented before the next phase begins [60]. Ultimately, the quality and design of the testing and evaluations will dictate the quality and efficiency of the user feedback and what changes need to be made and this is why having a dedicated usability engineer on a design team is important [61].

In terms of measurability, how do we know our methodology has provided any improvement or is measurably better than other methodologies? This is hard to measure and would only be realistic if we applied different methodologies to the design of the same product. In this publication, we have identified that there are many different methodologies which have been applied to the design and development of Connected Health and other similar medical devices. However, we identified a lack of standardised and guided approaches and therefore we wanted to derive a methodology which was guided by the principles and steps described in ISO 9241-210 and which has explicitly described steps and activities which other designers and engineers can follow. If this methodology is used in the future and is adopted by others, then we can start to measure its true effect and measure what its shortcomings may be, leading to improved HCD methodologies in future. The application of the methodology to the WIISEL system and the subsequent results of this application will be explored in more detail in a separate publication.

4.4 Conclusion

We conclude that our methodology brings a simple yet robust structure to Human-Centered Design and development, while maintaining a rapid approach which will suit modern design and usability engineering teams in fast paced and competitive industries. We have described in detail the activities which can be carried out in each phase. We have also presented our justification for this methodology and why we consider it to be a flexible and useful methodology, particularly for improving the usability, human factors and user experience of devices and systems to be used for

medical purposes. We acknowledge that at this point our methodology cannot be considered better or worse than other methodologies and that this can only be established through direct comparisons. However at this point we have derived a sufficient methodology which can now be applied to a connected health system.

Acknowledgments and Contributions

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The methodology for this study was conceived and designed by Harte, Quinlan and Ó Laighin. The experiments were carried out by Harte with the support of Glynn, Scharf and Rodriguez-Molinero, each of whom contributed both usability and medical knowledge to the testing. The data was compiled and analysed by Harte, Quinlan and Ó Laighin and reviewed by Glynn, Rodriguez-Molinero and Baker. All authors contributed equally to the introduction and discussion sections of the paper. The paper as a whole was reviewed and edited where necessary by all authors before submission.

Conflicts of Interest

The authors declare no conflict of interest.

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**Chapter 5 – The Application of a HCD
Methodology to Enhance the Usability
of a Smartphone App in an Integrated
Falls Risk Detection System for Use by
Older Adult Users**

*The work in this chapter was published in the Journal of Medical Internet Research (JMIR)
on the 30th of May 2017*

Using the methodology described in Chapter 4, we will now describe the results of application of the methodology to enhance the usability, human factors and user experience of the WIISEL Smartphone App. The results of the usability testing activities embedded in the methodology will be presented in detail. How these results were used to make informed changes to the design of the WIISEL smartphone interface will also be demonstrated. We expected that the application of the methodology would lead to measured improvement in the smartphone interface and its associated user manuals and would also inform designers of the needs and requirements of older adult smartphone users.

5.1 Introduction

Utilising a Human-Centered Design (HCD) approach, such as that outlined in ISO (International Standards Organisation) 9241-210 [1], during the design of Connected Health devices ensures that the needs and requirements of the user are taken into consideration throughout the design process. HCD is a multi-stage process, which allows for various iterations of a design and subsequent update to the requirements. The importance of involving end users in the design process of health products is recognised and different approaches have been demonstrated in literature [2–7]. In this paper, we present the implementation of a structured HCD Methodology, based on ISO-92419-210, which utilised standard, established techniques to assess and develop the usability and human factors of a smartphone interface with the full involvement of end users and stakeholders. The smartphone interface which was developed and tested is a component of the Wireless Insole for Independent and Safe Elderly Living (WIISEL, wiisel.eu) system, a system designed to continuously assess fall risk by measuring gait and balance parameters associated with fall risk. The system is also designed to detect falls. The architecture of the system is illustrated in Figure 5.1.

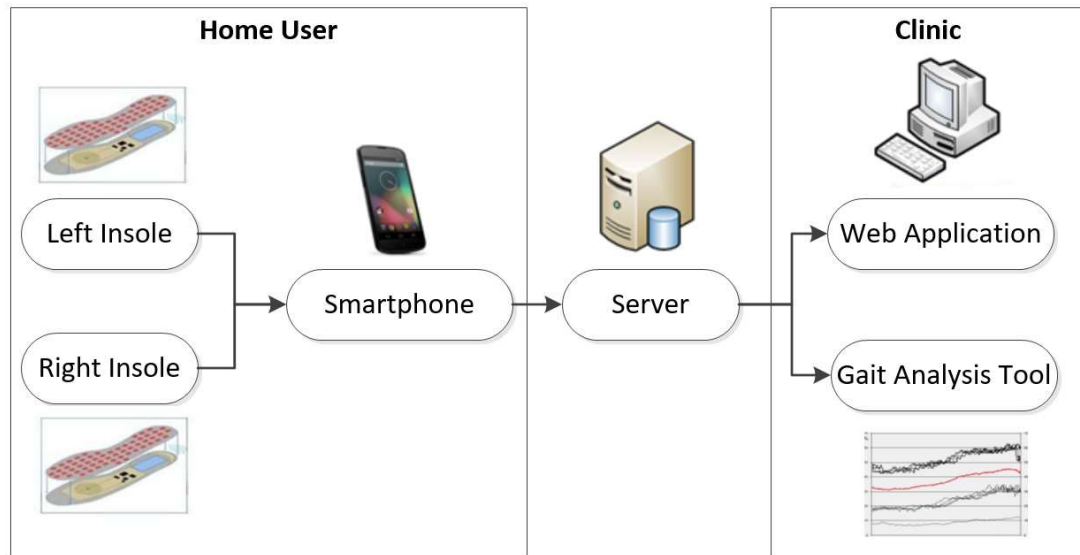


Figure 5.1: The WIISEL System [8]

It is proposed that the system can be worn in the home by a user for a period of time in order to identify specific gait and balance patterns that may be affecting a user's fall risk. The system is targeted at older adults who represent a high fall risk group. The system consists of a pair of instrumented insoles and a smartphone which are worn by the user. Data collected by embedded sensors in the insoles are sent to the smartphone, where they are then uploaded to a server in a clinic for processing and analysis. The smartphone represents a major interface in the system as this is how the home user will primarily interact with the WIISEL system with the WIISEL App allowing the user to check the system status, sync with the insoles, send data to their local clinic and monitor their daily activity.

5.1.1 Older Adult Users

The acquisition and comprehension of information from interfaces can become more difficult as a person progresses into older age. Interfaces in electronic health/medical applications can often be crowded with text and characters, have poor contrast, contain many different colours and may not present adequate haptic or audio feedback. In terms of visual perception, age-related declines in acuity, contrast sensitivity and ability to discriminate colours can affect reading rates, character and symbol identification and button striking accuracy, even with optimal corrections in place [9]. Age related cognitive decline in domains such as reasoning and memory can affect the ability of the user to comprehend the process they are perceiving on

the interface [10]. Deterioration of psychomotor processes such as fine motor control and dexterity can cause problems for users attempting to interact with the physical hardware of the interface [4]. Typically between the ages of 60 and 80, individuals can expect up to a 50% decline in visual acuity (particularly in low luminance, low contrast and glare environments), a reduction in hearing sensitivity by 20dBs, a 14% decline in short term memory and a 30% decline in power grip strength, all of which impact how one interacts with computer interfaces [11]. As well as these physical considerations, older adults can also present a complex user group in terms of attitude towards and previous experience with technology.

5.2 Methods

A three stage HCD methodology was utilised to enhance the usability and user experience of the smartphone Application, this methodology was previously described by Harte et al [12].

5.2.1 Phase 1: Establish Context of Use and User Requirements

Use Case Development: The Use Case document outlined 8 scenarios where the user must directly interact with the smartphone interface. These scenarios were; 1) the user logs in to the App; 2) the user syncs the App to the insoles; 3) the user checks the system status; 4) the user uploads the data; 5) the user minimises the App; 6) the user resets the App; 7) the user triggers a fall alarm. The Use Case, which was termed Paper Prototype Version 1, was exposed to two groups of stakeholders in the form of structured analysis in order to illicit their feedback [7, 13, 14]

Expert Use Case Analysis: 10 experts were selected to analyse the Use Case. The experts were selected from NUI Galway based on their involvement with work related to the use of technology by older adults. Multi-disciplinary perspectives were sought, so therefore the group consisted of nurses, occupational therapists, physiotherapists, GPs, gerontologists and engineers. The precise expertise of each expert, as well as a self-reported measure of their knowledge of 1) usability and human factors and how it can influence technology use 2) the end user, their capabilities and their preferences for technology 3) Connected Health devices which are used in the home, can be found in Table 5-1.

Table 5-1: Experts Involved in Use Case Analysis. Each of the experts was asked to mark out of 10 where they felt their own expertise of usability, the end user and Connected Health lay. (Know. = Knowledge)

#	Profession	Specific Experience	End User Know.	Usability Know.	Connected Health Know.
1	Clinical Researcher in General Practice	Industry experience in software design. Research interests include the perception of older adults in the media and the quality of life of dementia sufferers in long stay care.	9	8	7
2	Occupational Therapist	Experience in the delivery of occupational health solutions to older adults including ADL assessments, environmental risk assessments, cognitive assessments and fall prevention strategies.	9	6	3
3	Senior Lecturer in Nursing	Registered General Nurse with a PhD qualification in clinical nursing and has expert experience of treating older adults.	8	8	6
4	GP and Senior Lecturer	Research addresses chronic disease management and implementing Connected Health solutions for the management of chronic diseases.	9	5	7
5	GP and Head of General Practice Dept.	Senior Lecturer of General practice and lead researcher in clinical training/teaching practices and methods as well as workplace learning and development	9	6	4
6	Psychology Researcher	Holds a PhD in Psychology with research interest in team situation awareness in critical environments and designing instructional materials. Currently working in the area of examining lifestyle and technology factors associated with Gestational Diabetes Mellitus	7	8	7
7	Clinical Researcher in General Practice	Former practising nurse currently a Masters researcher pursuing projects in Connected Health and telehealth solutions in rural communities.	8	6	8

#	Profession	Specific Experience	End User Know.	Usability Know.	Connected Health Know.
8	GP and senior Lecturer in General Practice	HRB Cochrane Fellow currently practicing as a GP with expert experience of treating older adult patients. Research interests are in multimorbidity with a focus on Connected Health solutions.	10	6	8
9	IT Lecturer and Expert in User-Centred Design	IT researcher specialising in Human Computer Interaction (HCI). Research interests heavily focused on the employment of User-Centred Design techniques for mobile devices meet HCI needs.	6	8	4
10	Geriatrician and Professor of Gerontechnology	MD specialising in geriatrics and PhD qualification in Preventive Medicine and Public Health. Has expert experience of treating older adults as well as specific research interests in epidemiology, gerontechnology and tele-healthcare	10	8	8
		Average Expert Group Knowledge of Key Areas (self-measured)	8.4	7	6.4

As well as filling out the Likert statements at the end of each scenario, the expert was instructed to engage in a Think Aloud protocol as they walked through each scenario [15]. All feedback was captured by an audio recorder.

End User Representatives Use Case Analysis: 12 older adults were recruited using a typical purposive sample (inclusion: age 65+, community dwelling. exclusion: profound hearing or vision loss, psychiatric morbidities, severe neurological impairments) to analyse the Use Case. The same protocol and interview structure was used to expose the Use Case document to the older adults and was carried out in the home of the participant. Ethical approval to carry out the interviews and assessments was approved by University Hospital Galway (UHG) Research Ethics Committee. For this analysis we sought to measure, where applicable, the capabilities a user would call upon to successfully use an interface, so that we could be satisfied that test participants were representative of the target end user

population. For the purpose of the Use Case analysis we felt it was only necessary to measure the cognitive and visual capabilities of the user. The components of these processes which we measured are illustrated in Figure 5.2.

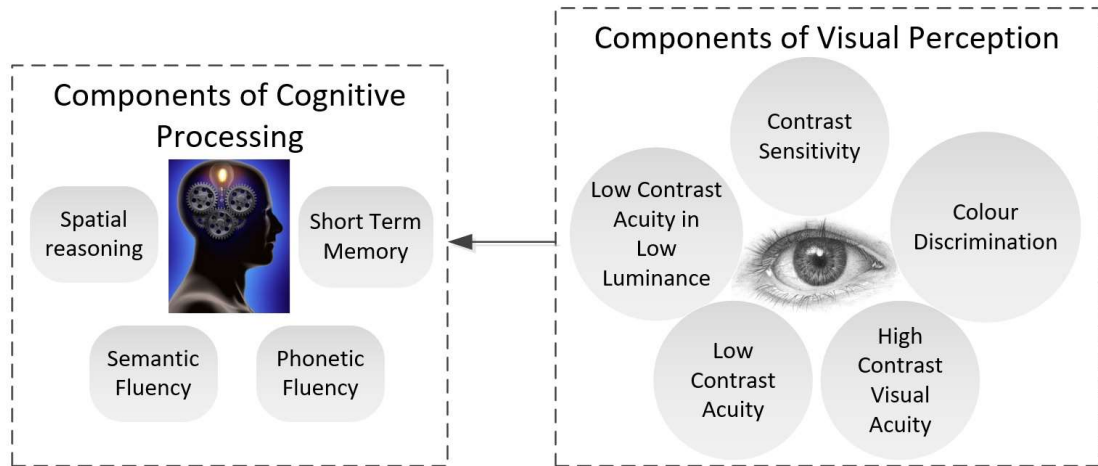


Figure 5.2: Physiological Capabilities required to interact with Use Case

We used a short battery of standardised tests to measure each of the capabilities presented in Figure 5.2. The tests and their relevance to the analysis are listed in Table 5-2.

Table 5-2: Standardised tests to measure each of the capabilities presented in Figure 5.2

Interactive Process	Measure	Meaning and Relevance
Visual Perception	High Contrast Acuity (HCA)	A general measure of visual capability and the ability to discern spaces between characters on a 100% contrast interface [16]
	Reading Acuity (RA)	A measure of acuity when reading full words on an interface [17]
	Low Contrast Acuity (LCA)	A general measure of visual capability and the ability to discern spaces between characters on a 5% and 25% contrast interface [18]
	Contrast Sensitivity Threshold (CS)	The contrast threshold at which the user can successfully identify a character [19]
	Colour Discrimination (CD)	Ability to discriminate colours on an interface [20]

Interactive Process	Measure	Meaning and Relevance
	Low Contrast Acuity in Low Luminance (LCALL)	The ability to discern spaces between characters on a low contrast and poorly illuminated surface
Cognitive Processing	Spatial Reasoning	The ability to interpret space on an interface and infer relationships between elements has been cited as a major component of website usability and software interfaces in general [9], [21], [22]
	Short Term Memory	Memory, specifically short term memory has been cited as an important factor in one's ability to maintain visual attention of an interface [22], [23]

HCA (See abbreviations in Table 5-2) was measured using a Snellen chart at a distance of 3m. LCA was measured for 5% and 25% contrast using SLOAN letter charts at a distance of 3m. Standardised illumination was provided for these two tests using a light box from Precision Vision (precision-vision.com). CS was measured using a MARS chart at a distance of 40cm, while LCALL was measured with a SKI chart at a distance of 40cm. CD was measured using a Farnsboro D-15 test. RA was measured using a Jaeger Chart at a distance of 40cm. Each participant also completed two cognitive performance tests based on the Whitehall Study [22]. Spatial reasoning was assessed using the Alice Heim 4-I (AH4-I). The AH4-I tests inductive reasoning, measuring one's ability to identify patterns and to infer principles and rules [24]. Short term memory was assessed with a 20 word free recall test. Expected values of each test per age group and the actual measured can be found in Table 5-3 and Table 5-4.

Table 5-3: Average Visual Performance Metrics measured, split by Age Group. The Average is compared to the Expected Score for that Age Group. Data presented in each column as (Expected / Measured)

Age (Yrs)	N (Number of Particip. who Fall into Age Group)	HCA Expected / Measured	RA Expected / Measured	LCA Expected / Measured	LCALL Expected / Measured	CS Expected / Measured	CD
61-65	1	1 / 1	1 / 1	0.67 / 0.79	0.33 / 0.41	1.68 / 1.8	No defects
66-70	2	1 / 1	1 / 1	0.62 / 0.71	0.29 / 0.27	1.54 / 1.55	No defects
71-75	3	0.91 / 0.83	0.91 / 0.8	0.49 / 0.64	0.25 / 0.22	1.42 / 1.33	1 participants with very mild blue yellow confusion (tritanopia)
76-80	5	0.83 / 0.88	n/a	0.4 / 0.54	0.2 / 0.22	1.2 / 1.42	1 participants with very moderate blue yellow confusion (tritanopia)
81-85	1	0.76 / 0.66	n/a	0.3 / 0.5	0.17 / 0.2	0.61 / 0.7	No defects

Table 5-4: Expected Scores and Mean measured Scores for Cognitive Tests for all 12 Participants. The Average is compared to the Expected Score for that Age Group. Data presented in each column

Age (Yrs)	N (Number of Particip. who Fall into Age Group)	Spatial Reasoning (Range 0-65) Expected / Measured	Short Term Memory (Range 0-20) Expected / Measured
61-65	1	(30-46) / 30	6.21-6.43 / 8
66-70	2	(30 - 46) / 38.5	4.79-5.74 / 6.5
71-75	3	(29.7 - 40) / 35	4.7- 5.5/ 6.3
76-80	5	(29.7 - 40) / 29.8	4.3-5.4/ 5.9
81-85	1	(25-40)/ 26	4-5.1/ 4

Identification and Categorisation of Usability Problems

The audio feedback acquired during the analysis of the Use Case Document by the experts and end users was ‘intelligently’ transcribed [25] and clearly defined usability problems were extracted from the transcript. All of the problems identified by each expert and end user were collated for each scenario. All problems were documented and illustrated in a structured usability and human factors problems report [26] and were accompanied by selected testimony from a corresponding expert or end user who elaborated on the nature of the problem for the purpose of the design team. This report was analysed by system designers who provided potential solutions to each problem where possible.

5.2.2 Phase 2: Expert Inspections and Walkthroughs

In response to the feedback from Phase 1, a new paper prototype was developed (Paper Prototype Version 2) and made available for expert inspection. A working version of the App with accompanying user manuals was also developed on a Google Nexus 5TM Smartphone (Working Prototype Version 1) and made available for expert walkthrough. We returned to the original experts and carried out a two part usability inspection. Firstly, the experts inspected the solutions to the problems they had identified in Phase 1 using a new version of the Use Case (Paper Prototype Version 2) as a guide. This Use Case only presented the problems which the experts identified in their original analysis and showed how the problems had been addressed. Secondly, they inspected the prototype App (Working Prototype Version 1) utilising a cognitive and contextual walkthrough methodology.

5.2.3 Phase 3: Usability Testing with End Users

The new manuals and updated interface (Working Prototype Version 2) were exposed to 10 older adults who had previously analysed the Use Case. As well as measuring the time taken to complete each task and the number of errors made; the ASQ (After Scenario Questionnaire) and the NASA-TLX (Task Load Index) was administered to the participant after the task was completed. The ASQ is a Likert scale which interrogates a user’s perception of efficiency, ease of use and satisfaction with manual support [27]. The NASA-TLX is a multi-dimensional rating procedure that provides an overall workload score based on a weighted

average of ratings on six sub-scales; Mental Demands, Physical Demands, Temporal Demands, Own Performance, Effort and Frustration [28].

5.3 Results

This section presents the summary of results from each phase, as well as the changes made to the interface and support documentation after each phase.

5.3.1 Phase 1: Use Case Analysis (Paper Prototype Version 1)

The combined expert analysis and end user analysis identified 21 problems. We have provided 13 examples of problems, which are presented in Table 5-5. The Problem ID number # assigned to each problem was used for the remainder of the design process to allow for easier problem tracking throughout the process.

Table 5-5: List of identified problems and which use case scenario it was identified in

Problem ID#.	Problem Description (Use Case Scenario)
#1.	The difference in operation between the HOME button and BACK button is not clear (User Minimises App)
#2.	Overall Login Sequence (User Must Login to the App)
#3.	Buttons on keypad are too small for this population (User Must Login to the App)
#4.	WIISEL icon not prominent enough on App menu (User Must Check the System Status)
#5.	Having to upload the data will be too hard to remember to do (Uploading Data by Exiting App)
#6.	Feedback during the process is not clear or may cause anxiety (Uploading Data by Exiting App)
#7.	No prompt to indicate to the user that a manual connection is now required (User must Connect to the Insoles)
#8.	Colours are too similar in places (Uploading Data by Exiting App)
#9.	Feedback regarding connection status is unclear (User Connects to Insoles Using App)
#10.	Homescreen information is not clear (User Must Check the System Status)
#11.	Options presented are not clear (Fall Alarm/Notification)
#12.	App text is too small (User Must Check the System Status)
#13.	Buttons on Exit Screen need to be bigger (Uploading Data by Exiting App)

The problems from Table 5-5 are presented now in Table 5-6 in order of severity rating based on the mean Likert scores assigned by the experts. The max individual score which was given by the 10 experts is also included to highlight the fact that some experts may have given a more severe rating than the mean or standard

deviation indicates. The heuristic category to which each problem belongs is also included in the Table 5-6.

Table 5-6: Problems uncovered by experts and rated based on mean Likert scores

Problem ID #	Heuristic Category	Severity Rating (0-4) \bar{x} (σ)	Max Severity Rating Given (0-4)
1	Cognitive Directness	2.5 (1.2)	4
2	Consistency and Compliance of task structure	2.4 (1.1)	4
3	Discernibility (Button Size)	2.2 (1.3)	4
4	Discernibility (Icons)	2.2 (1.3)	4
5	Consistency and Compliance of task structure	2.1 (0.9)	3
6	Completeness and Sufficiency of Meaning	2.1 (1)	4
7	Consistency and Compliance of task structure	1.9 (0.6)	4
8	Discernibility (Colour Tone and Contrast)	1.9 (1.2)	4
9	Completeness and Sufficiency of Meaning	1.7 (0.9)	4
10	Completeness and Sufficiency of Meaning	1.5 (0.8)	4
11	Consistency and Compliance of task structure	1.4 (1)	3
12	Discernibility (Text Size)	1.3 (0.75)	3
13	Button Size (Discernibility)	1.2 (0.9)	4

The older adult end user analysis found 14 problems, all of which were problems which had been identified by the expert group (the same Problem ID# is used). Of the 13 problems listed in Table 5-6, 9 were uncovered by end users. These are presented in Table 5-7 in order of severity (as in Table 5-6).

Table 5-7: Problems uncovered by end users and rated based on mean Likert scores

Problem ID #	Heuristic Category	Severity Rating (0-4) \bar{x} (σ)	Max Severity Rating Given
1	Cognitive Directness	1.83 (0.89)	3
2	Consistency and Compliance of task structure	1.5 (0.7)	2
4	Discernibility (Button Size)	1.5 (0.8)	2
7	Discernibility (Text Size)	1.33 (1)	3
13	Discernibility (Button Size)	1.2 (0.9)	3
8	Discernibility (Colour Tone and Contrast)	1.15 (0.6)	2
9	Completeness and Sufficiency of Meaning	1(1.2)	3
6	Completeness and Sufficiency of Meaning	0.91 (0.6)	3
12	Discernibility (Text Size)	0.91 (0.7)	3

Testimony from experts and users alike were used to provide insight into the problems and help designers better understand the problem. Themes were sought from the transcripts to uncover what characteristics of the interface experts and users most commonly found problematic. For example, regarding the login sequence for the smartphone app:

“If not absolutely necessary this sequence should be removed from the use of the phone. At the very least it should be made sure that this only needs to be carried out by the clinician in the clinic once.”

“Maybe a voice password could be used or simply a pin number that only requires numerical values and does not require an email address.”

Insufficient screen feedback and prompts for the user when carrying out certain tasks was identified as a recurring theme:

“There should be a prompt to upload the data. When he (the user) presses the back button it should prompt the user that the data is about to be

uploaded. The warning sign on the Exit pop-up box will cause anxiety and should be avoided.”

“I suggest that the interface should have one indicator saying if everything is working OK and if not, the interface should say specifically what the issue is”

“The battery icon needs to change colour/shape when it is decreasing.”;
“There needs to be a message which appears on the screen telling the user to initiate this (connection) sequence (PLEASE PRESS HERE TO ATTEMPT CONNECTION) and an indicator on the screen should tell them where to press (recommended by expert 8)”

The size of screen elements such as icons, buttons and text were identified as being problematic:

“(Made in reference to the pop up boxes in particular, for example ‘Invalid mail or Password’ during login,) the screen needs to be utilised better, pop up boxes need to be bigger and more prominent.”

“There is no reason why the large screen space could not be utilised more effectively for these buttons (referring to exit pop-up buttons). (Expert 1)”

“This (referring to an icon in top left hand corner to show that the app is running) is a good idea but it is just too small for older adult users.”

The results of the expert analysis and the end user analysis were compiled separately and then were presented in a problem report for system developers, with all problems listed with severity ratings and related testimony. The developers returned a proposal on how each problem could be solved which were then reviewed by the usability engineering team. Examples of proposals which were accepted by the usability engineers are shown in Table 5-8.

Table 5-8: Problems that were directly addressed by System Developers

Problem ID #	System Developer Comments
2	The login will be a once off action carried out at the clinic to simply match the data coming through to the patient who is using the app. We have debugged the app so that any crashes should not mean the user has to log back into the app (login cookie is stored on phone cache). We will also make it so that the user can see the password as they are typing to decrease the chance of error, as suggested by the experts.
4	We will change this to a more prominent symbol which will be slightly bigger although is constrained by the OS. We will make this symbol the same icon as the App icon
6	We will change the feedback text to “Are you sure you want to close this application? After closing, the data will be sent to the server”. We will also change the Caution symbol (⚠️) to an Information symbol (ℹ️) based on your suggestion
8	Contrast has been increased and text size increased to make it more prominent against the dark background
9	We will remove the text 'connect in 10 seconds popup' and just have 'Auto connection Started' and 'an everything is ok' pop-up once sequence is complete
10	The 'timer' text has been removed. We will also introduce colours for the symbols, red when the symbol is not in the ideal state and green when it is.
11	We will introduce a green and red button choice with related symbols
12	Text size will be increased and some redundant components will be removed from the interface to make more space

Not all identified problems could be easily fixed by the system developers. Some aspects of the interface were built into the Android™ operating system and therefore could not be changed, while some problems could not be solved within the time constraints of the project. Where it was clear that the developer could not affectively address a problem through interface changes, the usability team proposed an alternative as to how the problem severity could be at least reduced if not completely eliminated. Some of examples of these problems are shown in Table 5-9.

Table 5-9: : Problems that could not be directly addressed by System Developers and which in turn had a proposed solution by the usability team

Problem ID #	Problem	Scenario	System Developer Comments	Usability Team Proposal
1	The difference in operation between the HOME button and BACK button is not clear	User Minimises App	This is an Android™ design and cannot be changed and we feel that adding another button (an exit button) to the interface may cause further confusion	We will provide an instruction sheet which will show the user clearly the difference between the two buttons, emphasising in particular that the BACK button is only used for uploading the data
3	Buttons on keypad are too small for this population	User Logins to the App	This is an Android™ design and cannot be changed, The only solution would be to 'buy' another keypad design which will be expensive	Short Tutorials will be conducted for users on how to effectively use the keypad at the onset of use to improve confidence
5	Having to upload the data will be too hard to remember to do	Uploading Data by Exiting App	At this stage of development, an automatic data push is not feasible but will be considered for future	We will emphasise this scenario in our user manuals to reflect the fact that it needs to be carried out periodically
7	No prompt to indicate to the user that a manual connection is now required	User must Connect to the Insoles	We will improve the auto connection and introduce an option in the settings to turn off auto connection	We will describe the sequence in the short form manual, with steps for when a user should attempt a manual connection

Update of Paper Prototype and Development of First Working Prototype

Based on this communication between the development team and the usability engineers, a working App prototype for the Google Nexus™ 5 smartphone was developed as well as a full set of user manuals based on the Use Cases and the feedback from the Use Case analyses. The Use Case was also updated to reflect the changes to the interfaces. Figure 5.3 and Figure 5.4 shows examples of how the updated interface (Paper Prototype V2) compares to the Paper Prototype V1. In Figure 5.3(B) we see how colour indicators have been introduced to enhance the feedback on the system status screen as compared to Figure 5.3(A). Text size has been increased and some elements have been removed from the interface to reduce crowding. Figure 5.4(B) shows how the login screen has been updated with a decrypted password as well as increased text size and button size compared to Figure 5.4(A).

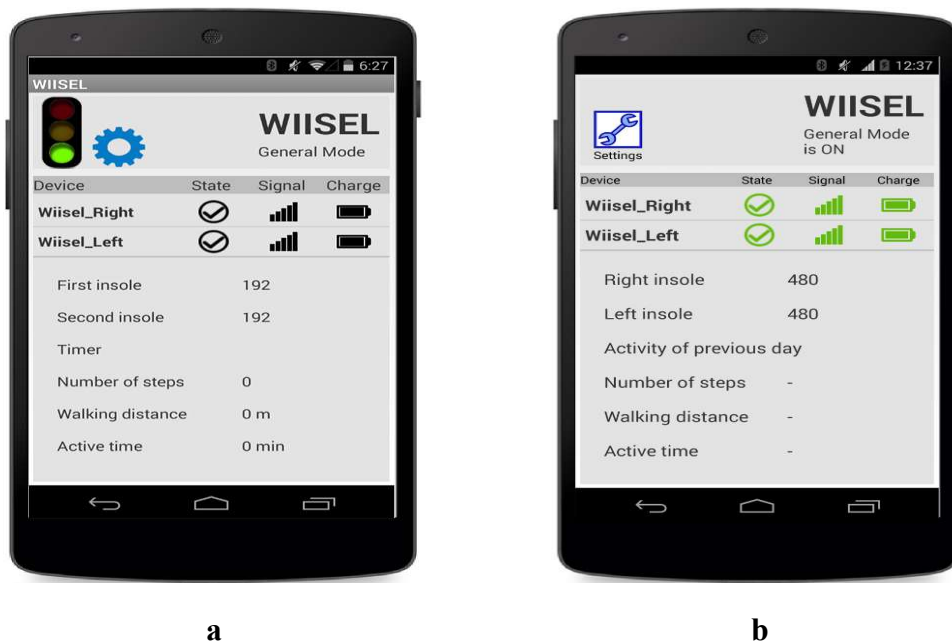


Figure 5.3: a) The Old interface showing the system status. Experts did not like the dull colours and crowded interface. Some users did not like the fact that there was no change of colours to indicate low battery, weak signal etc; b) The updated interface with colour indicators for connection, signal strength and battery life, as well as increased text size and contrast



Figure 5.4: a) Experts were concerned with the small button size and the fact that the password was encrypted meaning an older adult might lose their place when typing. This problem was also identified by end users; b) Increased text size and a larger, more prominent Sign In button as well as a decrypted password

Where the problems identified by the experts could not be addressed by an interface change, user manuals were created to offset any confusion or difficulties the user might encounter with the interface. In order to create an effective user manual, the original use case was updated with all the interface changes made by designers. Each Use Case scenario now became a section of the User Manual with the same chronological order maintained where applicable. For example, the Use Case scenario where the user connects to the insoles became a 'How to Connect' section in the user manual, and was followed by a 'How to Upload' section, as in the Use Case. Two forms of manual were created, a short form manual entitled the Basic Instruction Sheet which contained basic instructions on a double sided laminated sheet and a longer form manual laid out in similar style to the use case which elaborated on the instructions provided in the Basic Instruction Sheet and provided additional instructions for procedures which wouldn't be considered routine. Another version of these two forms were also created for clinicians with additional information on how to set up the system for the user, change settings, calibrate insoles and adjust fall detection settings. A selected sections of the manual is presented in Figure 5.5.

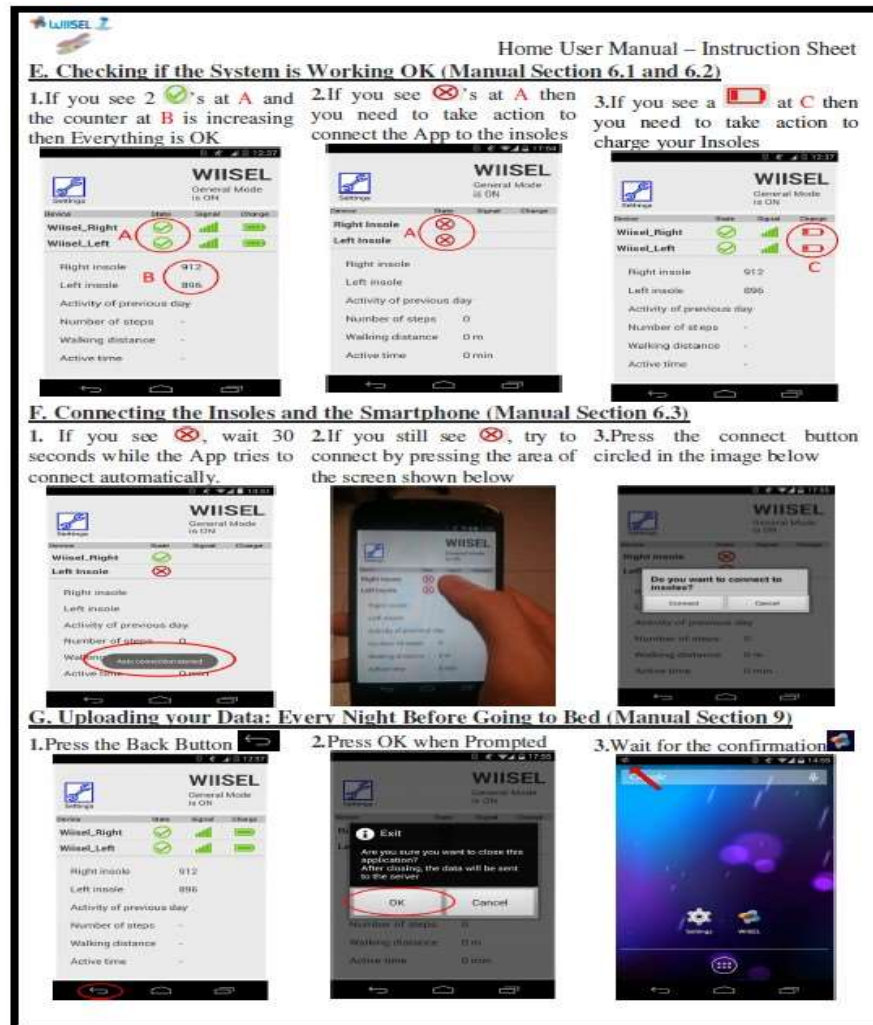


Figure 5.5: One side of the Basic Instruction Sheet (Short form manual) describing the connection and uploading sequences

5.3.2 Phase 2 Expert Inspection Results

Use Case Inspection of Paper Prototype Version 2

Table 5-10 presents examples of how the various problems uncovered during the Use Case analysis in Phase 1 were addressed and compares the problem rating it received from the first use case analysis (Paper Prototype V1) with the new rating it received from the analysis of the updated interface in Phase 2 (Paper Prototype V2).

Table 5-10: : Comparison of problem ratings between paper prototype V1 problems and the updated interface (paper prototype V2). The max individual score which was given by the 10 experts is also included to highlight the fact that some experts may have given a more severe rating than the mean or standard deviation indicates.

Problem ID #	Severity Rating (0-4) Paper Prototype V1	Max Severity Rating Given (0-4)	How was the Problem Addressed?	Severity Rating (0-4) Paper Prototype V2	Max Severity Rating Given (0-4)
1	2.5	4	A manual section was added which explained the operation of each button in the context of overall phone operation and in the context of the WIISEL App.	1.4	2
2	2.4	4	Debugging of the App and improved connection sequence means that App resets are not as likely, leading to a decreased need for the user to have to login. Button size was increased and the password decryption during the sequence was removed	0.3	1
5	2.1	3	Additional manual information was added and instructions on setting a daily reminder on the phone	1.4	2
6	2.1	4	The Caution symbol has been replaced with an information symbol, additional text information has been added explaining to the user what is happening regarding the data upload.	0.4	1

Problem ID #	Severity Rating (0-4) Paper Prototype V1	Max Severity Rating Given (0-4)	How was the Problem Addressed?	Severity Rating (0-4) Paper Prototype V2	Max Severity Rating Given (0-4)
11	1.5	3	Red and Green have been introduced as 'I have Fallen' option (red) and 'I am Ok' option (green). While experts agree with the notion of illustrations and colour coding, they are now concerned that there is no text labels on the buttons. One expert pointed out that Red could be confused for a cancel button (ie to cancel the alarm) in the same way as it would be when answering a phone call. This could lead to a user accidentally sending a fall alert to carer during a false positive sequence in which the user is forced to press a button in a hurry.	2.1	4
10	1.5	4	The addition of the green indicators for 'Good' and orange and red indicators for 'Bad' such as for the battery symbol have been welcomed.	0.1	1
12	1.3	3	While the Homescreen interface had improved, some experts felt that some space was not being utilised well and that small text and crowding was still an issue	0.44	1

The inspection found that of the 21 original problems identified by the experts, 3 had now received a rating of zero from the experts, 17 had received decreased ratings and 1 (ID #11) had received an increased rating.

Expert Cognitive/Contextual Walkthrough with Working Prototype Version 1

Table 5-11 shows the captured average metrics from each scenario, with the time and errors made metric captured. Accompanying the metrics are a selection of comments from experts.

Table 5-11: Average Metrics and consensus for 9 experts. ASQ scores range from 1-7, where 1 is the most satisfied and 7 is the least satisfied the user can be

Scenario	Time Taken (s)	Average Errors Made	ASQ Score	Comments
Check the system status	4.7	0.5	2	The increasing numbers (referring to the incrementing counters) on the interface are still unclear to some experts. While the experts acknowledge that this indicates 'data is streaming' the indication should be that it is either connected or it is not, any other information than that is completely redundant. Documentation is a little crowded, would like to see more space given in the manual
Connect to the insoles	48.0	0	3	This task but could be made easier by giving more feedback to the user and simplifying the interface somewhat. If the connection takes a couple of minutes then the user needs to be made aware that something is happening or else they will just keep pressing the connect button, possibly causing a crash or accidentally disconnecting it. The ambiguities in the connection sequence need to be made clear in the manuals, 'don't panic, give the system a chance etc'
Upload Data	4.3	0	2	There is a concern that there is no immediate feedback to let the user know they have completed the task successfully. The manual indicates that an icon will appear in the top left hand corner of the screen however it is obvious that this does not appear straight away if there is a lot of data, this should be made clear in the manual or just removed, as it may cause anxiety.
User Minimises App			4	The difference in operation between the BACK button and the HOME button, while addressed, is not made completely clear in the user manual. This will be important for users particularly if they intend to user other functions on the phone.

Scenario	Time Taken (s)	Average Errors Made	ASQ Score	Comments
Reset App	23.4	0.7	3	Not a very straight-forward sequence given the number of screens which need to be navigated, but under supervision this should be OK. This is quick if the user knows what they are looking for, although they could get easily lost. The user manual should explain to the user that they made need to scroll down in each menu to reach the option they need. If the user does not see the exact same screen that they see in the user manual they will think something is wrong.
Login to App	27.0	1.1	3	This will present challenges, particularly the keyboard. If the user can follow the manual then it will be easy but any digression from the main path will cause problems. The time is ok, although mistakes with the user credentials will obviously increase the time as well as the user frustration. More steps need to be added to this sequence in the manual
Respond to Fall Alarm	7	0.3	3	This is an easy sequence but the confusion over the options makes it a little bit more burdensome especially on users with any form of cognitive impairment. Very quick to do, provided the user is clear on what option they are pressing. The documentation here is inadequate and needs to explain the situations in which each option may need to be pressed

Of the 8 scenarios, three achieved a score of ‘satisfied’ and four achieved a score of ‘somewhat satisfied’, while one achieved a neutral score. No scenarios scored a perfect score of 1, indicating that all scenarios require some improvement, particularly regarding the clarity and flow of the supporting documentation. This is best illustrated in the radar plot (Figure 5.6), which shows how the ASQ score is distributed between satisfaction with ease of completion, time taken and supporting documentation.

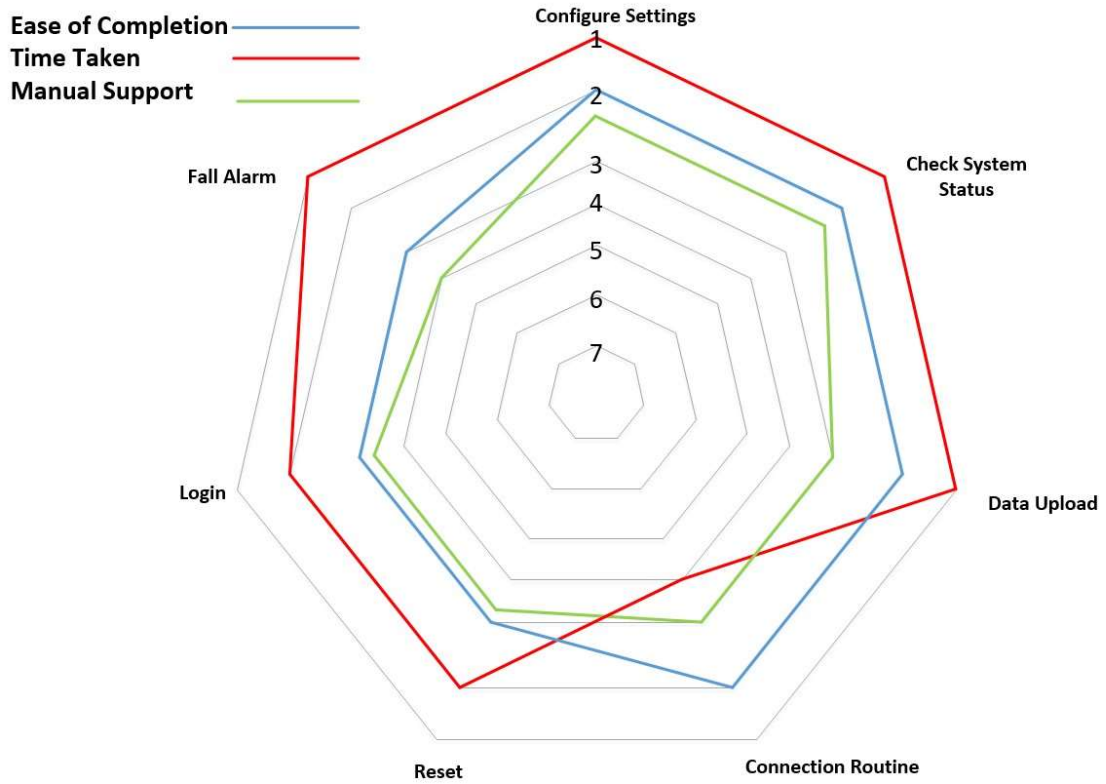


Figure 5.6: All basic scenarios scored consistently well regarding ease of completion (Blue) with just slight superficial changes, the more challenging scenarios such as login and reset registered higher (worse) scores. Only one scenario, connection routine, scored poorly in the time taken (red) metric, owing to the length of time it takes the insoles to sync with the App. Several experts were confused by some of the layout and instructions in the manuals (green), with improvement required for several scenarios, particularly the instructions for the fall alarm sequence

In response to comments by the experts during the Inspection, the user manuals were updated and several minor changes were made to the interface. These updates are listed in Table 5-12.

Table 5-12: Changes made to the user manuals and interface based on Expert Inspection

Scenario	Suggestions	Changes Made
Check the system status	This section of the manual needs to be less crowded	-The documentation now includes 6 steps instead of the original 4. A step is included to explain that the app may take several seconds to start up and how to lock the phone again. -Increased text size

Scenario	Suggestions	Changes Made
Connect to the insoles	Would like to see some explanation of the crash sequence in the user manual.	<p>-The same number of steps is maintained with additional labels indicating where on the screen the user may have to press during the connection sequence.</p> <p>-Increased button/text size</p>
Upload Data	Manual indicates that an icon will appear in the top left hand corner of the screen however it is obvious that this does not appear straight away if there is a lot of data, this should be made clear in the manual or just removed, as it may cause anxiety.	<p>-The third step, which explained that an icon would appear upon successful completion has been removed to avoid confusion as it does not always appear straight away. The section now also includes further explanation of what the BACK button is used for.</p> <p>-Increased button/text size</p>
User Minimises App (Home Button)	The difference in operation between the BACK button and the HOME button, while addressed, is not made completely clear in the user manual.	-A section explaining the function of this button was placed on the same page as the section explaining the use of the back button, this was done in order to provide a clear distinction between the function of the two buttons
Reset App	The user manual should explain to the user that they made need to scroll down in each menu to reach the option they need. If the user does not see the exact same screen that they see in the user manual they will think something is wrong.	-Expanded from a three step instructional process to a 5 step process. A section was also introduced to explain to the user how to best interact with the touchscreen in terms of scrolling and striking
Login to App	More steps need to be added to this sequence in the manual	<p>-Expanded from a 4 step process to a 6 step process including additional instructions on how to access the number keypad and find the @ symbol</p> <p>-Increased button size</p>
Respond to Fall Alarm	The documentation here is inadequate and needs to explain the situations in which each option may need to be pressed. As regards the options, it is suggested that red and green not be used to distinguish options and that text labels also be used for the buttons to accompany and supplement images	<p>-Expanded from 1 step to a 3 step process with clear illustrations to show when the user might experience</p> <p>-New buttons introduced to indicate cancel and confirm</p> <p>-Increased button size</p>

These changes led to Working Prototype Version 2 and a new set of user manuals which now contained four laminated sheets. Figure 5.7 shows an example of how the fall alarm interface has been updated.



Figure 5.7: a) Fall Alarm Interface before Expert Inspection, the red and green caused confusion as the red was associated with ‘Cancel’ as you would find on a phone call interface; b) Fall Alarm Interface after Expert Inspection, a more appropriate symbol was introduced for the help button while the cancel button was changed to a more neutral blue with appropriate labelling

5.3.3 Phase 3: Usability Testing with End Users

Table 5-13 shows the average metrics for the 10 test participants during the usability testing while Figure 5.8 illustrates the breakdown of the ASQ metric in terms of satisfaction with ease of completion, time taken and support documentation.

Table 5-13: Performance Metrics for each scenario with related commentary as observed during the testing

Scenario	Time Taken	Errors Made	ASQ	Comments
Check the system status	19	0.4	1	All users found this very easy to complete and manuals clear to follow, the only errors encountered were when users released the screen slide lock too early, which occurred with 4 of the 10 users.
Connect to the insoles	31	0.13	1	While users found the procedure and manual easy to follow, the time taken for the sync to complete caused minor frustration. The only error encountered were when some users held the manual connection button for too long
Upload Data	13	0.13	1	All users found this very easy to complete and manuals clear to follow, some minor errors included pressing the cancel button instead of the OK button. While the OK button was clearly marked as the button to press in the user manual, sometimes the user would press cancel without consulting the manual.
Reset App	112	1.0	2	While quite a complex sequence, most user's found it easy to complete, but were susceptible to minor errors, such as accidentally pressing the wrong menu option, or accidentally pressing while scrolling. These errors are down to unfamiliarity with touch screen interfaces and 'heavy handedness'. There was one error with regards to the layout of the manual.
Login to App	171	0.88	2	This sequence took the most time, due to most user's unfamiliarity with touchscreen keypads. There was a huge disparity in times, ranging from 30s to nearly 5 minutes, with those who had previous experience with smartphones faring generally better. The manual layout also caused some confusion with user's having to jump a step to find out how to enter numbers and then having to return to the previous step.
Respond to Fall Alarm	6	0.5	2	The original fall sequence caused an error for every second user, who thought the red option was the cancel option, as you would expect on a mobile phone call. (See Figure 5.7 (A))
Respond to Fall Alarm	6	0	1	The new alternative fall sequence proved more successful, with the removal of the red/green option causing less confusion with no errors reported. (See Figure 7.7 (B))

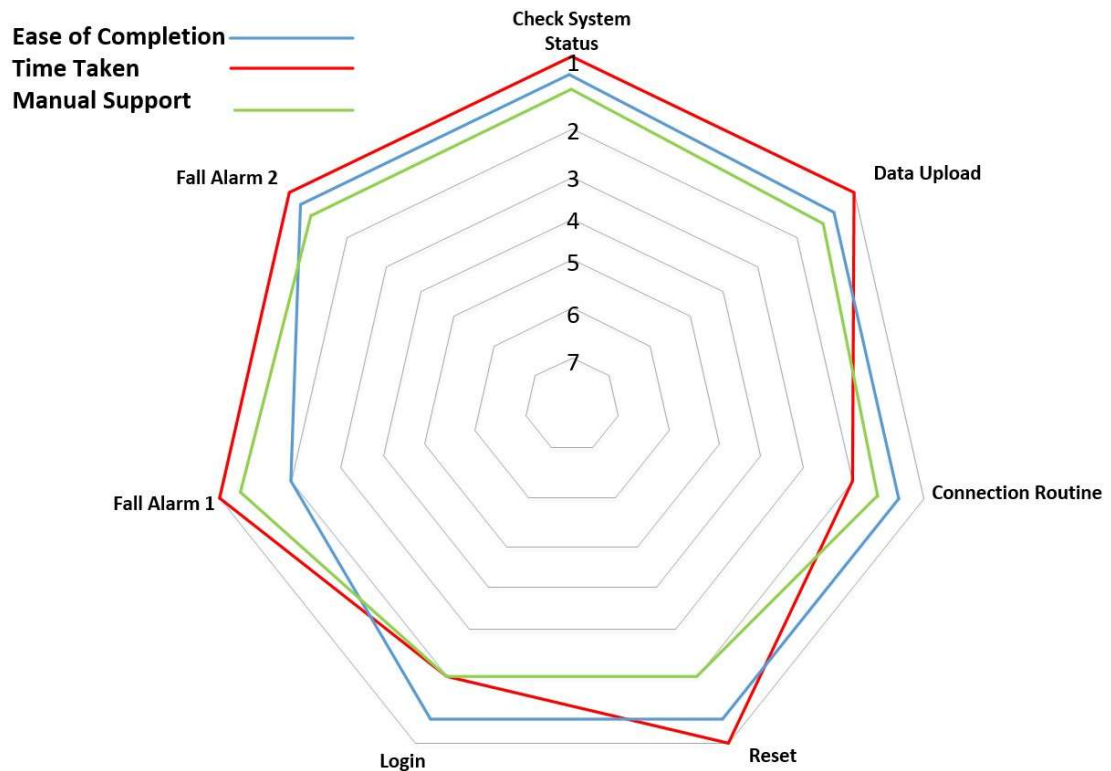


Figure 5.8: All scenarios scored maximum for ease of completion (blue) apart from the fall alarm 1 which caused slight confusion. Time taken (red) was not considered a major issue for any of the scenarios, with the connection routine not scoring maximum due to the nature of the syncing process, while the unfamiliarity with typing caused some users to mark down the login sequence. There was some confusion with the reset and login sequences in the user manual (green) which is explained further in Table 13

The results of the NASA TLX metric are shown in Table 5-14. A score of 100 indicates maximum burden on the user, while a score of 0 indicates no burden. The first four tasks scored very well, indicating little to no burden on the user. The login and reset procedures, due to the number of steps involved, created the most mental, physical and effort burden, as well as the most frustration, particularly the login procedure. The most temporal burden was created by the fall alarm procedure, due to the timer on the screen, forcing the user to make a hasty choice.

Table 5-14: NASA TLX Scale Breakdown by Scenario

Scenario	Score	Mental	Physical	Temporal	Performance	Effort	Frustration
Check the system status	4.9	3.8	8.5	4.3	4.3	4.7	4.0
Connect to the insoles	7.0	9.9	5.6	12.9	4.4	4.4	4.9
Upload Data	4.1	3.2	4.0	3.3	5.3	3.3	5.2
Minimise App	3.6	4.7	3.7	2.8	3.0	3.8	3.5
Reset App	30.3	42.3	16.3	15.0	17.5	53.3	37.2
Login to App	39.1	54.7	29.0	20.3	20.7	65.8	43.8
Respond to Fall Alarm 1	26.6	43.5	7.7	59.5	20.2	18.3	10.5
Respond to Fall Alarm 2	13.6	22.8	6.2	33.3	4.8	6.5	7.7
Most Burdensome Scenario	Login	Login	Login	Respond to Fall Alarm 1	Login	Login	Login

Table 5-15 shows the Likert response for different aspects of the interface in each scenario. The severity rating is calculated in the same manner as phase 1 and phase 2.

Table 5-15: Likert Items Severity Rating (Range 0-4, 0 = no problem, 4 = most severe problem) for Interface Ergonomics by Scenario. Some Likert items did not apply to certain scenarios. An x indicates that there was no Likert statement for that particular interface aspect for that scenario

Scenario	Colour	Text	Buttons	Keypad Buttons	Icons Size	Icon Meaning
Check the system status	0	0.25	x	x	0.12	0
Connect to the insoles	x	x	0.12	x	x	x
Upload Data	0	0.12	0.12	x	x	x
Login to App	0	0.12	0	0.37	x	x
Respond to Fall Alarm 1	0	0	0	x	x	x
Respond to Fall Alarm 2	0	0	0	x	x	x

5.3.4 Summary of Results

With combined expert and end user analysis of a comprehensive Use Case having originally identified 21 problems with the system interface, we have only seen observed 3 of these problems in User Testing (Problem ID 1, 2 and 12). Satisfactory ASQ ratings were obtained during validation testing by both experts and end users, and final testing by users shows the system requires low mental, physical and temporal demands according to the NASA TLX. Table 5-16 shows how three of the problems (problems involving flow, consistency and feedback) have evolved over the testing cycle. Problem 2 and 6 show a clear linear improvement from phase 1 through 3, with Problem 2 an example of a problem that despite best efforts remained a cause of potential user frustration due to the unfamiliar style of touchscreen keyboards. Problem 6 represents an example of a problem which was effectively mitigated through interface changes and manual support. Problem 11 is an example of a problem which was actually exasperated by an interface change, causing greater confusion to users, although this was effectively identified and mitigated between phase 2 and phase 3.

Table 5-16: Presents the evolution of three distinct problems through the testing lifecycle with the usability metrics taken at each stage

Problem ID	Phase 1	Phase 2		Phase 3		
	Severity Rating (0-4)	New Severity Rating after Inspection	Expert ASQ Score (0-7)	End user ASQ Score (0-7)	NASA TLX (0-100)	Caused Error During User Testing?
2	1.77	0.6	3	2	39	On average, users made 0.88 errors during this scenario
6	1.41	0.4	3	1	4	On average, User made 0.13 errors during this scenario
11	1.09	1.2	3	1	13	On average users made 0 errors during this scenario

The System Usability Scale metrics after each phase are presented in Table 5-17. The SUS is split into two scales, overall usability and learnability [29]. Early phases showed widely variable SUS scores, particularly among experts, while phase 3 scores showed agreement among end users that the interface had achieved some level of acceptability.

Table 5-17: SUS Metric, split into overall usability and learnability, captured at each phase

	Phase 1		Phase 2		Phase 3	
	Learnability \bar{x} (σ)	SUS Total \bar{x} (σ)	Learnability \bar{x} (σ)	SUS Total \bar{x} (σ)	Learnability \bar{x} (σ)	SUS Total \bar{x} (σ)
Experts	35 (24.23)	55 (23.6)	48.75 (26.36)	68.75 (11.6)	n/a	n/a
End users	58 (26.43)	78 (10.77)	n/a	n/a	87.5 (5)	88 (3.75)

5.4 Discussion

We have presented a multi-phase HCD approach to improve the user experience of a smartphone interface which forms part of a Connected Health system. Our approach was designed to uncover and mitigate any usability problems as early as possible, before they were exposed to end users during usability testing and in formal clinical trials. This paper presents one full cycle of our HCD process, with each phase representing an iteration where a design update or refinement took place. Our approach has met the specific recommendations for a HCD process [30]. We have adopted the input of multi-disciplinary skills and perspectives by eliciting the feedback of both an end user group and an appropriately experienced expert group throughout the process. We have sought to gain an explicit understanding of users, tasks and environments and consideration of the whole user experience through the adoption of a Use Case which provided context of use for system tasks and scenarios and through the examination of the perceptual and cognitive needs of the target end user. We utilised a User-Centered evaluation driven design using standard usability evaluation metrics at each point in the cycle. We involved users throughout the design process, at both early and later stages. Finally, we employed an iterative process, split into three stages/phases which allowed for user feedback to be worked into design updates.

5.4.1 Principal Findings

From our observation of older adults' interactions with smartphone interfaces, there were some recurring themes. Clear and relevant feedback as the user attempts to complete a task is critical, (in line with contemporary literature [31, 32]). Feedback should include pop-ups, sound tones, colour/texture changes or icon changes to indicate that a function has been completed successfully, such as for the connection sequence (Problem ID# 9). For text feedback, clear and unambiguous language should be used so as not to create anxiety, particularly when it comes to saving data such as in the Data Upload Sequence (Problem ID# 6). Older adults not familiar with technology are often afraid that they might delete something by accident or fail to save important data properly. Warning tones or symbols, such as a caution symbol, should only be used if absolutely necessary. For audio feedback, clear and low frequency tones should be used. Login sequences where the user is required to input text with a QWERTY keyboard should be avoided (Problem ID 2), particularly for those who have no previous touchscreen experience. If a login sequence is considered necessary for security or identification purposes, it should be ensured that a login process is made as simple as possible (do not hide password, be clear about what username is required, supply ample support documentation for process). For simple interface elements, text sizes should be at least 10pts (Didot system), while button sizes should have a surface area of no less than approximately 200mm² [11, 33].

In terms of metrics, we used four different subjective measurement systems (Likert Scales, ASQ, NASA-TLX, SUS) to assess the usability of the interface at different stages. The Likert scales allowed for quick satisfaction ratings of the perceived ease of use of each task in the Use Case and of the suitability of interface elements such as text and button size. The ASQ was more suitable for post-scenario ratings when the user had actually completed the task, while the NASA-TLX was used to supplement the ASQ to provide further details on what kind of burden, be it physical or cognitive, the task placed on the user. The SUS was utilised when the user had completed a full use of the system and carried out all tasks. We observed that all of these metrics are providing the similar information, just in slightly different resolutions and that a mixture of metrics allows us different insights into user

perceptions of usability. For example, in Phase 3, from looking at the ASQ scores of the login sequence, we could conclude that the user was satisfied with the ease of the task. However, when we looked at the NASA-TLX scores, we observed that the task was creating a large mental demand on them. These two metrics, while showing us seemingly conflicting pieces of information, may be telling us that the user judged the task as being easy simply because they completed it successfully, regardless of the difficulty they encountered or the time it had taken them. It is only when they think about the task in terms of the NASA metrics that they become honest about what kind of burden the task placed on them. The SUS was a useful general indicator of overall usability but its wide variability (Table 5-17) suggests that it is best used with larger sample sizes. High SUS scores do not guarantee the system will not suffer usability problems in the field [34]. These metrics are probably best used to supplement more objective metrics such as task times and error rates.

5.4.2 Procedural Observations

In terms of efficiency, our methodology proved to be successful. The utilisation of the Use Case analysis activities during Phase 1 provided a focus for all stakeholders on the context of and the intended use of the system. The time it took for each individual to analyse and provide feedback was on average 1 hour. Within this hour, the individual was experiencing and commenting on context, was being formally interviewed, was filling out questionnaires and was providing opinions on interface concepts. Therefore in one session the Use Case analysis provides multiple streams of data, whereas in previous literature, this kind of feedback would need to be gathered across multiple activities, such as surveys, interviews and ethnographic observations. In Phase 2 the use of expert inspection groups also proved highly efficient. We recommend that research groups and design teams maintain an inspection group who can carry out on hand inspections of new system versions. This group, which can comprise 4-6 members, need not necessarily be qualified usability engineers but can be trained in techniques such as heuristic evaluations and cognitive walkthroughs.

5.4.3 Limitations

Time and technology constraints meant that not all design requirements could be implemented. For example, the replacement of the manual data upload with an automatic periodic data upload could not be implemented in time by the engineering team. Similarly, the structure of the Android OS meant that some user and expert recommendations could not be implemented, particularly regarding the positioning of pop-ups or the nature of data storage. Some design changes led to a decrease in user experience, particularly for the fall alarm sequence (Problem ID# 11). It became clear during user testing that the use of red and green in an emergency situation may not be the best practice, with some users confusing the red emergency button for a cancel button, like it may be presented on a phone call screen (red for 'hang-up'). In this case the design team failed to take into account the recommendation of one expert who predicted that a red/green option may cause confusion. We can conclude from this that taking on board opinions from different stakeholders can present a challenge for designers. However, the nature of our iterative methodology meant that this problem was identified and addressed between Phase 2 and Phase 3.

In Phase 1, the older adult end users tended to be very optimistic about how they would handle the system and the smartphone interface, overall giving higher scores in response to Likert statements and for the overall SUS score. Experts tended to be more pessimistic but this was probably due to their vast experience with older adults and technology. Most experts conceded that the Use Case Analysis was a hypothetical one and that the capabilities of the older adult population are extremely variable, however they felt that it was an extremely useful exercise in identifying major potential problems and addressing them early in the design process. Despite the difference in outlook between the experts and older adults, both groups reached agreement on most problems, particularly about the perceived difficulty of the login process and the lack of clear feedback when checking the system status and during the data upload process. We can conclude from this that utilising multiple perspectives from different groups is an important feature of good human-centred design process.

5.5 Conclusion

The HCD Methodology we have designed and implemented based on the principles of ISO 9241-210 has produced a functional App interface which is now suitable for exposure to older adults in long term clinical trials. We have applied appropriate testing techniques given the context of the interface being assessed. We would consider this a thorough and robust method for testing and informing design changes of all types of interactive Connected Health systems.

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The methodology for this study was conceived and designed by Harte, Quinlan and Ó Laighin. The experiments were carried out by Harte with the support of Glynn, Scharf and Rodriquez-Molinero, each of whom contributed both usability and medical knowledge to the testing. The data was compiled and analysed by Harte, Quinlan and Ó Laighin and reviewed by Glynn, Rodriquez-Molinero and Baker. All authors contributed equally to the introduction and discussion sections of the paper. The paper as a whole was reviewed and edited where necessary by all authors before submission.

Conflicts of Interest

The authors declare no conflict of interest.

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**Chapter 6 – A Multi-Stage Human
Factors and Comfort Assessment of
Instrumented Insoles Designed for Use
in a Connected Health Infrastructure**

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Wearable Electronics are gaining widespread use as enabling technologies, monitoring human physical activity and behaviour as part of Connected Health infrastructures. Human Factors and Comfort Assessment of these devices can greatly influence user experience, with a subsequent higher likelihood of user acceptance and lower levels of device rejection. In this chapter, we take our methodology described in Chapter 4 and apply it to the design and human factors testing of the instrumented insoles which make up part of the WIISEL system. While the device being tested is not considered a traditional interactive device, we still maintained the same design and testing philosophy as described in Chapters 4 and 5. We utilised many of the same activities such as Use Case analyses, prototype inspection and controlled user testing. We expected that our methodology would help to enhance the human factors (ergonomics) and user experience of the device and we also expected that this study would demonstrate the adaptive nature of our methodology, which we feel can be applied to many different devices and systems.

6.1 Introduction

Instrumented footwear can refer to any custom-made insole or foot-wear which incorporates electronic circuitry used to capture measurements such as physical activity, push-off and contact forces, gait data or health metrics [1, 2]. An important consideration in the design of any kind of wearable device such as an instrumented insole is its comfort and human factors. Devices and systems used in healthcare settings, particularly those used in an unsupervised context require high standards of comfort and human factors to facilitate technology acceptance, reduce gadget intolerance and enhance the user experience, as well as to ensure the safety and comfort of the user. Recently, both the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality have called for human factors evaluation of medical devices and systems during the design process [3, 4] while knowledge of the user and their capabilities and characteristics has been highlighted as an important consideration within the design process [5].

It has been previously established that any improvement in subjective user scores on aspects of user experience of a device including ease of use, comfort and cosmetic appearance saw, a proportional increase in the frequency of use of the prescribed

device [6, 7]. From these findings we can infer that comfort and human factors are key aspects in the usability of prescribed footwear and that accurate comfort assessment is a critical activity within the design and testing process. The specific design, materials utilised and construction of footwear devices greatly influence their comfort [8].

Previous studies have sought to find objective and reliable measures of comfort for footwear and insoles, highlighting the subjective nature of comfort rating [9-11]. Recognising these difficulties, we propose a systematic comfort and human factors assessment approach grounded in the principles of Human-Centered Design [12] to influence the design of an instrumented insole. Our approach seeks to involve stakeholders, experts and human users. This approach allows the application of robust comfort testing techniques within a cyclical process to mitigate possible problems before the device is exposed to potentially high-risk user groups, such as older adults with chronic conditions.

The Wireless Insole for Independent and Safe Elderly Living (WIISEL, <http://www.wiisel.eu/>) system, developed as part of an FP7 project, is designed to continuously assess fall risk by measuring various gait and balance parameters associated with fall risk. The system is also designed to detect falls. The system consists of a pair of instrumented insoles and an associated smartphone which are both worn by the user. The insoles are inserted into the user's shoes and worn on a continuous basis, throughout the day. Data collected by embedded sensors in the insoles are sent to the smartphone, where they are then uploaded to a server in a clinic for processing and analysis. At this point the data can be presented in various ways to a specialist via a web app and desktop-based Gait Analysis Tool. The overall architecture of the system is illustrated in Figure 6.1.

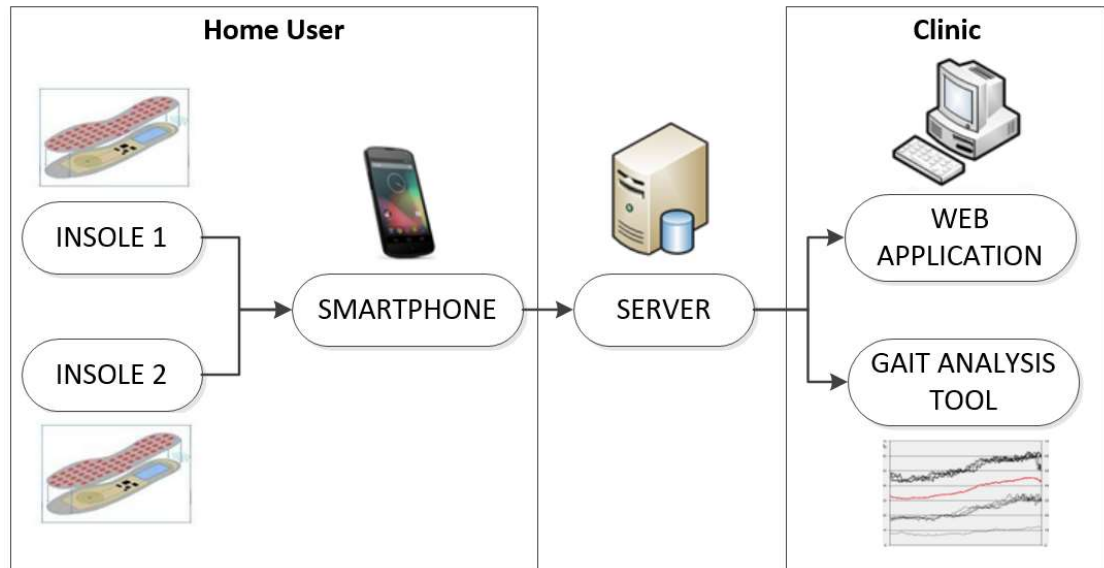


Figure 6.1: The WIISEL system architecture

The system was designed to be worn by a user throughout their waking hours in order to identify specific gait patterns that may be contributing to a user's fall risk. The system was targeted at older adults who may represent a high-risk group for falls.

6.2 Methodology

Our methodology was designed using the principles of Human-Centered Design with direct contributions from experts, stakeholders and volunteers. The process was designed to be iterative and consisted of three phases.

Phase 1: Establish Context of Use and User Characteristics:

In this phase a Use Case was constructed with input from all stakeholders. Constructing a Use Case is a commonly used method to capture user requirements and user preferences [13-15]. Our Use Case was an interactive, scenario and task-driven, descriptive document which provided a common platform for project stakeholders to communicate their vision for the insole's role within the overall WIISEL system and the interactions it would have with the various system actors. The Use Case was used as a point of reference throughout this study and the wider WIISEL project to provide all stakeholders and analysts with the device's context of use, and user characteristics.

Phase 2: Expert Human Factors and Comfort Inspection of Prototype:

Human Factors inspection involves a multi-disciplinary expert group inspecting the device and attempting to identify human factors problems [16, 17]. Human Factors inspection is commonly used as a precursor to user testing. By identifying problems during the inspection process, it acts as a means to avoid subjecting users to testing devices which may be unsafe even for short periods of testing [18, 19]. Our Human Factors inspection process consisted of individual experts inspecting the latest device prototype in a structured manner, attempting to identify potential comfort problems, using the Use Case as a reference.

Phase 3: Human Volunteer Testing

Human testing involves monitoring volunteers while they wear the device and recording and documenting any problems the volunteer encounters [20, 21]. Our Human Volunteer Testing was informed by the recommendations from the experts during the inspections carried out in Phase 2. The full methodology utilised is illustrated in Figure 6.2. The methodology was designed to be cyclical, where decisions are made at different points on whether to continue to the next phase of the process or to return to a previous phase. Most critically, expert consensus is used at the end of Phase 2 to decide whether or not a prototype is suitable to continue for Human Volunteer Testing. If it is deemed not suitable for Human Volunteer Testing, then suggestions are offered on how to improve the prototype to better meet comfort and Human Factors requirements. For Human Volunteer Testing we sought to establish statistical significance between a ‘normal’ control footwear condition (the user wearing their typical footwear without the WIISEL insole) and the condition where the user was wearing the insole.

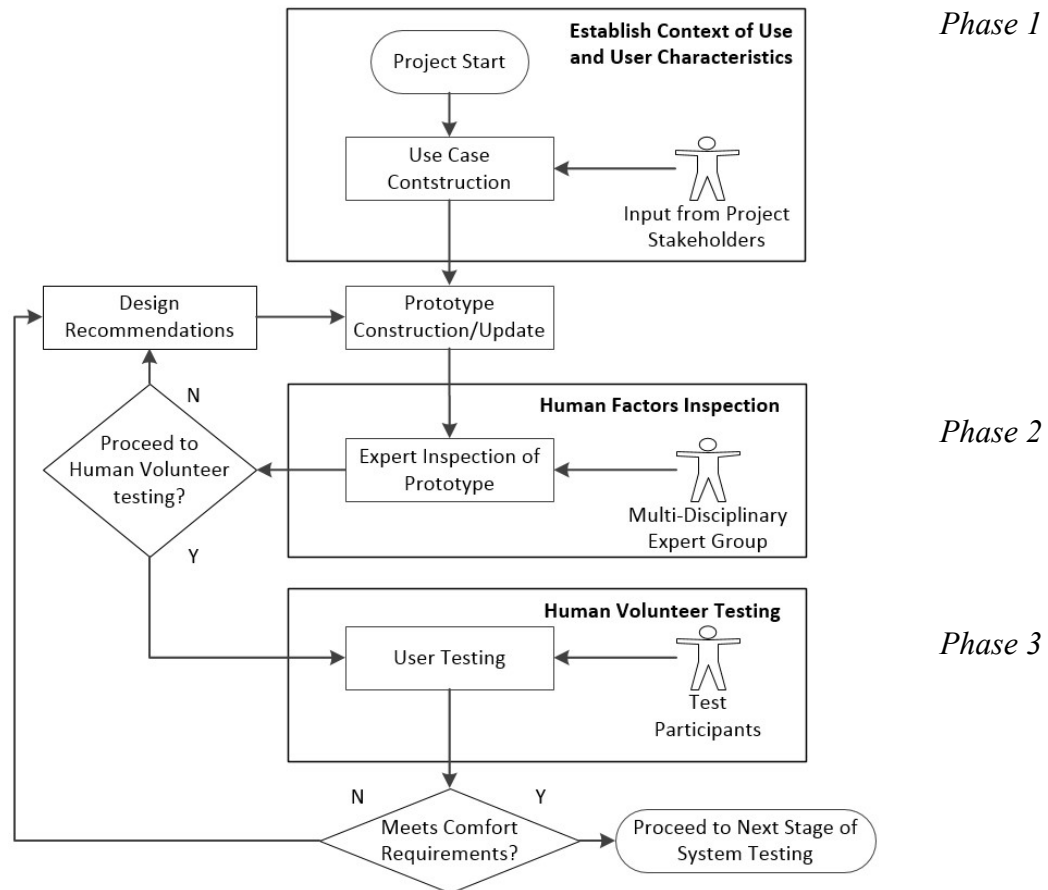


Figure 6.2: Iterative Human Factors and Comfort Assessment Methodology

6.2.1 Use Case Development

The Use Case is a document designed to provide the context of use for the proposed device and to build a profile of the end user. The Use Case described in detail the scenarios in which the insole is prescribed and then used by an older adult in their daily life. The document was presented in a storyboard format and includes illustrations, images and functional information about how the user interacts with the insole (Figure 6.3 and 6.4). The Use Case was directly informed by contributions from the different stakeholders. The Use Case was developed using an iterative process. In response to the completed and agreed Use Case, the first prototype insoles were built.

GP

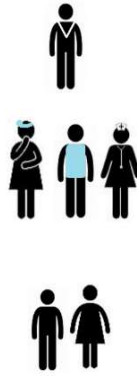
John's GP is his primary health contact and is the person who refers him to the falls clinic. The GP may also act as a system administrator.

Clinical Health Professionals

The health professionals present at the falls clinic will introduce John to the WISEL system. They will register John on the system and will also train him in the use of the insoles. The professionals at the clinic may consist of nurses, occupational therapists, physiotherapists, research assistants, podiatrists and geriatricians.

Relatives/Carer/Neighbours

John may have carers who visit him on a regular basis. These could include family, friends or neighbours. A relative/carer may attend the clinic with him.



A

3.1 Profiles of Possible Users

User A: A Person with Poor Dexterity and Low Grip Strength

User A suffers from osteoarthritis like approximately 25% of women over the age of 70. On average she can exert 10% less grip power than those without the condition. She sometimes suffers pain when she must stretch her hand out to grip something or when she must employ a controlled pinch grip such as when writing or handling small objects. Holding a steady grip of a small object can be difficult due to her hands shaking. She also finds it difficult to manipulate lacing and buttons on clothing.

This means she may encounter the following difficulties with the insole:

- Removing or inserting the insole into her shoes, particularly when the fit is very tight
- Having to tighten laces or straps on shoes to



B

Figure 6.3: Section of the Use Case describing: (A) the different actors who would be interacting with the system; (B) the possible physical limitations of the target users

John now completes his **Bedtime Routine** as in Day 1.

Alternative Bedtime Scenario

If John is particularly active in the evening around the house and likes to wear slippers, he can place the insoles in the slippers if the slippers have firm soles and firm sides. He transfers the insoles from his daily wear to his slippers.

He then completes his bedtime charging sequence as normal.



Figure 29: John sometimes wears slippers

Please mark your level of agreement with the following statements

Statement 14	Strongly Disagree	Disagree	I Don't know	Agree	Strongly Agree
Wearing slippers around the house would be common for an Older Adult					

A

John Outside the House

John goes for a walk. He is wearing the insoles and the smartphone (Figure 27). The insoles send gait data to the smartphone. The fall detection system will also work provided he is wearing both the insoles and the smartphone.



Figure 27: John wears the system outside the house

While John is out he is careful to avoid excessive surface water (Figure 28). While the insoles can afford some moisture exposure he has been advised to not expose the insoles to an environment where they may become submerged.



Figure 28: John is careful to avoid puddles and excess surface moisture

B

Figure 6.4: Section of the Use Case describing: (A) how the user might interact with the insole in an evening setting; (B) how much daily activity the user might carry out while wearing the insole

Criteria Required to Proceed to Prototype Construction

All project stakeholders must agree that:

- The Use Case represented the correct context of use in which they proposed the device/system be used
- The Use Case presented an appropriate description of the target users of the system

6.2.2 Prototype Construction and Electrical and Environmental Test

A technical specifications document was written to accompany the Use Case and designers worked from these specifications. It was decided that the WIISEL insoles would consist of a number of electronic components which required encapsulation. Components included 14 pressure sensors, 2 inertial sensors, a microcontroller, a battery, an antenna and a charging coil. For the first prototype, the sensors were encapsulated in a 1mm polyurethane layer Figure 6.5(A)), while electronic components were encapsulated in a 4mm clear polyurethane layer (Figure 6.6(A)). These two combined layers (Figure 6.5 (B)) are completely encapsulated in a leather top layer and an EVA foam bottom layer (Figure 6.6 (B)).



Figure 6.5: a) 1mm polyurethane sensor layer; b) Sensor and PCB layer glued together



Figure 6.6: a) PCB components embedded in a clear 4mm polyurethane layer b) Top layer (black artificial leather) and bottom layer (Brown EVA Foam)

Criteria Required to Proceed to Human Factors and Comfort Inspection

Before being made available for human factors and usability testing, the prototypes were subject to numerous electrical and environmental assessments such as waterproofing, electrical leakage/safety, sensor sensitivity and durability. Prototypes

were only made available for usability and human factors analysis after designers were satisfied with their functional integrity.

6.2.3 Human Factors and Comfort Inspection of Prototype

A cognitive walkthrough protocol is a popular approach to Human Factors inspection and involves the inspectors carrying out an analysis of the device in the context of how the user would interact with it [22, 23]. The inspection methodology was split into three parts:

- a) Establishing Device Characteristics, User Profile, Context of Use through an analysis of the Use Case Document
- b) Inspection of the Device and Problem Identification
- c) Problem Severity Score and Final Recommendation

Six Experts were recruited to carry out the inspection and all followed our defined methodology, their occupation and specialities are listed in Table 6-1.

Table 6-1: Description of each of the Experts who were recruited to carry out Human Factors and Comfort Inspection of the Insole

Expert	Occupation	Relevant Expertise
1	Physiotherapist	Physiotherapist and clinical rehabilitation specialist at a primary care clinic.
2	Professor of Podiatry	Professor of Podiatry and Head of the Discipline of Podiatry. This Expert has a specialist research interest in tissue viability and diabetic foot disease
3	Podiatry Researcher	Expert in Fall Risk and Diabetes in the Older Adult population
4	Clinical Podiatrist	Vast experience with biomechanical issues, orthotic prescription and insole design.
5	Occupational Therapist	Experience working with community dwelling older adults and research interests in Fall Risk
6	Podiatry Researcher	Specialist in Foot Biomechanics and Arthritis

Human Factors and comfort inspection sessions were carried out using a one-to-one format with the researcher. The Expert was presented with the latest version of the

WIISEL Insole Use Case. Having established in what context the device would be used and who would be using it from the Use Case, the Expert was formally asked whether they understood a) the context in which the device would be used (Context of Use) and b) the nature of the target end user (User Characteristics). At this point the Expert could ask for further clarification on the Context of Use or on the User Characteristics, at which point the researcher who had an intimate knowledge of the system and the potential users would provide the required information.

The insoles were then shown to the experts and a cognitive walkthrough methodology [24] was employed to evaluate the quality, safety and ergonomics of the insoles. The Expert studied the insoles in relation to the Context of Use described in the Use Case and was encouraged to think aloud and explicitly identify problems as they examined the device [16]. Experts were made aware of how the insole was constructed and what materials were used. If any problems were identified by the expert, these were described in the Expert's own words. The full list of problems were then listed and read back to the Expert by the researcher. The Expert had an opportunity to then combine related problems into single problem statements or remove problems that they felt in retrospect were not critical enough to be listed. The expert then applied a Severity Score to each problem based on Nielsen ratings [21, 24]. Severity scores ran on a scale of 0-4. Table 6-2 lists what each score means in usability terms and its potential implications for users.

Table 6-2: Severity Scores from Nielsen inspections [21,24]

Score	Classified As	Implications for Future Design
0	Not a Usability Problem	Something to consider for future design iterations but will not affect general use
1	Cosmetic Problem	Need only be fixed if time, resources available. Problem should not affect the majority of users
2	Minor Problem	Low priority fix, problem will affect some users
3	Major Problem	Important to fix, high priority, fix as soon as possible, problem will affect majority of users
4	Catastrophic Problem	Must be fixed before product is tested with end users, problem will affect all users

All problems identified during the inspections were rank ordered in terms of how many Experts identified the problem and the corresponding severity score. These two metrics were used to apply a Severity Rating to each problem identified. This, and other similar weighting systems, are used commonly to prioritise which problems are most important to fix [25]. The *Severity Rating* is defined as the number of times a problem was identified multiplied by the mean Severity Score. The maximum possible Severity Rating in this study for a particular identified problem was 24 (all Experts identifying a problem and assigning it a Severity Score of 4). With this number, the problems could be prioritised. The priority levels are defined in Table 6-3.

Table 6-3: Showing how Severity Rating are used to categorise problems based on priority

Score	Usability Implications
1-6	Cosmetic Problem; Should be fixed only if resources time are available, these problems should not affect the majority of users
7-12	Low Priority Fix; Will cause problems for some users and should be addressed as soon as resources are available
13-18	High Priority Fix; Will affect many users and lead to severe reduction in user acceptance, should be fixed as soon as possible
19-24	Usability Catastrophe; Will affect all users and may cause danger, development should be halted until problem is fixed

Finally the Expert made a recommendation based on their inspection using a simple questionnaire, summarised in Table 6-4.

Table 6-4: Simple Questionnaire for Experts to provide recommendations for the User Testing Phase

<i>This device is suitable for user testing with the following user groups >></i>	Young Healthy Users	<input type="checkbox"/>	<i>And can be worn for a period of:</i>	Please specify the maximum periods of exposure you would recommend this device could be worn safely by each of the user groups:
	Healthy Older Adults with no Fall Risk	<input type="checkbox"/>		
	Older Adults with Fall Risk	<input type="checkbox"/>		
	No User Groups	<input type="checkbox"/>		

Criteria Required to Proceed to Human Volunteer Testing

Proceed to Human Volunteer Testing if:

- A. There are no problems identified which receive a Severity Rating corresponding to a Human Factors catastrophe (See Table 6-3)

OR

- B. The majority of Experts reached a consensus on whether older adults should be tested with the insoles or not, the Human Volunteer Test phase was initiated. If the majority of Experts (>3) selected, ‘No User Group’ then it was deemed that the device must re-designed prior to human testing.

6.2.4 Human Volunteer Testing

In comfort assessment, it is considered best practice, to have a control condition or baseline measurement such that all experimental conditions assessed can be compared to the baseline measurement [10]. To provide a controlled observation of comfort of the prototype insoles, 10 participants were recruited for four sessions of comfort assessment over 4 consecutive days. The participants provided written informed consent and presented themselves at the Human Performance and Locomotion Laboratory in NUI Galway. Ethical approval for testing was granted by the NUI Galway Research Ethics Committee. Participants were excluded if they had a previous lower limb surgery, currently had an injury or used an orthotic device. The itinerary for the 4 days of testing is outlined in Table 6-5. Before testing, participants were instructed to attend the lab in their most comfortable ‘typical daily’ footwear and to wear these for all four days of testing.

Table 6-5: Outline of activities carried out by users during user testing

Day and Condition	Activity	Activity Time (Hours)
Day 1 (Normal Footwear <u>without</u> instrumented insoles)	Outdoor Walking	1
	Treadmill	2
Day 2 (Normal Footwear <u>with</u> instrumented insoles)	Outdoor Walking	1
Day 3 (Normal Footwear <u>with</u> instrumented insoles)	Outdoor Walking	1
	Treadmill	1

Day and Condition	Activity	Activity Time (Hours)
Day 4 (Normal Footwear <u>with</u> instrumented insoles)	Outdoor Walking	1
	Treadmill	2

Outdoor Walking consisted of walking on paved roads around the city of Galway and around the NUI Galway campus. All participants walked the same route. Participants filled out Visual Analogue Scales (VAS) at certain points during the testing. This is illustrated in Figure 6.7.

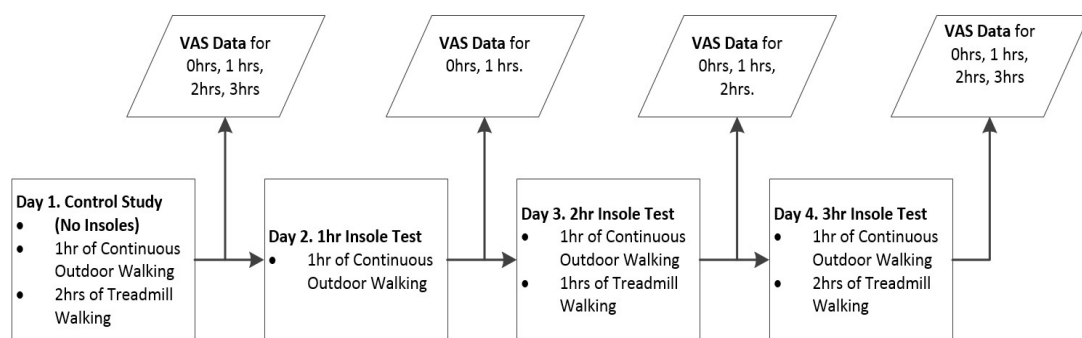
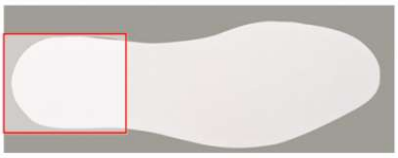




Figure 6.7: Procedure for testing insole comfort with young healthy volunteers

VAS have been shown to be a reliable method for capturing personal comfort levels. Studies comparing the use of different types of VAS have shown that the sensitivity and reliability of VAS are somewhat influenced by the words used to anchor the endpoints, by the length of the VAS, and by other factors. Those VAS that most clearly delineate extremes (e.g. the best condition imaginable, the worst condition) and are 100–150 mm in length have been shown to have the greatest sensitivity and are the least vulnerable to distortions or biases in ratings [26]. Participants were all given the same written and verbal instructions about how to fill out an anchored continuous 100mm Visual Analogue Scale (VAS) with the left end labelled Very Uncomfortable and the right-side labelled Very Comfortable [10, 11]. The questionnaire to be filled out at each stage of testing contained 8 separate VAS querying the overall comfort of each foot as well as the comfort of specific part of each foot: the heel, midfoot and forefoot areas of each insole. An example of the scales presented to participants is shown in Figure 6.8.

Heel Comfort	Comfort of the area of your shoe around the heel
	
Left Shoe	
Right Shoe	
Comments:	

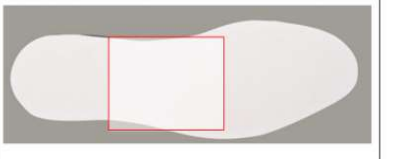


Mid-foot Comfort	Comfort of the area of your shoe around the middle
	
Left Shoe	
Right Shoe	
Comments:	

Figure 6.8: Example of the Visual Analogue Scales used during user testing. Participants marked with an X or a vertical line along the scale where they perceived their current level of comfort

After each activity, the participants, as well as providing the VAS scores, also provided qualitative feedback on what aspects of the insoles they found comfortable or uncomfortable.

Criteria required to pass Human Factors and Comfort Assessment

Comparison of mean VAS scores for all users between the baseline condition (normal footwear with no WIISEL insoles) and the insole condition (wearing the WIISEL insole in normal footwear) should show no statistically significant difference when comparing similar time periods of wear for each condition, if the insole is not affecting comfort. Statistical significance was demonstrated using paired t-tests ($\alpha = 0.05$) [11].

6.3 Results of First Prototype (V1 Prototype) Test Cycle

The results of the Human Factors and Comfort Inspection and the subsequent Human Volunteer Testing for the V1 Prototype of the insoles are presented in this section.

6.3.1 Human Factors and Comfort Inspection

From reading the Use Case, all Experts agreed that they understood the Context of Use and the User Characteristics, which the device was designed for. The problems in order of priority based on the Problem Severity Rating are presented in Table 6-6 and visual descriptions of selected problems are shown in Figure 6.9 and Figure 6.10. The explicit description was based on the general consensus of the Experts.

Table 6-6: Problems ordered in terms of a weighted aggregate of frequency reported and severity rating (see Table 5-3 for colour code breakdown)

#	Problem Identified	# Experts who Reported Same Problem (Range (1-6))	Severity Rating Mean (Range 0-4)	Problem Severity Rating (Range (0-24))
1	The Medial-Longitudinal Arch is too firm (the firmness of the insole in general was cited as a problem but the Medio-longitudinal arch was cited as the most critical)	6	2.85	17
2	Lack of flexibility in the Midfoot to Rear foot Region	4	3	12
3	Sensors are not flush with the surface of the insole	2	3.5	7
4	Length and thickness for manipulation and fitting	3	2.3	7
5	Pinch ridge around the outside of the insole causing problems for lateral movement and fit	3	2	6
6	Lack of a proper heel cup	2	2.5	5
7	Forefoot Rigidity	1	3	3
8	Slippery Surface	2	1.5	3

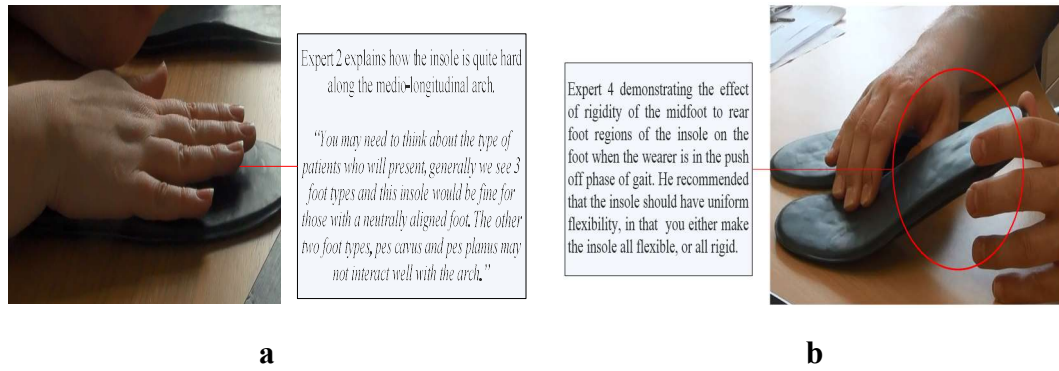


Figure 6.9: An expert a) demonstrating how the firmness of the medio-longitudinal arch could cause discomfort for a user b) demonstrating the lack of flexibility in the heel-mid-foot region

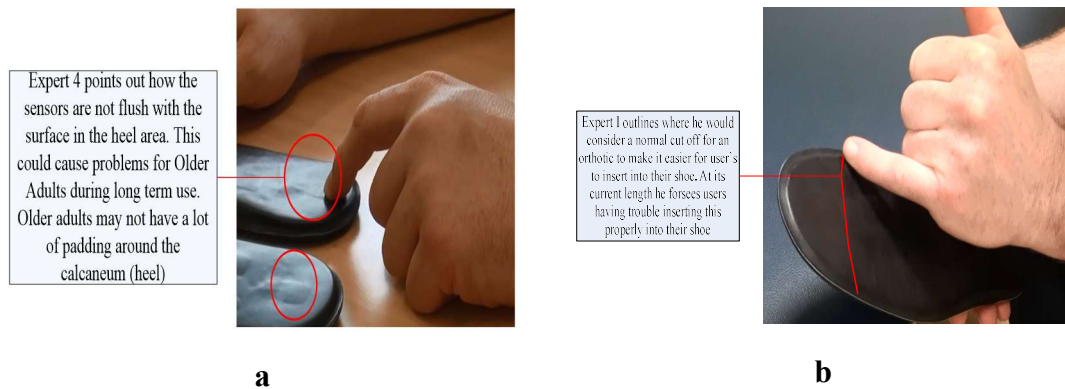


Figure 6.10: An expert a) pointing to the protruding sensors at the heel of the insole b) explaining how fitting problems might occur and where he would consider a normal cut-off for more universal fit insoles

6.3.2 Expert Recommendations

All Experts agreed that the insoles could be tested on young healthy users. Only half of the Experts agreed that they could be tested on older adult users. One Expert suggested that they could be tested on older adults with a high fall risk. These recommendations are summarised in Table 6-7.

Table 6-7: Expert recommendations for what groups can be exposed to User Testing

	Young Healthy User (under 60)	Healthy Older Adult User (over 60)	Older Adult User with High Fall Risk
Percentage of Experts who Approved Use with this Group	100%	50%	16%

All Experts also agreed that the manner of exposure to the insoles should be extremely controlled with close observation. A common suggestion was to allow the user to wear the insole for one hour on the first day, and then add an hour of use for every day after until eventually the insole could be worn on a continuous basis after a period of 1-2 weeks. These points are reflected in a range of comments made by Experts during the Human Factors and Comfort inspection sessions:

“Any kind of device we would introduce to the shoe in the clinic, we would ask the patient to wear for 10 minutes to assess the comfort and then build up to full-time wear within two weeks. Typically, clinicians allow patients a break-in period of about two weeks during or after which orthotics/devices may be modified or withdrawn altogether.”

“When somebody puts something into their shoe, it’s going to take time to get used to it, so usually you break into it, maybe for an hour a day. There has to be a lead-in period where wear is built up. If a user suffers pain when they first introduce something to their shoe they are unlikely to continue wearing it.”

6.3.3 Human Volunteer Testing

Ten participants (7 Male, 3 Female) carried out the full protocol (mean age = 23 years \pm 4.2, mean body mass = 72kg \pm 7.3, mean height 179cm \pm 9.3). VAS scores were collected, collated and compared between the *Control Condition* (Day 1, 3 hours of walking with no insole fitted) and the *Insole Condition* (Day 4, 3 hours of walking with insole fitted). In clinical terms, a change in VAS score of 9.6mm between the two conditions, indicates a clinically meaningful change in comfort level [11]. Table 6-8 shows the change in VAS score. The VAS scores obtained for the left and right insoles were averaged. In addition, paired T-tests were carried out to test for statistical significance between the VAS scores for overall foot, the heel, the mid-foot and the forefoot comfort ($\alpha=0.05$).

Table 6-8: Comparison of mean VAS Score for the Control Condition and the Insole Condition. Paired T-Tests were used to test for statistical significance between the same time points for each condition

	Left and Right VAS Average Control Condition (After 3 hrs)	Left and Right VAS Average Insole Condition (After 3 hrs)	Difference	Clinically Meaningful Difference According to Mills et al?	P-Value
Overall Comfort	79.5	60.5	19	Yes	0.0002
Heel Comfort	76	59.5	16.5	Yes	0.0002
Midfoot Comfort	83.5	53.5	30	Yes	0.0001
Forefoot Comfort	87.5	73	14.5	Yes	0.0002

At each time point there was significant differences for overall, midfoot and heel comfort, particularly at the 3 hour point of day 1 and day 4 (Figure 6.11 and Figure 6.12).

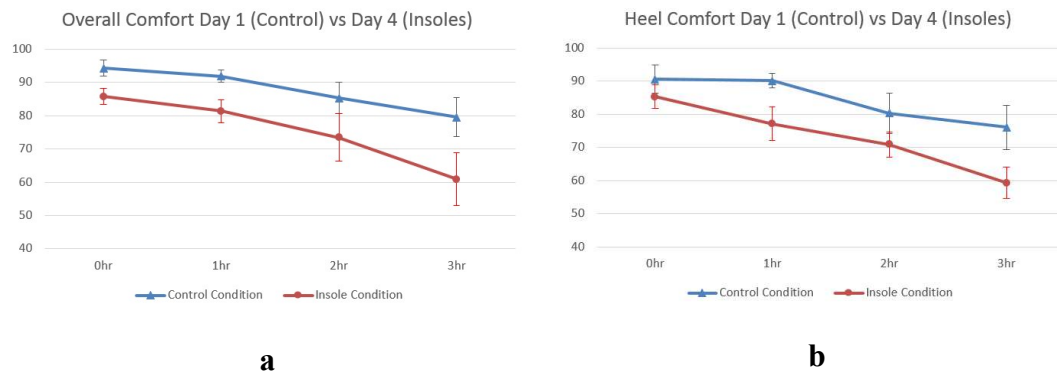


Figure 6.11: Control Condition vs Insole Condition with error bars showing confidence intervals for VAS scores taken for a) overall foot comfort and b) heel comfort

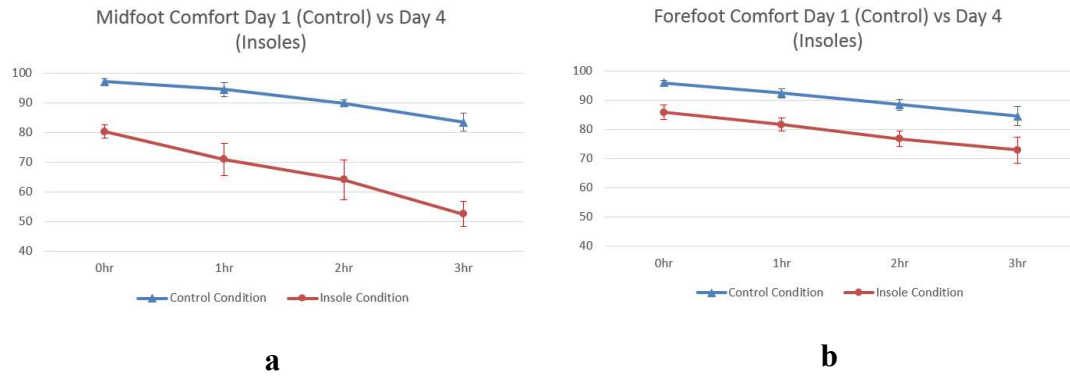


Figure 6.12: Control Condition vs Insole Condition with error bars showing confidence intervals for VAS scores taken for a) midfoot comfort and b) forefoot comfort

6.4 Changes to the Insoles Based on Results

Based on these findings, a Human Factors and Comfort Report was generated and disseminated to the insole designers, to provide them with the opportunity to address each problem the Experts had identified in addition to the testimony from the experts and the data from the Human Volunteer Testing. The report included high definition photographs of the identified problems and suggestions from Experts as to how to address each identified problem (See Figure 6.10 for examples). Insole designers attempted to address each problem in turn based on priority. The Experts who inspected the insoles were aware of the electronic circuitry which was contained in the insoles and therefore took this into account when making recommendations, so as not to propose unattainable objectives for designers, who were seeking to not affect the durability and integrity of the insole. Table 6-9 summarises the Expert recommendations and the proposed design solutions.

Table 6-9: List of Problems Identified, recommendations for addressing them and how they were ultimately addressed

#	Problem Identified	Priority Category	Expert Recommendations	How was the Problem Addressed in New Version?
1	The Medial-Longitudinal Arch is too firm	High	Poron is a spongy shock absorbing material often used as a top cover for insoles, recommended that this or a similar spongy material such as EVA foam be used to alleviate the potential discomfort caused by the firm arch and by any other inconsistencies in the hardware layer of the insole	Introduction of softer EVA top layer which provided more cushioning and shock absorption than the leather.
2	Lack of flexibility in the Midfoot to Rear foot Region	Low	Review the materials that make up the middle layers and consider more flexible materials	Removal of clear polyurethane layer and replaced with foam EVA layer to encapsulate PCB layer. Polyurethane sensor layer replaced with Kapton
3	Sensors are not flush with the surface of the insole	Low	Introduction of a softer top layer may negate the effect that protruding sensors have on the sole of the foot, Addressing of problem 1 may also solve this problem	Because the EVA layer is looser fitting than the leather layer, there is less chance of the sensors sticking out on the surface.
4	Length and thickness of the insole will cause problems for manipulation and fitting	Low	The thickness of the insole needs to be reviewed as the current thickness was going to exclude too many types of shoes. Judging from the rigidity of the insoles it is clear that there users with dexterity problems will experience problems manipulating the insoles into certain types of shoes	Insole was less rigid and >1mm thinner therefore manipulation into the shoe was easier
5	Pinch ridge around the outside of the insole causing problems for lateral movement and fit	Cosmetic	While it is clear that this exists due to nature of the encapsulation method being used, every effort should be made to reduce this so as to allow a better fit for the insole in the shoe. This ridge should be pared down to the minimum possible without affecting the integrity of the encapsulation	New insole slightly narrower with a smaller pinch ridge. A smaller pinch ridge was required because there was no need to bond (pinch) the leather layer

#	Problem Identified	Priority Category	Expert Recommendations	How was the Problem Addressed in New Version?
6	Lack of a proper heel cup	Cosmetic	While this may not be possible given the nature of the electronics, this heel should either be softened or shaped in some way to accommodate the contours of the foot	Unaddressed as introduction of Heel Cup would affect sensor output, the introduction of softer materials will afford more comfort for heel
7	Forefoot Rigidity	Cosmetic	See Problem 2 recommendations.	Removal of polyurethane layer
8	Slippery Surface	Cosmetic	The introduction of poron/EVA will prevent slippage. This population is susceptible to sores and irritation on the feet and any kind of movement of the foot against the insole was not recommended	EVA top layer has more grip and did not create a slippery interface with the foot

The replacement of the top artificial leather layer and the middle clear polyurethane layer with EVA foam layers for the top and middle layers and the replacement of the polyurethane sensor layer with a thinner more flexible Kapton layer were the major changes made to the insoles. It was proposed that these materials would increase flexibility, reduce firmness and rigidity and provide more cushioning and shock absorption for the wearer. These changes also allowed designers to make the insoles both thinner (by at least 1mm) and narrower (at least 3mm) allowing them to fit in a wider range of shoes and reduce tightness for the wearer. Figure 6.13(A) shows the new thinner, more flexible sensor layer using the material Kapton, Figure 6.13(B) shows the battery and PCB embedded in the EVA foam middle layer, Figure 6.14 shows a cross-sectional view of all layers.



Figure 6.13: a) The clear polyurethane layer was removed to improve the flexibility of the insoles and the sensors were embedded in a thinner green Kapton (0.1mm versus 1mm for the previous sensor layer encapsulation); b) The PCB were now embedded in an expanded EVA foam layer 5mm



Figure 6.14: A cross-sectional view of the new version of the insoles showing the different layers from top to bottom

Like the first version of the insole, this version was exposed to numerous electrical and environmental assessments before being released for Human Factors Analysis, such as waterproofing, electrical leakage/safety, sensor sensitivity and durability. This new version of the insole was now exposed to a second cycle of testing using the same Use Case as a guide to the context of use.

6.5 Results of Second Prototype (V2 Prototype) Test Cycle

The results of the Human Factors and Comfort Inspection and the subsequent Human Volunteer Testing for the V2 Prototype of the insoles are presented in this section.

6.5.1 Human Factors and Comfort Inspection (V2 Prototype)

The same six Experts used to inspect the V1 Prototype also inspected the new V2 Prototype of the insole using the same methodology. For this inspection, the Experts were presented with the new prototypes and the list of the problem areas they identified in the V1 Prototype. They were not made aware that the current devices were updated in response to the problems they identified and the recommendations they made. Experts were also not told what severity score they had originally assigned to each problem area. They were simply asked to assign severity scores to each of the original problem areas based on their inspection of the new prototype. Table 6-10 shows how the problems areas identified with the V1 Prototype were severity rated for the V2 Prototype.

Table 6-10: Problems Severity Ratings (see Table 6-3 for colour code breakdown)

#	How was the Problem Addressed?	V1 Prototype Severity Ratings	V2 Prototype Severity Ratings
1	Introduction of softer outer material, EVA layer which provides more cushioning and shock absorption than the leather	17	6
2	Removal of polyurethane layer and introduction of middle EVA layer to increase flexibility	12	9
3	Because the EVA layer was not as tight as the leather layer, the sensors protruded less out on the surface.	7	4
4	Insole was less rigid therefore manipulation into the shoe was easier	7	6
5	Insole was slightly thinner with a smaller pinch ridge. A smaller pinch ridge was required because there was no requirement to bond (pinch) the leather layer to the bottom EVA layer	6	4
6	The issue was not addressed as the introduction of a Heel Cup would affect sensor output, however some experts reduced the severity score for this problem by virtue of the softer materials used which afford more cushioning for the heel	5	4

#	How was the Problem Addressed?	V1 Prototype Severity Ratings	V2 Prototype Severity Ratings
7	Removal of polyurethane layer and introduction of middle EVA layer to increase flexibility	3	1
8	EVA had more grip and does not create a slippery interface with the foot	3	0

Of the eight problems, one was reduced from high priority to cosmetic, two were reduced from low priority to cosmetic and one was eliminated completely as a problem. Four maintained their original classification but received lower severity ratings. Experts were also asked to identify any new problems but no new problems were identified.

6.5.2 Expert Recommendations

Experts recommended carrying out the controlled protocol again with younger adults before moving onto further limited testing with older adults.

6.5.3 Human Volunteer Testing (V2 Prototype)

Ten participants (6 Male, 4 Female) carried out the full protocol (mean age = 25 years \pm 9.3, mean body mass = 70kg \pm 7.2, mean height 176cm \pm 4.6). The same test and data analysis methodology was applied to the V2 Prototype, comparing VAS scores for the *Control Condition* to VAS scores for the *Insole Condition* in order to establish if there was any significant comfort differences between the two conditions. These results are illustrated in Figure 6.15 and Figure 6.16. Comparing all VAS scores for the *Control Condition* and *Insole Condition*, at no point do we see a statistically significant difference between the normal footwear condition and the insole condition, according to error bars, showing the 95% confidence interval.

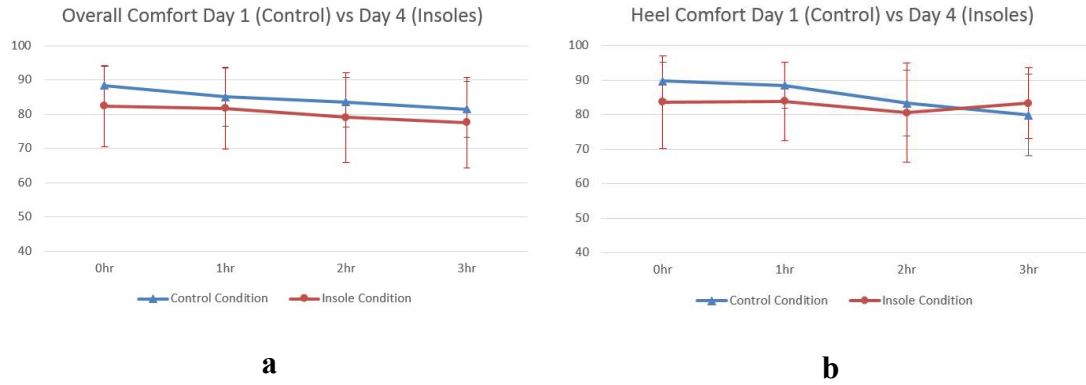


Figure 6.15: Control Condition vs Insole Condition with error bars showing confidence intervals for each set of VAS scores taken for: (a) overall foot comfort (b) heel comfort

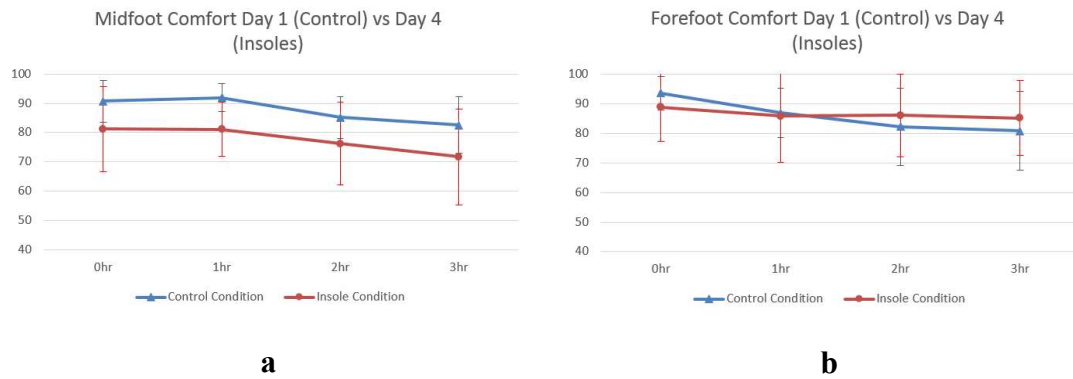


Figure 6.16: Control Condition vs Insole Condition with error bars showing confidence intervals for each set of VAS scores taken for: a) midfoot comfort b) forefoot comfort

Again we used Mills et al to check for clinical significance and paired t-tests to test for statistical significance. The results are summarised in Table 6-11.

Table 6-11: Comparison of mean 3hr VAS scores for Control Condition and Insole Condition. Paired T-Tests were used to test for statistical significance between the same time points for each condition

	Left and Right VAS Average Control Condition (After 3 hrs)	Left and Right VAS Average Insole Condition (After 3 hrs)	Difference	Clinically Meaningful Difference According to Mills et al?	P-Value
Overall Comfort	81.5	77.5	4	No	0.39
Heel Comfort	80	83.5	3.5	No	0.41

	Left and Right VAS Average Control Condition (After 3 hrs)	Left and Right VAS Average Insole Condition (After 3 hrs)	Difference	Clinically Meaningful Difference According to Mills et al?	P-Value
Midfoot Comfort	82.5	72	10.5	Yes	0.14
Forefoot Comfort	81	80	1	No	0.49

6.6 Discussion

Through the use of a Human Factors and Comfort Assessment Methodology we have guided the design of an instrumented insole, which at end of this cycle of development is suitable for testing with the target older adult end user population. By using robust usability testing techniques within an iterative process starting with a Use Case, we set the parameters which informed the development of the initial V1 Prototype. By engaging early in the process with all stakeholders and experts, we defined the Context of Use and User Characteristics. The outcome of this process, lead to the development of the V1 Prototype, which was subsequently put through a rigorous comfort assessment. The comfort assessment revealed significant differences in the mean VAS scores recorded for the *Control Condition* and the *Insole Condition*. Expert-identified concerns expressed during the Human Factors and Comfort Inspection about the midfoot and heel region of the insoles were validated during the Human Volunteer Testing phase, with significant differences between *Control Condition* and *Insole Condition* VAS scores for each of these regions. Participants complained about the firmness of the arch at the midfoot region and also that the thickness of the insole meant that their foot felt tight in their shoe. The Experts' concerns presented in the Human Factors Report highlighted, for the insole designers, the comfort and human factors problems present in the V1 Prototype. It was made clear to designers that the current insole design rendered it unsuitable for testing with older adults.

The V2 Prototype saw the leather top layer and polyurethane middle layers change to EVA layers. Furthermore the insoles overall dimensions were reduced. These changes to design resulted in significantly improved ratings in the Expert inspection phase, with all of the originally identified problems being reduced in severity rating and half of the original problems being downgraded to a lower priority problem category. These improved ratings were attributed to the designers taking on-board the feedback gathered by our Human Factors and Comfort Assessment Methodology. The reduction in severity ratings from the V1 Prototype to the V2 Prototype, during the Human Factors and Comfort Inspection, corresponded with improved VAS scores in the Human Volunteer Testing of the V2 Prototype. There was no statistical significance observed between VAS scores for the *Control Condition* and the *Insole Condition* for each area of the insole and as well as overall for the V2 Prototype insole. In Figure 6.17 we compare VAS scores for the V1 prototype and the V2 prototype, as well as their respective controls.

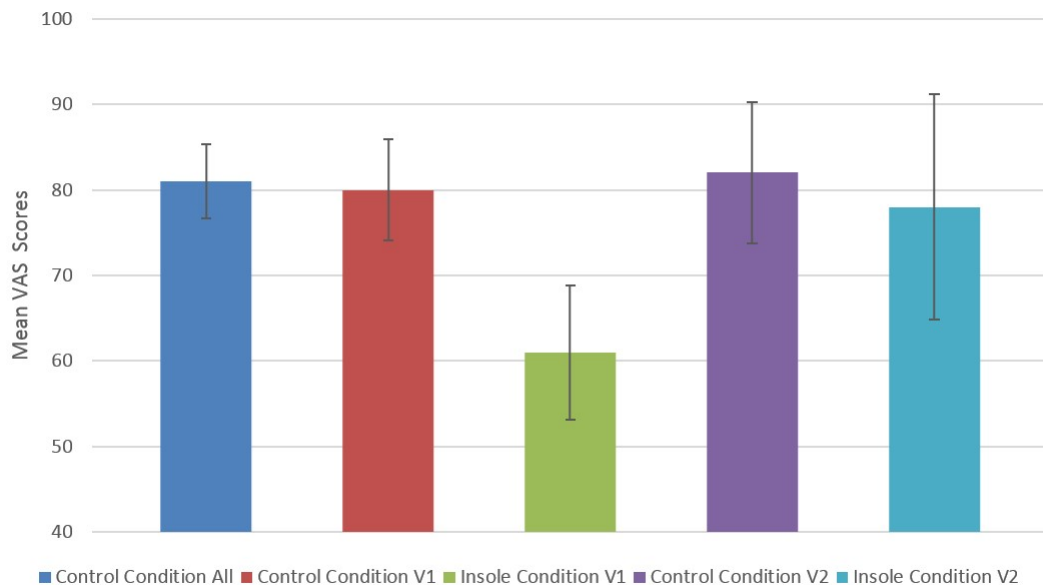


Figure 6.17: Comparison of VAS Means after 3hr Exposure to Each Condition. The First Column shows the Combined Mean of Both Control Conditions from the two Human Testing Phases

It is interesting to observe that no statistical significance exists when the mean 3 hour VAS score of the V1 Prototype and V2 Prototype are compared. When we consider the question ‘*Did we Meet or Exceed our Goal?*’ a commonly asked question during a Human-Centered Design process [27], we can be confident based on the data

presented in Figure 6.17, that the latest version of the insole is at worst no different to the user's normal footwear. We feel that this was a realistic and valid goal to set. While Human Factors and usability goals are not easy to set we felt it was important to at the very least establish some specific goals before the process began [28]. It should be noted that the constraints of the design created a problem for designers. The trade-off between providing a comfortable, wearable and safe insole against creating a functional, instrumented device is not easily achieved. The nature of the electronic components limits the flexibility, firmness and dimensions of the insoles, while certain materials affect the sensibility of sensors and the vulnerability of the components to water spoiling. The trade-offs required, were made known to all stakeholders at an early stage of the project through the Use Case, thereby reducing the impact of design changes further down the line. The Experts who inspected the insole were able to influence the design of the insole to improve Human Factors and comfort characteristics. However, the influence that the Experts can have on the design is limited by their expertise and experience. Therefore the choice of Experts is an important one and can be the difference between informed and accurate design recommendations and redundant recommendations, which could hinder or mislead the design process. Podiatrists, particularly those with experience in insole design were the highest priority for this particular process, while occupational therapists and physiotherapists were also sought for their knowledge of what might influence foot fatigue or discomfort. Depending on the context of use of the device, certain Experts will inevitably provide more insight into the potential problems the device may cause.

6.7 Conclusion

The Human Factors and Comfort Assessment Methodology we have designed and implemented based on the principles of Human-Centered Design (ISO 9241-210), has produced an instrumented insole which is now suitable for exposure to older adults in clinical trials. Following the human-centred design process, we have established a clear context of use through the Use Case, adopted the use of multi-disciplinary skills and perspectives and followed an iterative evaluation-driven process [29]. We have applied appropriate testing techniques given the context of the device being assessed [30]. The nature of the device and advice of Experts prevented

us from testing with older adult user so therefore in order to complete the Human-Centered Design process, the device will need to be fully exposed to older adult end users. The influence of project stakeholders, impartial expert inspectors and volunteer test participants has produced an insole which reaches a comparable level of acceptance to normal footwear conditions without affecting the functionality, durability and integrity of the instrument. Six Experts (at two different phases) and 20 test participants took part in the methodology, as well as numerous WIISEL project stakeholders and designers. This methodology provided an efficient means of assessing and validating prototype designs, using stakeholder, independent experts and user perspectives. The integration of independent experts who had no vested interest in the project was a critical part of the methodology and allowed a fresh and critical perspective of prototype designs. The methodology is flexible, allowing for multiple iterations or mini-iterations (for example two inspections in a row before user testing) as desired.

While Human-Centered design is typically applied to interactive systems such as websites and mobile device, we have utilised its principles to influence the design of a non-interactive wearable device. We contend that our Methodology, or a customised version of it, can be successfully applied to influence the design of many kinds of devices, systems and interfaces, particularly if four key resources are present in the process. Firstly, a usability or Human Factors engineer must oversee the development and evolution of the Use Case and the subsequent administration of the test protocols. Secondly, experts must be available to carry out Human Factors inspections. We suggest the implementation of permanent multi-disciplinary groups who are available to inspect new prototypes within a certain notice period (2 weeks for example). We have created an inspection protocol which can be carried out in under 1 hour, although this could vary depending on the complexity of the device or system being inspected. Thirdly, the availability of volunteers to carry out user testing is important. University campuses and a broad range of volunteer and advocacy groups provide rich potential sources of recruitment and these should be utilised. Finally, a dynamic, fluid and responsive design team is required to respond to design suggestions within short time periods. This again depends on the complexity of the device. The job of the usability and Human Factors engineer is to impart the results of usability testing to the design team, in some cases to interpret

the wishes of stakeholders, so that designers are clear as to what changes need to be made and why. If these four criteria are achieved to some standard, then our methodology will prove effective in both research institutes and in industrial settings.

Acknowledgements

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Conflicts of Interest

The authors declare no conflict of interest.

6.8 References

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**Chapter 7 – Can Home Health
Smartphone App Usability Challenges
be minimised by a Period of
Concurrent General Smartphone
Training? A Usability and Learnability
Case Study**

*The work in this chapter was submitted to the Journal of Medical Internet Research (JMIR)
on the 27th April 2017*

The final study in Chapter 7 tested the UX of the WIISEL Smartphone App over a number of days and also assessed the effect that a simple smartphone training routine had on the overall user experience with the WIISEL smartphone interface. All participants received training on how to use the smartphone App, while half the participants (training group) also received supplementary preliminary training on how to use basic functions of the smartphone such as making calls and sending text messages. A comparison of training group and non-training group was carried out using metrics such as satisfaction rating, time taken to complete tasks, cues required to complete task and errors made during task. It was expected that the Group who received supplementary preliminary smartphone training would become proficient with the use of the WIISEL system in a much shorter time, as shown by better usability metric scores. Results showed that the training group fared better in the first 3 days of using the system. There were significant recorded differences in cues required and errors committed. By the 4th and 5th day of use both groups were performing at the same level. In conclusion, supplementary basic smartphone training may be critical in trials where a smartphone or similar device is being introduced to a population who are not proficient with technology. This training could prevent early technology rejection and increase the engagement of older participants and their overall user experience with the system.

7.1 Introduction

Digital mobile telephony potentially creates new opportunities to augment healthcare. Owing to their interactive features, large storage capacity, communication capabilities and ability to access large knowledge databases, smartphones can present a novel means to deliver healthcare to individuals in the home. Consequently, smartphones are being used to deliver an increasingly wide range of personal healthcare solutions [1, 2]. While older adults have traditionally adopted new technology at lower rate than other age cohorts, the Pew Internet Research Centre reports that the use of internet technology by older adults is steadily increasing, with 2012 the first year where more than half of people in the USA aged 65 years and older were using the internet [3]. Recent studies have shown that older adults have a rich technology profile in terms of home appliances, TVs, PCs and telephone applications and only differ from other technology using age groups in

terms of internet based technology [4]. While today's older adults have better uptake of mobile technologies than previous older adult groups [5], contemporary mobile devices such as smartphones still present a substantial challenge for older adults [6]. These challenges can be a result of numerous factors such as unfamiliarity or fear of technology, lack of perceived usefulness, lack of perceived ease of use, diminished interactive capabilities and poor usability characteristics of the devices in question [7, 8].

Methodological steps can be taken during the design process for these devices to ensure that the demands of the device do not exceed the capabilities of the older adult user. For example, steps can be taken to ensure that interface elements such as buttons and text are usable, the device navigation can be designed to ensure that basic tasks only require a small number of steps and the supporting documentation can be presented in an intuitive and simple manner [9-11]. However these design aspects may not mitigate a new user's unfamiliarity with the device and therefore the potential for technology rejection may remain quite high [12]. This could have adverse effects when attempting to introduce smartphones to older adult users for the delivery of healthcare using an mHealth, telemedicine or Connected Health infrastructure. In a previous study, a smartphone based fall detection and prevention system (wiisel.eu) was tested on a group of 39 older adult users over a 10 day period. Despite the system having undergone a full Human-Centered Design process and despite the participants receiving adequate training on how to use the system, the system scored 70 out of 100 on the System Usability Scale, indicating only average usability [13]. We suspected that unfamiliarity with smartphones and the specific demands of interaction with a smartphone, particularly the unique touchscreen interactions required, may have led to poor usability outcomes. From this experience we concluded that the outcomes of many trials and studies that involve the use of home health App design to run on smartphones could be compromised due to a lack of familiarity with the basic functioning of the device.

A period of pre-trial introductory smartphone training in conjunction with concurrent recall based learning tasks could present a potential solution to this problem. Effective training could provide a complete novice with a better chance of adopting the technology, thereby increasing the potential effectiveness of smartphone based

mHealth and Connected Health interventions for that person. In a study of a group of older adults who were being introduced to an mHealth pain management Smartphone App, 61% of the participants cited ‘provide training on device use’ as the main requirement if their potential use of the technology was to be enhanced and ultimately sustained, followed by 30% who cited ‘tailoring the device to the user’s functional needs (i.e. usability)’ as the secondary requirement [14]. Therefore we can conclude that twice as many participants felt that adequate introductory training was more important than enhancements to the design of the App in terms of usability. With this important finding in mind, this paper will provide an enumerative and detailed methodology to achieve this introductory training as efficiently as possible and therefore potentially mitigate any potential usability problems the technology may have.

In this study we trained 22 participants to use the same smartphone based fall detection and prevention system, as described in [13], over a period of 5 days. This system is the Wireless Insole for Independent and Safe Elderly Living (WIISEL) system [15]. The system is designed to continuously assess fall risk by measuring various gait and balance parameters and is also designed to detect falls. The system is targeted at older adults who are at high risk of falling [16]. The system consists of a pair of instrumented insoles and a smartphone which are worn by the user during daily activity. Data collected by embedded sensors in the insoles are sent to the smartphone and then uploaded via an internet connection to a server in a clinic for processing and analysis. The data are presented in various ways to a specialist via a web app and desktop based Gait Analysis Tool. The architecture of the system is illustrated in Figure 7.1.

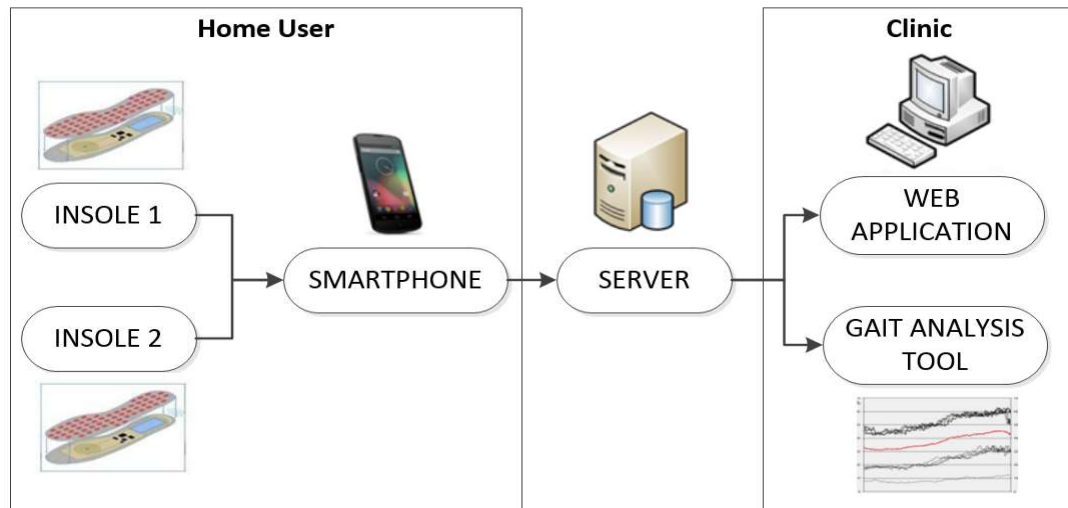


Figure 7.1: The WIISEL System

The 22 participants were instructed to carry out a number of specific tasks with the WIISEL smartphone App (see the Methodology section for details of these tasks). Half of the participants were provided with additional concurrent training in the general use of the smartphone, which began two days before the trial and continued. Our hypothesis was that the group who received the additional smartphone training would have a better user experience with the system.

7.2 Methodology

7.2.1 Participants

Participants were recruited from the Galway city area. 22 participants were recruited ($\bar{x} = 74$, $\sigma = 5.5$) providing informed consent under ethical approval provided by University College Hospital Galway. Participants were split into two groups as outlined in Table 7-1. Whether a participant belongs to group 1 or group 2 was decided at random with 50% of participants belonging to each group.

Table 7-1: Participants were split into two groups based on what kind of training they would receive

Group	Training
1 (Non-Supplementary Training Group)	Receive no smartphone training, except that which is necessary to operate the WIISEL App (see tasks in). This group used the WIISEL system in their home for 5 days
2 (Supplementary Training Group)	This group also used the WIISEL system in the home for 5 days carrying out the same tasks as Group 1, but received additional smartphone training during the two days prior to starting the WIISEL trial. The smartphone training was intended to make these participants familiar with the functions of the phone (see tasks in Table 7-5).

All training was carried out in the home of the participant by the lead researcher who followed the same protocol for each participant. The researcher visited the participant's home each day to teach them new tasks and to observe them carrying out previously learned tasks. A systematic cuing hierarchy approach and a *think aloud* protocol [17] were used by the lead researcher for the training procedure. These will presently be outlined in greater detail.

7.2.2 Technology Acceptance Indicators

To give an indication of how participants would fare with the introduction of the new technology, we assessed their current mobile technology capability. We split participants into sub-groups based on their previous experience with mobile technology to allow for further analysis. When it comes to classifying users based on their expertise or previous experience with mobile technology there is no set classification system. Most so called 'expert' users are simply users who have gained hands-on experience of using the technology and may not have used a user manual for their device [18]. However, using an understanding of users' prior technology knowledge to predict their future adoption of technology is well supported [19]. We classified the participants into three separate categories based on their observed performance in carrying of a series of simple functional tasks with their mobile device. The functional tasks were chosen as representing real-world use requirements of the mobile device and were sufficiently challenging to highlight

differences in skill level among user groups [18]. The three categories are outlined in Table 7-2.

Table 7-2: Participants within each group were further classified based on their demonstrable. In this context, ‘Feature Phone’ is a retronym used to describe low-end mobile phones which are limited in capabilities in contrast to smartphones i.e. they are phones which have basic call and SMS functionality but do not have extensive media or internet capabilities

Category	Definition	Example
1 (Novice User)	No experience with smartphones and basic capability with feature phone	A user who does not own any sort of mobile phone OR a user who does own a feature phone but cannot demonstrate to satisfactory level that they can make a call, receive a call and send/receive a text message without problems
2 (Intermediate/ Average Tech User)	Perfect capability with feature phone but limited capability with smartphones, may have been exposed to touchscreen interfaces before	A user who does own a feature phone and can demonstrate to a satisfactory level that they can make a call, receive a call and send a text message OR a user who owns a smartphone who can demonstrate to a satisfactory level that they can make and receive a call but who cannot effectively send a text message
3 (Competent User/ familiar with internet technologies and mobile devices)	Adequate capability with (own) smartphone or with related touchscreen devices (such as a tablet)	A user who owns a smartphone and can demonstrate satisfactorily that they can make/receive a call, receive a call and send a text message OR a user who owns a tablet and can successfully send an email to the researcher.

This procedure for practically dividing participants into technology experience groups is illustrated in the flow chart in Figure 7.2. An equal proportion of novice, intermediate and expert participants were assigned to Group 1 (non-supplementary training) and Group 2 (supplementary training). See 7.6 in Section 7.3.1 for further details.

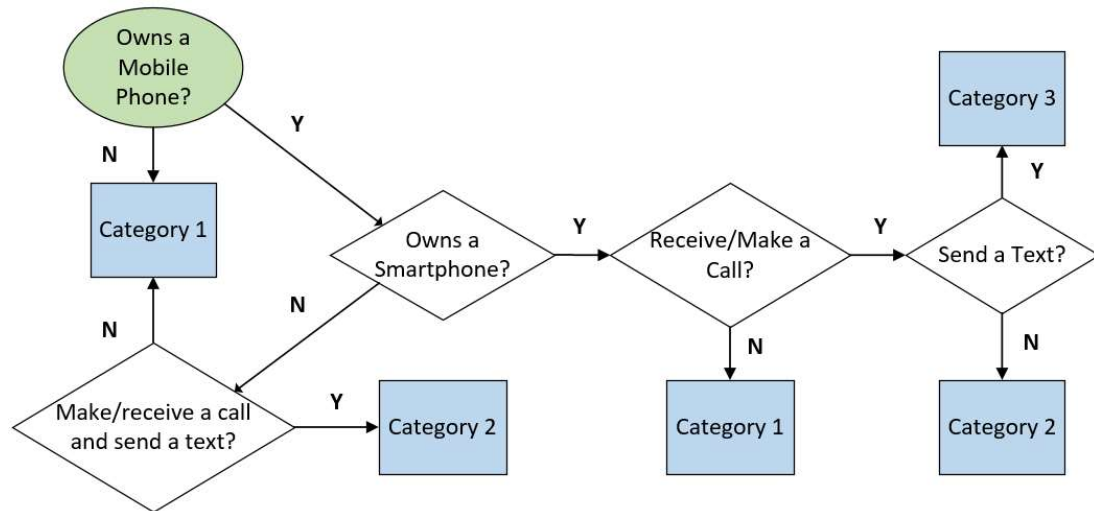


Figure 7.2: Flow Chart showing how each participant is classified in terms of mobile technology capability

Perceived Ease of Use (PEoU) and Perceived Usefulness (PU)

Perceived Ease of Use (PEoU) and Perceived Usefulness (PU) are two key usability indicators pertaining to technology design. The influence of PEoU and PU on behavioural intent, and hence technology adoption have been supported for use of technology by older adults and specifically for use of communication technology [20]. In order to measure if there was any correlation between PU/PEoU and the eventual usability outcomes we measured the participant's PEoU and PU of smartphone technology before the trial started. We used a 7 point Likert scale using items from the Technology Acceptance Model [21, 22] to establish PU and PEoU.

7.2.3 Training Procedure

Our training procedure was based on an approach known as the errorless fading of cues technique [23]. This technique involves reducing the cues on repetitive tasks until the user can complete the task without error. The overall training schedule for both Groups 1 and 2 is outlined in Table 7-3. Training blocks are broken up to ensure that the participants were not overburdened with new training. Overall, each participant in Group 1 was subject to 0.75 – 1 hr of training or testing time per day, while each participant in Group 2 was subject 1.5 - 2 hours of training or testing time per day. This included regular breaks and the time taken for the researcher to record metrics after each task. The number of days of training was chosen to be long

enough to give participants the best chance of achieving some sort of mastery [23] but short enough to allow for convenience in having participants and trainer available for consecutive days.

Table 7-3: Training Schedule for Each Group. Light grey boxes indicate an introductory lesson while dark grey boxes indicate observational cue-assisted testing. White boxes indicate no training/testing on that day for that lesson block.

Schedule for Group 1	Lesson Block	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5
WIISEL App Training	Block 1								
	Block 2								
Schedule for Group 2	Lesson Block	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5
Smartphone Training	Block 1								
	Block 2								
	Block 3								
WIISEL App Training	Block 1								
	Block 2								

The WIISEL specific tasks which were to be carried out by both groups 1 and 2 are listed in Table 7-4. These tasks were selected based on a Use Case analyses of the WIISEL system [24] and were split into two different lesson blocks in order to reduce the burden on the participant by implementing small measurable objectives [25].

Table 7-4: WIISEL Tasks

Lesson Block	Task #	Task	Notes
1	1	Check System Status	Turn on Phone from Power Off State, enter WIISEL App and view status
	2	Connect to the Insoles	Enter App and carry out connection procedure
	3	Upload WIISEL Data	Carry out data upload procedure
	4	Minimise App	Minimise the App using the Home Button

Lesson Block	Task #	Task	Notes
	5	Fall detection	Respond to the Fall Alarm according to manual instructions
2	6	Reset the App	Carry out the App reset procedure via the phone settings
	7	Login to the App	Login to the App using the supplied username and password

Both groups were exposed to the WIISEL system over a course of 6 days (Day 0 was training only, Days 1-5 were used to record performance, there was also some training on Day 1, see point 2 below). This exposure consisted of the following steps:

1. On Day 0 (1st training day), the researcher carried out a walkthrough for all the tasks in Lesson Block 1 (Table 7-4). For each task, the researcher walked the participant through the task and demonstrated it, using the WIISEL user manual(s) as a reference (see Figure 7.3). The participant repeated each task until no further cues were required. There was no recording of metrics on this day.
2. On Day 1 (2nd training day, 1st day of testing), the researcher carried out a walkthrough for all the tasks in Lesson Block 2 (Table 7-4), going through the same training routine as with Lesson Block 1 on Day 0. The researcher also asked the participant to carry out the tasks in Lesson block 1 by recalling their lessons from the previous day. The participant was instructed to try and complete the Block 1 tasks without cues or input from the researcher, with the researcher providing cues only when it was clear that a cue was needed. The participant carried out each task 3 times.
3. At the end of each completed Block 1 task, the user provided satisfaction ratings using the After Scenario Questionnaire (ASQ) [26]. Usability metrics such as task completion time, number of errors made and number of cues required were recorded. The cuing hierarchy provided by the trainer comprised of 5 different cue classifications [23], 4 = full explanation and demonstration; 3 = the same verbal explanation as above but pointing to the next step prior to the participant executing it; 2 = no verbal guidance

provided, only pointing to the correct response prior to the participant executing it; 1 = Confirmation of a correct query, e.g., “Do I tap details?”; and 0 = no support provided. A lower score indicates greater proficiency with the device. Participants were given the standard instruction to think aloud [27].

4. From Day 2 and Day 5 on a daily basis, the participant carried out the WIISEL tasks from Block 1 and Block 2 (Table 7-4) under observation by the researcher. The researcher used the same metrics from Day 1 (see point 3 above) to measure performance.
5. At the end of Day 5, a semi structured interview was carried out with each participant and they also filled out the System Usability Scale (SUS) questionnaire provide an overall score of their user experience with the WIISEL system [28].

An example of the user manual for the WIISEL App is shown in Figure 7.3. This manual was the product of a comprehensive Human-Centered Design Process which tested and informed design changes of the WIISEL Smartphone interface and the layout and content of the manual. Both Group 1 and 2 used this manual.

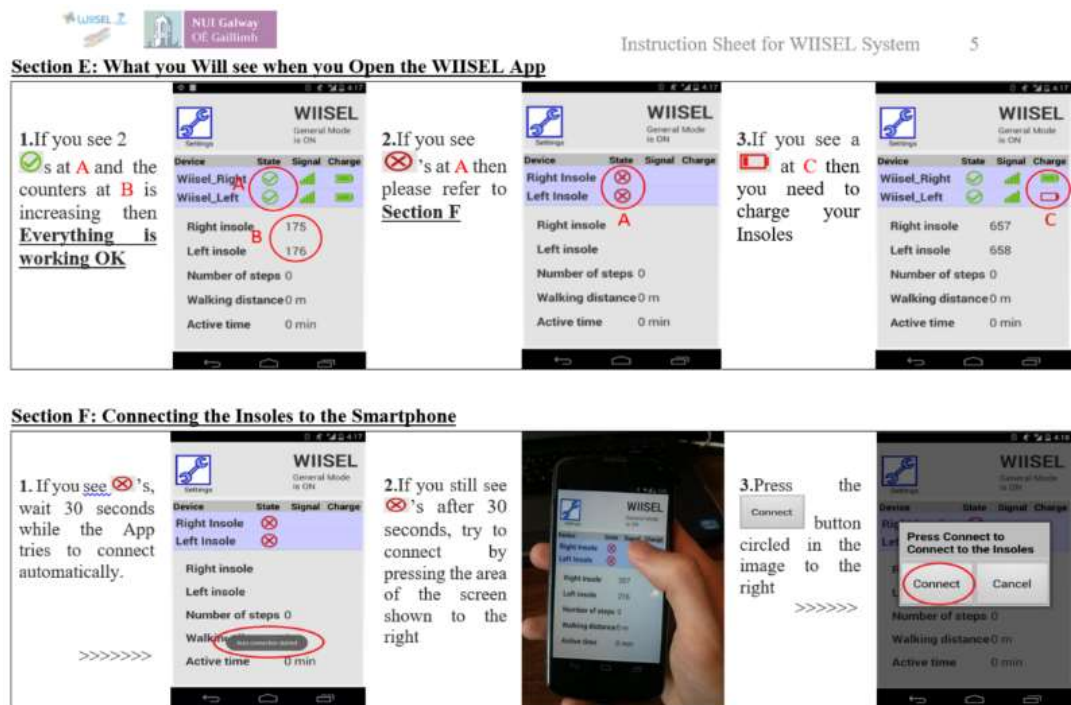


Figure 7.3: WIISEL User Manual

Group 2 were also provided with smartphone specific training in parallel with their WIISEL training. The smartphone specific tasks are listed in Table 7-5. The smartphone tasks were selected based on recent studies on most popular usage patterns for smartphones [29, 30].

Table 7-5: Smartphone Tasks

Lesson Block	Task #	Task	Notes
1	1	Power and Lock Settings	Turn on Phone from Power Off State/Unlock phone/Lock Phone
	2	Dial a Number to Call	Dial a number into your phone and call it (present an arbitrary number)
	3	Phone Call	Receive a phone call and hang up and reject a phone call
2	4	Store a Number in your Phone and then Call the Stored Number	Store a Number in your phone, go to contacts to call the stored number
	5	Text message	Read a text message/Reply to the text message
3	6	Install an App	Install the RTE player (or similar) on the phone
	7	Google Search	Search for the term 'Cinema Times Galway' in google
	8	Camera	Take a picture with the camera and go to Gallery to see where the picture is stored

This training was started two days before the WIISEL exposure began (we will refer to these days as Day -2 and Day -1). The routine was completed as follows:

- On Day -2, Lesson Blocks 1 and 2 (Table 7-5) were completed. For each task, the researcher walked the participant through the task and demonstrated it, using the NEXUS user manual(s) as a reference. The participant repeated each task until no further cues were required. There was no recording of metrics on this day.
- On Day -1, Lesson Block 3 (Table 7-5) was completed. Also on this day, the researcher asked the participant to try and recall their tasks from the previous day. The same recording of metrics was carried out as for the WIISEL training. This continued up to Day 3.

- It was seen as essential to gradually embed the task in its natural context with regular time constraints and less predictable occurrence [18]. Therefore participants were asked to ring the lead researcher each day at a pre-agreed time and to send an SMS to accompany the in-situ observations [23].

The LG-Nexus 5 User Manual (found at <http://nexus4manual.net/>) outlined in a step-by-step format how to complete basic tasks such as making phone calls and sending text messages (Figure 7.4). This manual was used for the Group 2 specific smartphone training.

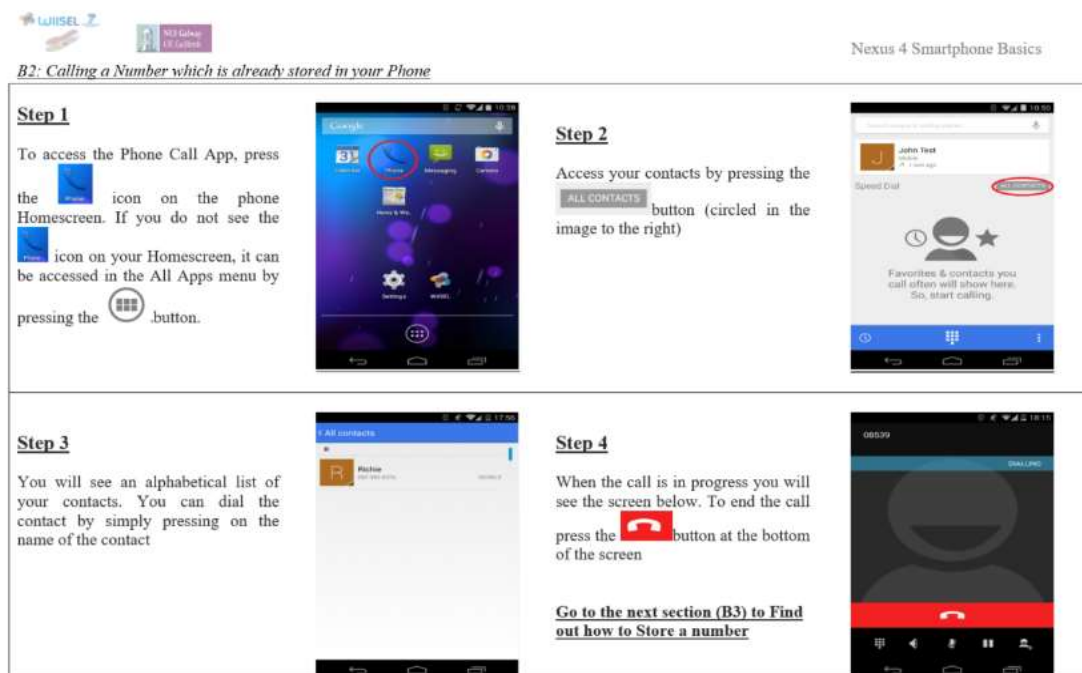


Figure 7.4: Phone User Manual

7.2.4 Analyses of Data

Data were interrogated using both qualitative and quantitative approaches. To compare how each group performed in terms of the WIISEL tasks (Table 7-4), t-tests were used to seek statistical significance between groups for metrics such as errors made, cues required, completion time and ASQ scores for each task. In order to reduce the effects of potential outliers for the task completion time metric (for example a participant takes an unusually long time due to very slow typing, or has to return to the beginning of the task due to a serious error), the logarithmic based geometric mean was used [31]. Mean SUS scores were also compared for each group

using t-tests. Ethnographic observations were also made on the types of errors committed with the smartphone by reviewing notes and videos of the lessons.

7.3 Results

The results are presented in a series of stages. Firstly we will present our findings on the technology profiles of the participants. Next we will compare the individual metrics of task times, errors made, cues required and ASQ score between the two groups for each WIISEL task. Next, we will compare the SUS score for the two groups from their use of the WIISEL system. Finally, we compared the results to some other usability studies which have been carried out with the WIISEL system.

7.3.1 Technology Profiles

The breakdown of participants into the different technology categories and age categories are presented in Table 7-6. The only significant correlation which was observed indicated that users with greater experience with mobile technology had a higher level of PU of smartphones. There was a minor correlation observed between increased technology experience and PEOU of smartphones. No significant correlations were observed between age and PU and between age and PEOU of smartphones.

Table 7-6: Number of participants who fell into each different age groups and technology experience categories (based on demonstration). This table shows the results of the PE and PEOU questionnaire applied to each participant before the study began. The scale runs from 1-7 with 7 indicating a higher level of perceived Usefulness/Ease of Use. The Table provides a summary of correlation analysis between these questionnaires and age and technology categories of the participants

		Number of Participants	PEoU of Smartphones*	PU of Smartphones**
Total Participants (N)		22	5.3	5
Age	65-69	5	5.3	4.7
	70-74	7	5.2	5.1
	75-79	5	4.7	5.6
	80+	5	5	6

	Summary	No significant correlation found between age and perceived ease of use* ($R = 0.2, p = 0.21$) or between age and perceived usefulness** ($R = -0.04, p = 0.86$)		
		Number of Participants	PEoU of Smartphones*	PU of Smartphones**
Technology Category	1 (novice)	6	4.4	4.5
	2 (intermediate)	10	4.9	5.2
	3 (expert)	6	5.6	6.3
	Summary	Weak positive correlation found between technology experience and perceived ease of use* ($R = 0.39, p = 0.15$); Strong positive correlation between increased technology experience and perceived usefulness** ($R = 0.6, P = 0.005$),		

In terms of mobile technology ownership, only 3 of the 22 participants (13%) did not own any sort of phone, while 6 (27%) owned a smartphone. The rest of the participants (60%) owned feature mobile phones, with the Nokia feature mobile phone (various models) proving the most popular (Figure 7.5A). Five participants owned Tablets (Figure 7.5B) although only 2 could be said to be proficient and frequent users. Of the 5 tablets users, none owned smartphones (all owned feature mobile phones). Therefore the number of participants with some sort of touchscreen experience was measured at 11 (50%).

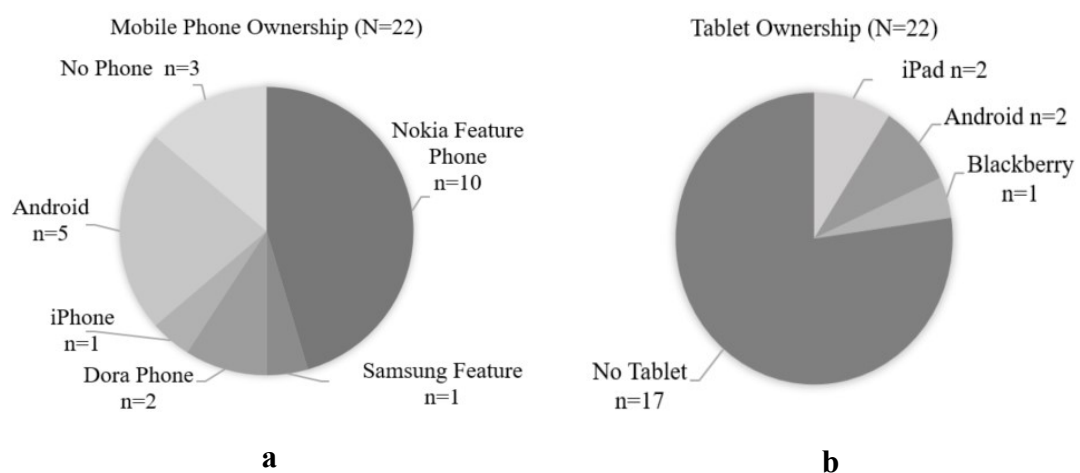


Figure 7.5: a) Mobile Phone Ownership among the 22 Participants; b) Tablet Ownership among the 22 Participants

7.3.2 Group Comparison of WIISEL Tasks

Task Completion Time

Although in general **Group 1** took longer to complete tasks, particularly on days 1-3, none of these differences were found to be statistically significant ($\alpha=0.05$). It was observed that there was much wider variance in the task times for **Group 1** than for **Group 2** (Figure 7.6 and Figure 7.7), particularly for the early days of testing. By days 4 and 5 however, variances were relatively equal and the difference in means was negligible

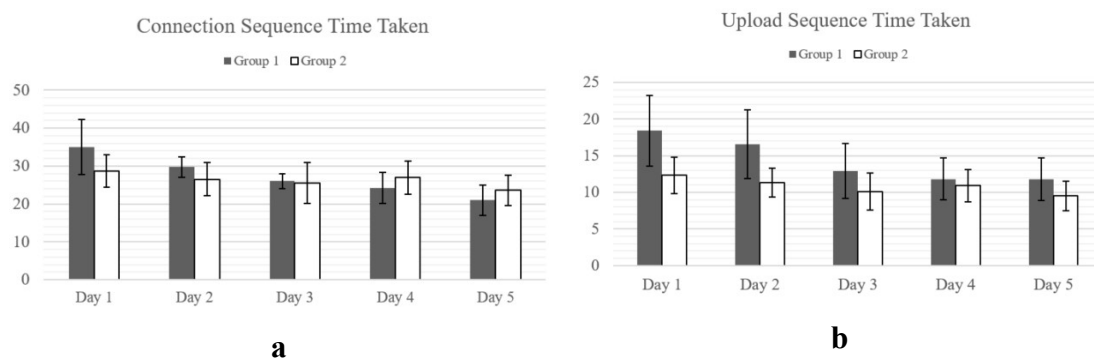


Figure 7.6: All times are shown in seconds; No significant difference in mean task completion time between group 1 and group 2 was observed for the (a) connection sequence or the (b) upload sequence

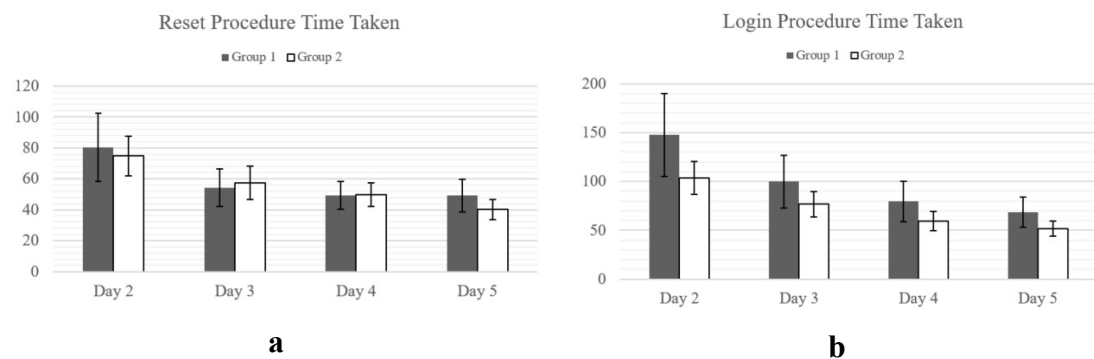


Figure 7.7: All times are shown in seconds; No significant difference in mean task completion time between group 1 and group 2 was observed for the a) reset sequence or the b) login sequence

Cues Required to Complete Task

The cues required for the routine tasks such as connection and upload sequences were negligible for each group with no significant differences found (Figure 7.8).

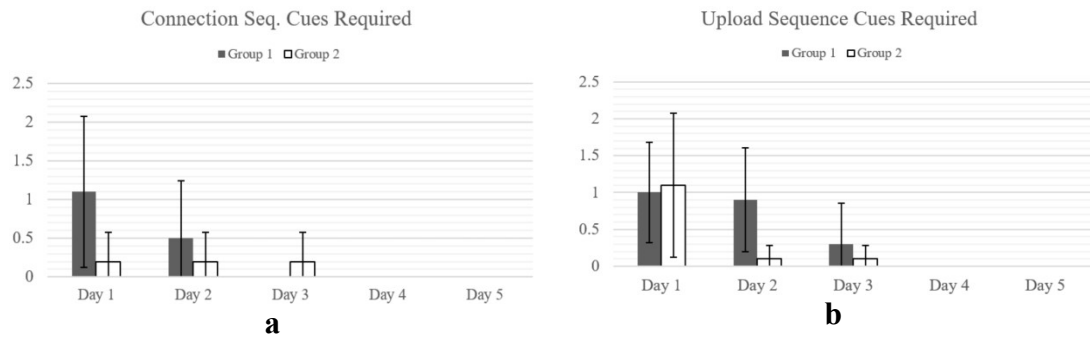


Figure 7.8: Cues required are measured as the total number of cue scores accumulated over the course of a task. No significant difference in cues required for group 1 and group 2 was observed for the a) connection sequence or the b) upload sequence

However significant differences ($\alpha=0.05$) in cues required were observed for the more complex tasks, Reset and Login procedures. Group 1 required more cues on average than Group 2 for the Reset and Login procedures, occurring on Days 2 and 3 (Figure 7.9). By Day 5 both groups had reached parity.

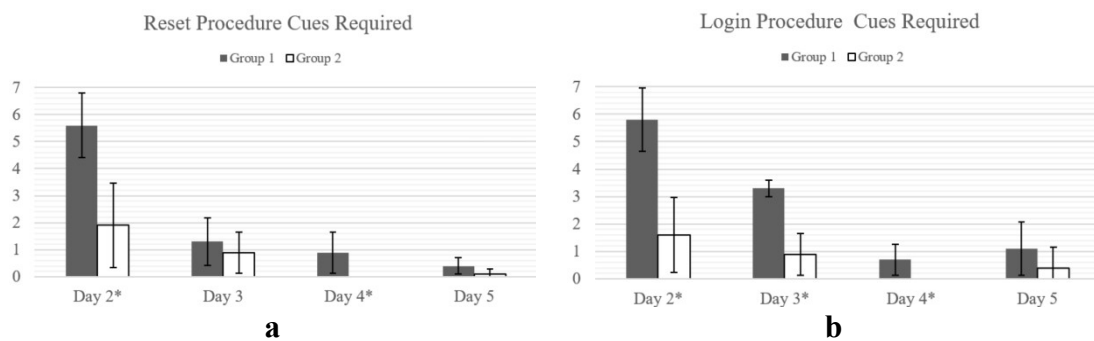


Figure 7.9: Cues required are measured as the total number of cue scores accumulated over the course of a task. *indicates a p value of <math><0.05</math>. Statistically significant differences are observed between group 1 and group 2 for the more complex a) reset and b) login procedures. By Day 5 however, no difference is observed between each group.

Errors Committed during each Task

Errors were counted as when a user reached a point in a task where they could not continue without carrying out either a reversing action or required them to start the task again. No significant difference were observed between groups during the connection and upload sequences (Figure 7.10).

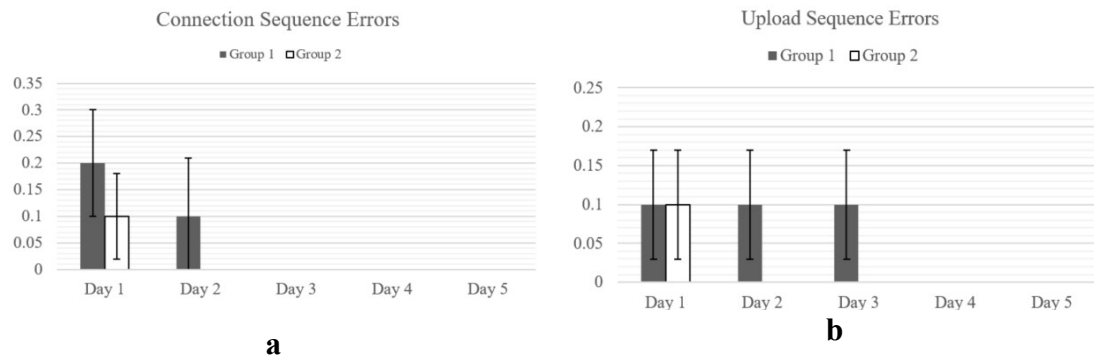


Figure 7.10: Average Errors committed over the course of completing each task, No significant difference in errors committed between group 1 and group 2 was observed for the a) connection sequence or the b) upload sequence

Significant differences were observed. Statistically significant differences were observed between group 1 and group 2 for the reset procedures but not for the login procedure (Figure 7.11). By Day 5, no difference was observed between groups for any task.

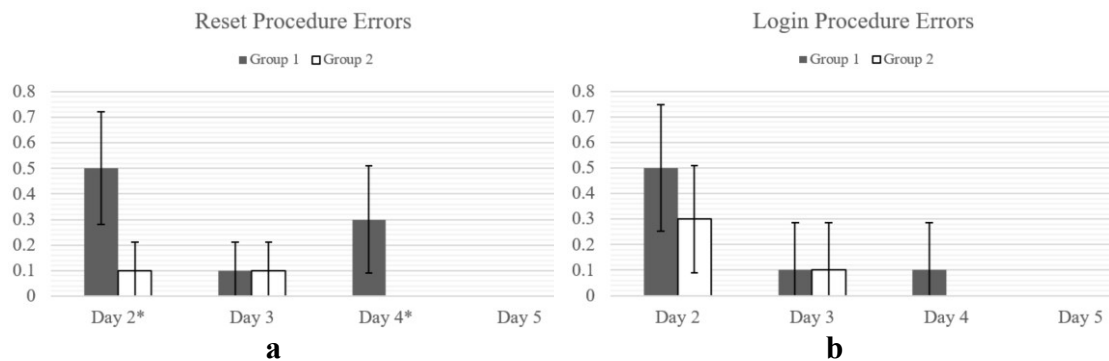


Figure 7.11: Average Errors committed over the course of completing each task, *indicates a p value of <math><0.05</math>. Statistically significant differences are observed between group 1 and group 2 for the a) reset procedures. By Day 5, no difference is observed between groups for any task.

ASQ Scores

ASQ scores show close agreement between groups on the ease of the connection, upload and reset procedures (Figure 7.12).

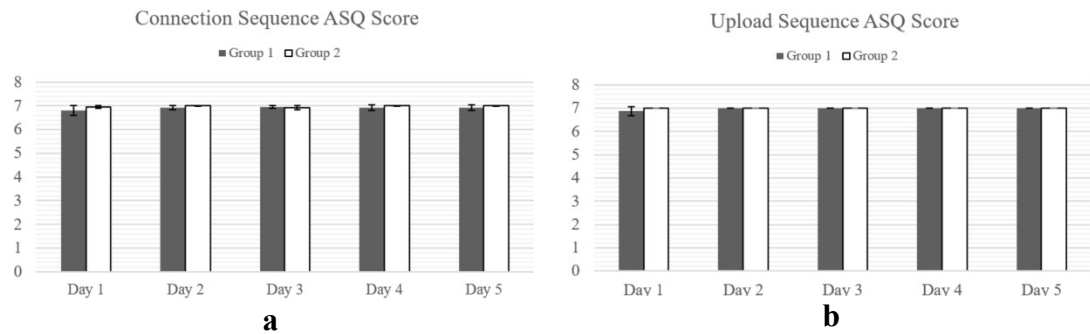


Figure 7.12: A score of 7 indicates maximum satisfaction with the task in terms of ease, time taken and supporting documentation. *indicates a p-value of <0.05 . No differences were observed for the a) connection or b) upload tasks, although significant differences were observed for the login procedure on Day 2 and Day 3.

The only statistically significant ($\alpha=0.05$) difference was seen in Day 2 and 3 of the login procedure, when **Group 1** was shown to have scored significantly lower than **Group 2** (Figure 7.13). By Day 4 both groups had reached parity.

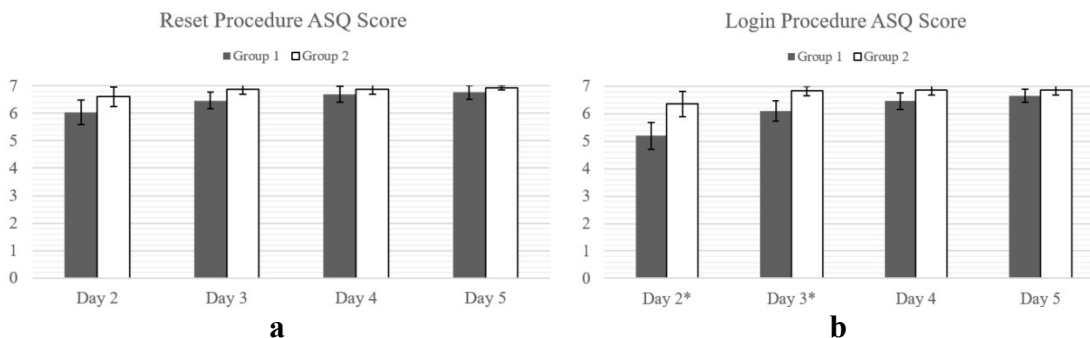


Figure 7.13: A score of 7 indicates maximum satisfaction with the task in terms of ease, time taken and supporting documentation. *indicates a p-value of <0.05 . No differences were observed for the connection, upload and a) reset tasks, although significant differences were observed for the b) login procedure on Day 2 and Day 3.

7.3.3 Overall User Experience

SUS scores showed significant differences ($\alpha=0.05$) between groups (Figure 7.14). As well as measuring the total SUS, the scale was also split into its sub scales to show learnability and usability scores. **Group 1** versus **Group 2** averages showed scores of 73 versus 87.25 ($p=0.007$), 36.25 versus 63.75 ($p=0.04$) and 82 versus 93 ($p=0.02$) for SUS total, learnability and usability respectively.

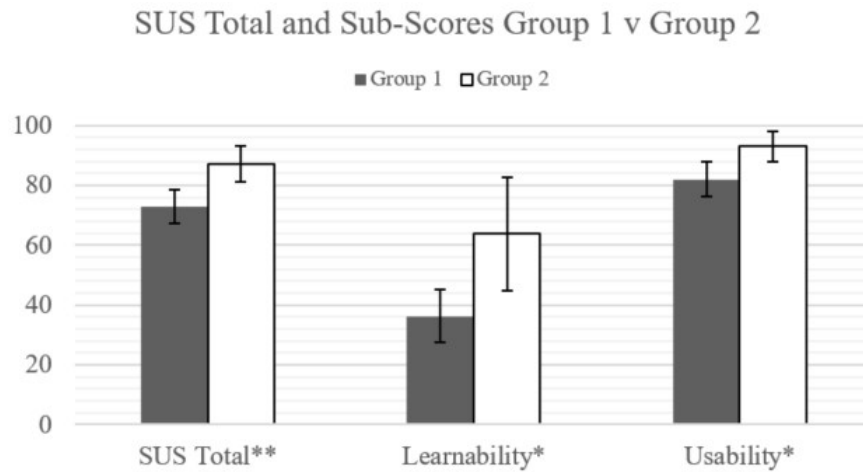


Figure 7.14: A score of 100 indicates maximum satisfaction with the usability of the device. * indicates a P value of <0.05, ** indicates a P value of <0.01. Significant differences are observed between groups for each SUS metric.

Predictors of Positive User Experience

The regression analysis showed that there was a moderate to strong correlation between PEOU and PU and some of the SUS measures for each group. There was no significant correlation for age and technology experience as a predictor of SUS measures (Table 7-7).

Table 7-7: Regression Analysis of Satisfaction Measure against Predictors such as Technology Experience, Perceived Usefulness, Perceived Ease of Use and Age. * indicates a p-value <0.1, ** indicates a p-value <0.05, *** indicates a p-value <0.01

Group	SUS Measures	Tech Category (Experience)	PU	PEoU	Age
Group 1 (No Extra Training)	Overall SUS	0.33	0.47	0.61*	0.12
	Usability Sub-Scale	0.27	0.19	0.6*	0.34
	Learnability Sub-Scale	0.33	0.66**	0.63**	0.51
Group 2 (Extra Training)	Overall SUS	0.35	0.57*	0.59*	0.19
	Usability Sub-Scale	0.33	0.69**	0.07	0.11
	Learnability Sub-Scale	0.18	0.133	0.82***	0.43

The Impact of Performance Metrics on Overall User Experience

The regression analysis indicates that cues required, errors made and the ASQ all influenced the SUS outcomes. Time taken was observed to be less of a factor, only showing strong correlation with learnability for Group 2 (Table 7-8).

Table 7-8: Regression Analysis of Satisfaction Measure against Performance Metrics. * indicates a p-value <0.1, ** indicates a p-value <0.05, *** indicates a p-value <0.01

Group	SUS Measure	Time Taken	Cues Required	Errors Made	ASQ
Group 1 (No Extra Training)	Overall SUS	0.29	0.47	0.7**	0.634**
	Usability Sub-Scale	0.37	0.48	0.8***	0.63**
	Learnability Sub-Scale	0.07	0.78***	0.4	0.39
Group 2 (Extra Training)	Overall SUS	0.32	0.84***	0.44	0.42
	Usability Sub-Scale	0.1	0.7**	0.55*	0.21
	Learnability Sub-Scale	0.62**	0.54*	0.305	0.58*

7.3.4 Comparison of Results with Previous WIISEL Usability Studies

When comparing the SUS outcomes to previous studies of the WIISEL system, we can see how dramatic the effect of the supplementary smartphone training on the Group 2 participants in this study really were. In Figure 17.5, we can see that Group 1 exhibited similar SUS results to the participants who took part in a controlled usability test [24] and an open trial [32]. In both of these studies the participants received no supplementary smartphone training. The Group 2 participants scored significantly higher than the other three groups.

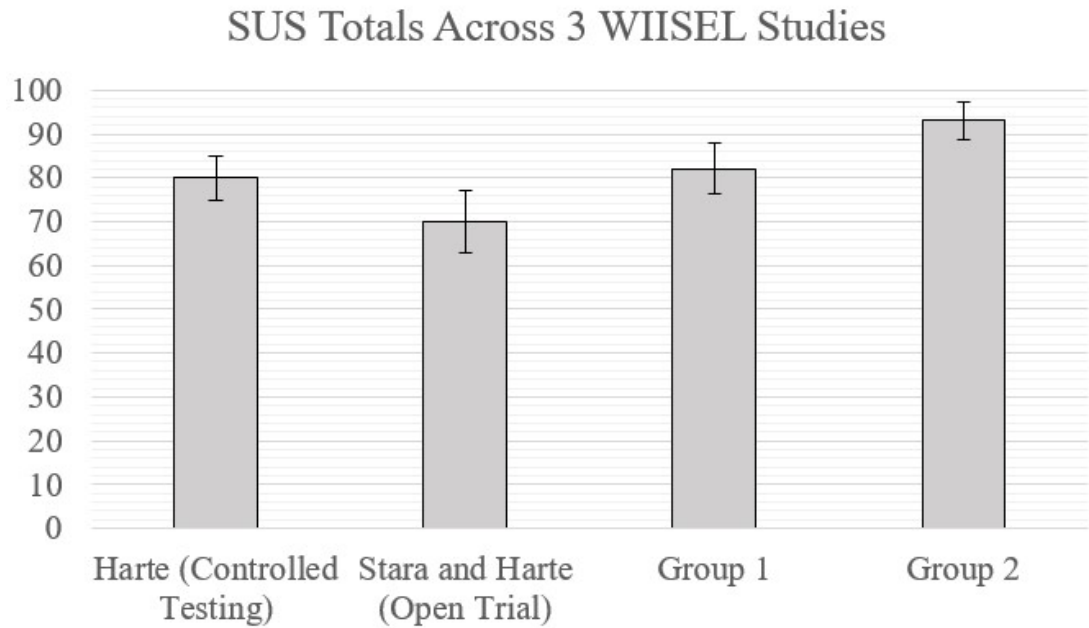


Figure 7.15: Comparison of SUS scores from various assessments of the User Experience of the WIISEL system

7.4 Discussion

7.4.1 Review of Findings

This study aimed to understand how supplementary smartphone training could enhance an older adult's user experience of a smartphone based Connected Health system (WIISEL). The results show that overall the group (Group 2) who received the supplementary had a more positive user experience with the WIISEL system according to the statistically significant difference observed in the System Usability Scale (and its sub-scales) scores between the two groups at the end of the 5 day use period. We observed that in the first three days of WIISEL use, Group 2 outperformed the non-training group (Group 1) in key usability categories such as errors committed, cues required and After Scenario Questionnaire (ASQ) scores. No significant difference was observed in task times between each group. It was observed that by the 4th day of use, both groups were recording similar performance metrics implying that there was a ceiling effect, above which no extra smartphone training could have any significant influence on WIISEL use performance. Based on the evidence presented in the results section we can conclude that providing the users with extra systematic training on the device had a highly positive affect on user experience.

7.4.2 Observed Problems

We observed a number of recurring problems encountered by the older adult users in each group. These problems occurred with more frequency in Group 1, which resulted in poorer usability metric outcomes. We grouped these problems into three categories; Touch Sensitivity, Touch Quality/Accuracy and User Interface Feedback. Within the first category, the users encountered problems when they held buttons for too long which would either deactivate the button press or initiate a secondary undesired function of the button. For example, holding a keypad letter for too long would input a number or symbol instead of the letter. A related problem was observed when users were scrolling through a menu, such as in the settings page. Heavy touches while scrolling resulted in the user unintentionally entering an option (see Figure 7.16 (A-C)). The user would then quickly become lost as they would not recognise the screen they were now presented with.

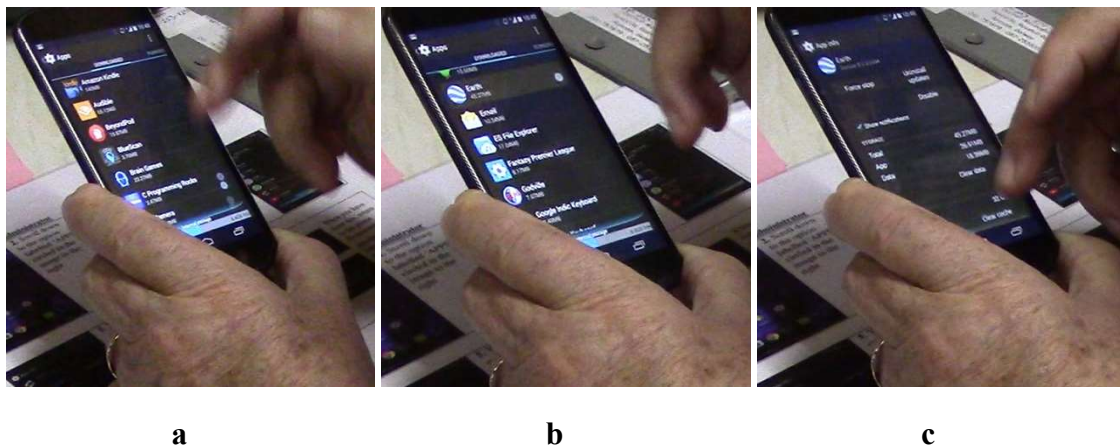
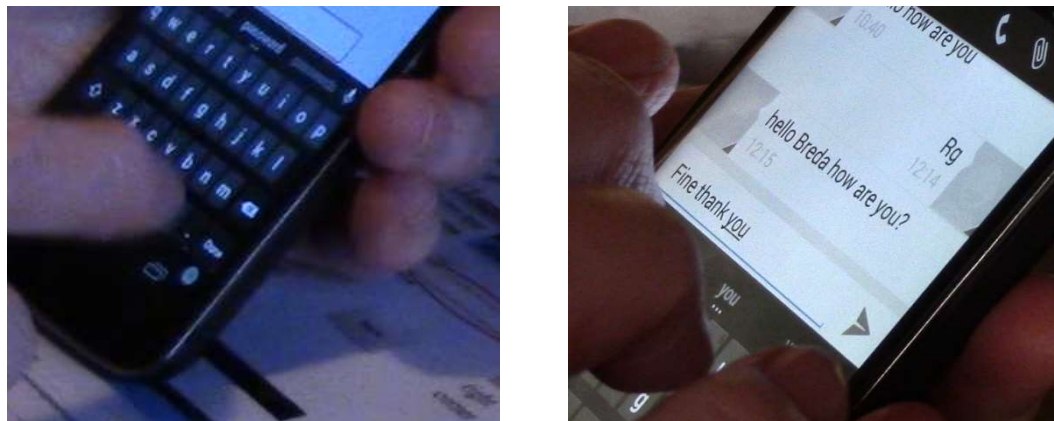


Figure 7.16: a) The User is scrolling down to access the WIISEL Option in the menu; b) The user is tapping the screen too hard while scrolling and unknowingly presses the Earth App Option (the white dot indicates the strike location); c) the User is now suddenly in an unfamiliar screen and is at risk of pressing further buttons within this option as their hand may still be carrying out a scrolling action

Users unfamiliar with touchscreens had a tendency to leave their touch finger hovering near the screen when they were not interacting with the screen, causing unintentional and sometimes unnoticed screen presses. Unintentional touches also occurred if the user gripped the phone incorrectly. Problems within the second category, Touch Quality/Accuracy, included inaccurate button striking and poor quality striking. For example, there was tendency to aim too low when attempting to

strike a button, usually owing to the angle at which the user held the screen (see Figure 7.17A). This at times led to excessive tapping, where the user would rapidly tap the screen in the hope of hitting the button correctly, leading them to unintentionally press a button in close proximity or to inadvertently press a button on the next screen. Finally, inadequate or unrecognised feedback on screen caused problems for some users. For example, many touchscreen elements do not look like traditional buttons with clearly marked borders. This caused problems with striking accuracy. Sometimes users did not recognise the subtle changes in colour or form that indicated a button had been successfully pressed. Other buttons had strange shapes which the user did not recognise (Figure 7.17B), such as a triangle or an arrow for a send button, which led to hesitation and confusion.



a

b

Figure 7.17: a) The User attempts to strike the ‘Done’ button but aims too low (white dot indicates the location of the strike); b) During Smartphone training there were times when users felt that feedback on the screen was not appropriate, in this example the user struggles to find the Send button to send the text message (the horizontal triangle)

7.4.3 Comments on Usability Metrics

The regression analysis performed on the usability metrics and how they affected the overall usability outcome from the SUS, show that increased errors made and cues required were related to lower overall SUS scores. Increased ASQ scores (indicating greater task satisfaction) were related to higher SUS scores. Task completion times showed a weak to moderate relationship with SUS scores. This could be explained by the fact that many of the required tasks were not time intensive and had a very linear path towards the desired goal. Participants could not really ‘get lost’ within a

task or deviate too much from the optimum task path. Most participants who took longer to complete tasks did so because they were simply progressing at that pace. Therefore task completion time may be a good indicator of overall usability and may depend on the context of the interaction and tasks involved.

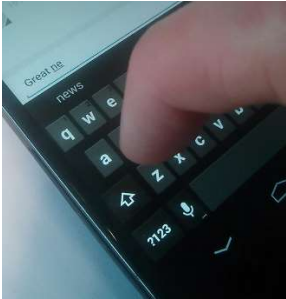
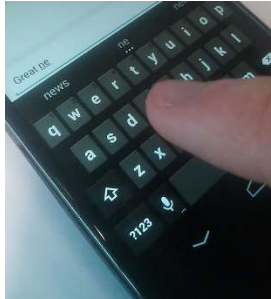
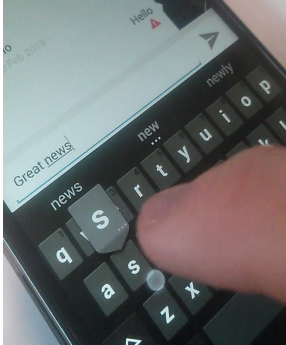

In regards to the relationship between technology adoption predictors such as age, technology experience and PU/PEoU on usability outcomes, we found no strong link for age and technology experience category, while there was a moderate link for PU and PEoU.

7.4.4 Limitations and Recommendations going forward

Our methodology meant that the smartphone specific training was maintained in parallel with the first three days of WIISEL training for Group 2 (see Table 7-3). There is a concern that this concurrent exposure, rather than implementing a cut off where the smartphone specific training ceased before Group 2 began using the WIISEL App, affected the outcome of the WIISEL usability data for Group 2, owing to the group having more total smartphone exposure time during the WIISEL App exposure. However, this approach was chosen such that the participant could achieve the benefit of the training they received on Day -2 and Day -1, by recalling what they had learnt from Day 0 onwards and receiving the appropriate guidance to optimise the training [33]. It is in this context that the participant achieves the benefit of the extra training, thereby improving their user experience and increasing their PEoU with the WIISEL system. We understand that for this training approach to be further operationalised, it may need to be streamlined or indeed undergo some structural changes. However, given the context of the study, we felt that our approach worked for the groups in question and allowed us to properly observe and measure their progress with the smartphone and the WIISEL App.

Regarding the specific problems we observed, we can make some instructional recommendations based on our training experience. These are presented in Table 7-9 and are presented within the categories of problems we identified in Section 7.4.2

Table 7-9: Recommendations for introducing smartphones to older adults

Category	Solution / Recommendation	
Touch Sensitivity	<p>Instruct the user to:</p> <p>Touch and not press the screen. Instruct the user to strike deliberately and with the pad of the fingertip, not the finger nail. <i>(see images below)</i></p> <p>Carry out slow deliberate scrolls rather than quick stabbing motions.</p> <p>Remove fingers completely from the screen area when not interacting and teach them to hold the phone by the rails rather than with the digits wrapped around</p> <p>When moving the textbox cursor, use light, slow, deliberate movement of the index finger</p>	
	 <p style="text-align: center;">X</p>	 <p style="text-align: center;">✓</p>
Touch Quality/ Accuracy	<p>Instruct the user to:</p> <p>Aim for the top portion of the button when striking <i>(see images below)</i></p> <p>Hold the phone parallel to their eye line</p> <p>Say the word ‘Smartphone’(or similarly long word) after a button press before attempting to press it again if a button does not respond immediately</p> <p>Avoid touching the tops or bottoms of the screen when swiping</p> <p>Avoid fingers of the holding hand coming in contact with the touchscreen surface</p>	
	 <p style="text-align: center;">X</p>	 <p style="text-align: center;">✓</p>

Category	Solution / Recommendation
User Interface Feedback	<p style="text-align: center;">Teach users about:</p> <p>The different types of touch elements on the screen which may not look like traditional buttons. For example, triangles/arrows for sending messages.</p> <p style="text-align: center;">Teach users to recognise the subtle feedback signals used to indicate button presses, such as slight colour changes and button jumps</p> <p style="text-align: center;">Teach users to recognise ‘wait’ feedback such as tail chasers, loading bars and hours glasses</p>

Further to the specific recommendations for training older adults outlined in Table 9, we can make some more general recommendations. First, when approaching the older adult population it is important to consider any cultural resistances and concerns that could act as hindrance for the uptake of technology enabled healthcare. In particular, security, intrusiveness, lack of control, confidentiality and usability issues can lead to a lack of trust in such technologies. We can assume that some cases of technology rejection are due to a lack of proper, scaffolded and systematic introduction to the new technology [34, 33]. This planned exposure, which should come in the form of appropriate training, must achieve the desired positive impact within a short window in order for technology acceptance rather than technology rejection to occur. The training must not only overcome apprehensions about how difficult the technology is to use, but must also overcome any misconceptions about how useful the technology is. Older adults, as with many other user groups, overwhelmingly reject technology when there is unclear evidence of personal benefit or improvement in quality of life [35-37]. A key strategy of the training is to build and increase the user’s perception of and trust in the technology. While instructional activities can take the form of written materials, computer based programs, or face to face communications, our experience in this study shows the benefit of short yet intensive periods of task based learning with direct corrective feedback. This approach may have applications in other domains such as mobile learning in education [38].

7.5 Conclusion

In this paper we have discussed significant findings from a usability design study where a training intervention was developed and tested to introduce elderly users with limited or novice technology experience to a smartphone-based Connected Healthcare system. Our findings show the importance of properly introducing – in a scaffolded and systematic fashion - older adults to technology, in order to improve their technology acceptance and enhance their user experience. Through our research in this specific context, we feel that it is possible to build or increase trust in connected, mobile and wearable health technology through the design and deployment of meaningful instructional activities. While there currently does not exist a structured training methodology for m-health with older users, the methods and lessons learned in this paper can be used to conceptualise, design and implement appropriate, bespoke training strategies. While we understand that effort and time will not always be available to carry out training on a prolonged basis, scaffolded and structured intervention is necessary to ensure successful adoption of useful m-health technology by elderly users. As well as informing our future work, we hope the development of the WIISEL system, and the guidelines and geragogical activities enumerated here will be widely useful for those designing and developing Connected Health devices and infrastructures for older adults. Crucially, the involvement of end users is a key strategy for recognizing and removing barriers and mitigating design limitations, but our research has shown that this must be carefully planned to influence, drive and refine systematically the iterative development of connected, mobile and wearable healthcare technologies. We think this paper provides a useful enumerative approach to plan and conduct usability evaluations of smartphone apps and how to gather user experience validation data, particularly in the domain of education and learning.

Acknowledgments and Declarations

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also provided methodological support. Recruitment and ethical application support was provided by Scharf. All authors contributed equally to the writing and editing of the paper. The authors declare no conflict of interest.

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Chapter 8 –Discussion and Conclusion

8.1 Discussion

Human-Centered Design (HCD) and User-Centered Design (UCD) are design approaches that aim to place the human user at the centre of the design. These approaches are particularly important when designing Connected Health devices and systems, as they are typically intended to be used in an unsupervised fashion by non-healthcare professionals, thereby increasing the chances of them being used improperly and hindering the delivery of effective healthcare. Connected Health is becoming increasingly important and popular in order to ease the burden on traditional healthcare services and older adults are a growing population group who are increasingly utilising Connected Health devices to manage their own healthcare. The work outlined in this thesis explored the design of Connected Health devices, analysed the user characteristics of older adults and suggested a design methodology which was then applied to the design of two elements within a Connected Health system. The aim of this methodology was to enhance the usability, human factors and the associated user experience of this system. The system known as WIISEL was a fall detection and fall risk prediction system consisting of a smartphone and a pair of instrumented insoles. This system was specifically targeted at older adult end users living at home.

From a review of some common Connected Health devices and a subsequent comprehensive analysis of older adult capabilities in Chapter 2, we found it reasonable to assume that some older adults may struggle with certain aspects of the use of these devices. Due to the natural process of ageing which can affect the interactive faculties of perception, cognition and psychomotor ability as well as the effects of comorbidities and psychosocial determinants, it was clear that some of these devices may present usability and human factors problems for the typical older adult user. These problems can arise due to inadequate text size, button size, button layout, interface presentation or audio feedback. Problems can also arise when donning and doffing a device, manipulating clips and connections or from the general complexity of completing tasks or following a user manual. Chapter 2 concluded by making some specific design recommendations but more importantly we highlighted the need for a HCD methodology, which takes into account the capabilities and preferences of the human user. Using the guidelines from ISO-

92410-210 as a starting platform, four phases were described which are central to a successful HCD methodology: a) Understand and specify the context of use; b) Specify the user requirements; c) Produce design solutions; d) Evaluate the solutions by carrying out usability and human factors testing activities.

In Chapter 3, a structured literature review was carried out to find out what kinds of UCD and HCD methodologies have been applied to the design of Connected Health devices and systems. Methodologies from 14 different studies were described in detail. There was a range of activities which were utilised within these design methodologies. The design activities can be split into five distinct categories: 1) Understanding the User and Context of Use (Interviews, Focus Groups and Observations); 2) Generating, Analysing and Prioritizing User Requirements (Use Cases, User Stories and Storyboards); 3) Producing Prototypes and Mock-Ups; 4) Evaluation and Inspection Methods; 5) User Testing. At the end of the review it was concluded that there was both variations and similarities across the 14 methodologies reviewed. It was also concluded that design methodologies should be tailored to fit the type of device or system being designed and the particular purpose it is being designed for.

In Chapter 4, a three phase design methodology was described based on the principles of Human-Centered Design (HCD) and which was informed by the literature review in Chapter 3. The three phases of this HCD methodology were 1) Establishing Context of Use and User Requirements; 2) Expert Inspections and Walkthroughs of Prototype; 3) Usability Testing of the Prototypes with End Users. Using the six process requirements for a Human-Centered Design process, and having derived three other requirements specific to Connected Health devices and systems based on an analysis of the literature, nine requirements were listed which the methodology had to meet. The steps in the methodology are described in detail in the context of its application to the WIISEL system and each of the activities in each phase are also described.

In Chapter 5, the results of the application of the methodology described in Chapter 4 to the WIISEL smartphone App interface are described. In phase 1, a Use Case analysis exercise was conducted. With combined expert and end user analysis, 21 problems with the system interface were identified. Two subsequent design and

evaluation iterations, which involved usability inspections and user testing, effectively solved the majority of the originally identified problems, with only three usability problems uncovered during final user testing with end users. As well as testing the efficacy and effectiveness of the methodology in what could be described as a case study, the opportunity was taken to observe first hand some of the problems older adults encounter with smartphones. It was observed that older adult users used the smartphone App more effectively when feedback was clear and simple, when there was a small number of steps for each task and when interface feedback, which may cause anxiety such as warning tones or symbols were avoided. It was observed that in the early stages of design, specifically during the Use Case analysis, the views of both the older adult end users and the views of experts who had experience with similar devices and with usability, were very valuable. Each group was able to provide a different outlook on what kinds of usability problems may be encountered in the final system. The older adult participants provided valuable feedback on the context of use, leading to clear definitions of use scenarios, and were also able to relate first-hand experience of their own problems with technology due to issues such as poor eye-sight, hearing loss or dexterity limitations. The Use Case analysis was able to combine a number of activities described in Chapter 3, such as interviews, user stories, storyboards, paper prototypes and ethnography, into one activity.

In Chapter 6, the methodology was adapted and was applied to the design of the instrumented insoles to be used as part of the WIISEL system. This study focused on the human factors, specifically the comfort, of the insoles as opposed to the pure usability aspects, recognising the fact that human factors has just as much impact on user experience as usability. This was also an important study due to the increasing popularity of wearable health electronics. Like the smartphone study in Chapter 5, by engaging early in the process with stakeholders and experts, the context of use and user characteristics were clearly defined. The methodology again utilised an expert inspection as in Chapter 5, although this time experts were chosen based on their expertise in podiatry, physiotherapy and occupational therapy. In this study, end users were not used for user testing owing to advice from experts on the potential harm the introduction of such a device may cause to an older adult user. It was found that the experts who inspected the insole were able to influence the evolution of the

insole to improve its human factors characteristics. It was apparent that had this methodology not been employed in the manner it was, the insole could easily have been directly exposed to older adult users in its original form (1st prototype), potentially leading to early rejection of the device.

At the end of these two studies, we could now conclude that the WIISEL system had reached an acceptable level of usability, human factors and UX for older adults based on the data collected using our methodology. However, it was recognised that we were introducing a smartphone to a user group who may have limited experience with such devices. Therefore, regardless of how usable the WIISEL app became for example, problems were foreseen arising with the usability of the system due to the lack of user proficiency with smartphones in general. The final study in Chapter 7 tested the UX of the WIISEL smartphone App over a number of days and also assessed the effect that a simple smartphone training routine had on the overall user experience with the WIISEL smartphone interface.

Splitting participants into two groups, the same level of WIISEL specific training was applied to both groups. One group, was also exposed to supplementary basic smartphone training. This allowed a first-hand observation of the learning curve of a typical older adult as they learned to use various features of the smartphone as well as learning how to use the WIISEL App. The results show that the group who received the supplementary training had a more positive UX with the WIISEL system based on a statistically significant difference observed in the System Usability Scale (SUS) scores between the two groups at the end of the 5 day use period. We were also able to observe first hand some of the problems older adult users encounter when using smartphones for the first time. Many of these problems were related to the use of the touchscreen. Problems related to touch sensitivity and touch accuracy with the touchscreen were frequently observed. Users also encountered problems when insufficient feedback was presented on the screen related to actions and tasks being carried out, something which was also observed in Chapter 5. When introducing older adults to smartphones, the small introductory window of time where technology acceptance or rejection is most likely to occur, is very important. A simple and effective training routine within this time window, where the user is shown how to use the most basic functions, has been demonstrated

to be an effective way to improve the chances of technology acceptance. It could also be argued that this is not a convenient or efficient way to introduce new users to technology, however this introduction can be carried out by peers whom have regular contact with the prospective user, such as friends, family members (in particular younger members such as children) and caregivers.

HCD has developed with input from numerous fields, including product design, human-computer interaction, software engineering and cognitive and social sciences. From this we could surmise that HCD requires a large range of expertise to apply it successfully. I have approached, learned about and applied HCD from the perspective of an electronic engineer. This has several advantages, for example having experience in the analyses and understanding of complex systems behaviour and experience in technical writing and reporting. I have noticed that HCD has many similarities with classic systems engineering, whereby user needs and requirements are identified at an early stage and then system specifications are developed to meet these needs and requirements. Regardless of background, whether it be electronic engineering, computer science or psychology, within the HCD process one should assume the role of the HCD engineer. The novelty of HCD lies in the early and often focus on end-users, utilizing them as stakeholders throughout the development process. Therefore, a key role for the HCD engineer is to involve users in an active and effective way, and as an electronic engineer this was the biggest challenge owing to a lack of experience dealing directly with users. A critical pre-requisite to interacting with users was to acquire the necessary social science skills, such as interviewing, observations, note-taking, transcribing and designing appropriate questionnaires to gather the right feedback from users. The next biggest challenge was to correctly interpret this feedback and accurately describe it to the design team, who would have to make the appropriate system changes.

Following on from this engineering perspective, I can offer some recommendations for readers of this thesis who are looking for guidance with their own current or future undertakings with HCD. We can offer some general recommendations for this design methodology based on the case studies described. Firstly, planning is the key to success. With limited time and limited resources, it is important to know before beginning your process what methods you will employ and what data will be

gathered from them at each phase. Key considerations when planning should be, what is the nature of the system being tested (hardware/software/types of interface)? What is it being used for (primary operating function)? Who will be using it (target end-users)? While the design process can benefit from fluidity, it does not mean that extensive planning should be ignored. Guidance for planning can come from various sources including ISO 9241-210 and IEC 62366-1/2 and these sources will also help with consistency of key terminology. Secondly, as stated above, social science skills are invaluable to effectively gathering and correctly interpreting user feedback, particularly in Phase 1 of the methodology described in this thesis, where users are interviewed or observed to establish context of use and user requirements. Prospective usability engineers should familiarize themselves with the key literature on these methods [1-4]. Thirdly, appropriate time should be dedicated to precise and comprehensive reporting. This is critical for accurately communicating the user feedback to the design team, any loss of fidelity or insight in the feedback due to poor communication will lead to wasted resources and frustration within the process. Again, guidance can be sought from ISO 9241-210 and IEC 62366-1/2, although there can be no substitute for a proper review and editing protocol for reports before exposing them to designers. Finally, there is no miracle shortcut to effective design, particularly in an engineering sense where regulations and standards will affect market entry. There is no replacement for robust, well documented and thorough processes, even with limited resources. From the case studies described in this thesis, prospective designers should form their own ideas about what lessons they need to take other than the ones described above, and fit them to their own particular projects.

8.2 Conclusion

The work outlined in this thesis can be considered to be a comprehensive case study on the usability, human factors and user experience of a Connected Health system designed for use by older adults. A suitable Human-Centered Design methodology based on best practice and standard guidance was applied to the design of the system. While no sweeping generalisations can be made about how successfully this methodology might be when applied to the design and testing of other systems, Connected Health or otherwise, we can conclude that the methodology did positively influence the usability, human factors and therefore User Experience of two distinctly different components within the WIISEL system. Going forward we would like to see this methodology being applied to other devices and systems, specifically within the Connected Health domain. The best way to further develop and enhance the methodology is to apply it to fresh design tasks, which will bring fresh challenges. Every chapter in this thesis has represented a huge learning experience for the both author of this thesis and the research group who conducted the research. The work proved challenging owing to the complexity of designing home health devices for a large heterogeneous user group, but was also extremely rewarding in that it allowed the group to gain first-hand experience in the application of a HCD methodology. This experience will be invaluable as the group moves on to new studies and new projects, possibly outside the domain of Connected Health.

With the increase in popularity and importance of the Connected Health model, the importance of producing devices and systems which adhere to the principles of HCD is greater than ever. Products which are usable, safe and allow the user to complete their personal health goals with effectiveness, efficiency and with satisfaction will lead to a greater uptake in technology among users who are not used to mobile or wearable devices. This will progress Connected Health, taking the burden off traditional healthcare systems as the population of older adults starts to increase. It is hoped that the work presented in this thesis contributes to that progress.

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Publications Arising from this Project

Journal Publications:

RP. Harte, L. G. Glynn, B. J. Broderick, A. Rodriguez-Molinero, P. M. A. Baker, B. McGuinness, L. O’Sullivan, M. Diaz, L. R. Quinlan, and G. Ó Laighin, “Human-Centered Design Considerations for Connected Health Devices for the Older Adult,” *J. Pers. Med.*, vol. 4, no. 2, pp. 245–281, Jun. 2014.

This work was core to Chapter 2 of this Thesis, therefore only the first page that appears in the *Journal of Personalized Medicine* appears here (See Page 230)

RP Harte, LR. Quinlan, L.G. Glynn, A. Rodriguez-Molinero, T. Scharf, C. Carenas, E. Reixach, J. Garcia, J. Carrabina, G. Ó Laighin, ‘A Multi-Stage Human Factors and Comfort Assessment of Instrumented Insoles Designed for Use in a Connected Health Infrastructure’, *J. Pers. Med.*, vol. 5, no. 4, pp. 487–508, Dec. 2015.

This work was core to Chapter 6 of this Thesis, therefore only the first page that appears in the *Journal of Personalized Medicine* appears here (See Page 231)

Conference Publications:

V. Stara, RP. Harte, M. Di Rosa, L. Rossi, and G. ÓLaighin, ‘Toward a Connected Health System for Older Adults: Lessons Learned’, in *Advances in Physical Ergonomics and Human Factors*, vol. 489, R. Goonetilleke and W. Karwowski, Eds. Cham: Springer International Publishing, 2016, pp. 849–857.

Human Centred Design Considerations for Connected Health Devices for the Older Adult

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Abstract

Connected health devices are generally designed for unsupervised use, by non-healthcare professionals, facilitating independent control of the individuals own healthcare. Older adults are major users of such devices and are a population significantly increasing in size. This group presents challenges due to the wide spectrum of capabilities and attitudes towards technology. The fit between capabilities of the user and demands of the device can be optimised in a process called Human Centred Design. Here we review examples of some connected health devices chosen by random selection, assess older adult known capabilities and attitudes and finally make analytical recommendations for design approaches and design specifications. [View Full-Text](#)

Keywords: eHealth; ageing adult; elderly; medical devices; human-centred design; human computer interaction; usability; human factors; user experience; user acceptance

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A Multi-Stage Human Factors and Comfort Assessment of Instrumented Insoles Designed for Use in a Connected Health Infrastructure

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Abstract

Wearable electronics are gaining widespread use as enabling technologies, monitoring human physical activity and behavior as part of connected health infrastructures. Attention to human factors and comfort of these devices can greatly positively influence user experience, with a subsequently higher likelihood of user acceptance and lower levels of device rejection. Here, we employ a human factors and comfort assessment methodology grounded in the principles of human-centered design to influence and enhance the design of an instrumented insole. A use case was developed and interrogated by stakeholders, experts, and end users, capturing the context of use and user characteristics for the instrumented insole. This use case informed all stages of the design process through two full design cycles, leading to the development of an initial version 1 and a later version 2 prototype. Each version of the prototype was subjected to an expert human factors inspection and controlled comfort assessment using human volunteers. Structured feedback from the first cycle of testing was the driver of design changes implemented in the version 2 prototype. This prototype was found to have significantly improved human factors and comfort characteristics over the first version of the prototype. Expert inspection found that many of the original problems in the first prototype had been resolved in the second prototype. Furthermore, a comfort assessment of this prototype with a group of young healthy adults showed it to be indistinguishable from their normal footwear. This study demonstrates the power and effectiveness of human factors and comfort assessment methodologies in influencing and improving the design of wearable devices. [View Full-Text](#)

Keywords: [instrumented insole](#); [gait analysis](#); [comfort](#); [human factors](#); [human centered design](#); [mHealth](#); [eHealth](#); [connected health](#); [wearable electronics](#); [older adult](#)

Article

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Original Paper

Human-Centered Design Study: Enhancing the Usability of a Mobile Phone App in an Integrated Falls Risk Detection System for Use by Older Adult Users

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ABSTRACT

Background: Design processes such as human-centered design (HCD), which involve the end user throughout the product development and testing process, can be crucial in ensuring that the product meets the needs and capabilities of the user, particularly in terms of safety and user experience. The structured and iterative nature of HCD can often conflict with the necessary rapid product

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Original Paper

A Human-Centered Design Methodology to Enhance the Usability, Human Factors, and User Experience of Connected Health Systems: A Three-Phase Methodology

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ABSTRACT

Background: Design processes such as human-centered design, which involve the end user throughout the product development and testing process, can be crucial in ensuring that the product meets the needs and capabilities of the user, particularly in terms of safety and user experience. The structured and iterative nature of human-centered design can often present a challenge when design teams are faced with the necessary, rapid, product development life cycles associated with the competitive connected health industry.