



DEVELOPMENT OF A SMART WEARABLE

To monitor the physical activity of elderly hip fracture patients during their rehabilitation

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Creative Technology BSc.V1.0 - 05/07/2019Client:Ziekenhuisgroep TwenteSupervisor:Prof. Dr. M.M.R. Vollenbroek-HuttenCritical Observer:D. van Dartel MSc.

Abstract

The rehabilitation of elderly hip fracture patients can be a slow and demanding process. The goal of rehabilitation is for the elderly patients to functionally recover and return to their previous living situation. However, within a year after surgery, 29 - 50% of these elderly patients are unable to do this. Ziekenhuisgroep Twente and the University of Twente are researching ways to get more insight into the rehabilitation process of elderly hip fracture patients. A smart wearable, capable of measuring signals and data from the user, could prove to be useful for this. The implementation of a smart wearable could prove to be successful in remotely monitoring the rehabilitation process of elderly patients recovering from hip fractures. This paper aims to find an answer to the following research question: "How can a smart wearable be designed to monitor the rehabilitation of elderly hip fracture patients?". The Creative Technology Design Process is used to answer this question and realize a functioning prototype. The activity of the legs of the patients is measured to monitor their rehabilitation process. The user experience of the elderly hip fracture patients and their physical therapists is central in designing a smart wearable to monitor the rehabilitation of the patients. Their goals, needs an motivations yield a set of product requirements that a design solution needs to meet. The patients require physical and emotional comfort, while the therapists require ease of use and access to reliable data. The prototype design solution has been evaluated on end-users and proved to be successful in meeting the product requirements and in monitoring the rehabilitation of the elderly hip fracture patients.

Acknowledgements

I am grateful for all the people who have assisted me during the course of this project. I would personally like to thank my supervisors, Dieuwke van Dartel and Miriam Vollenbroek-Hutten, for providing me with the feedback and motivation necessary to successfully complete this project. Additionally, I would like to express my gratitude towards the teachers of the Creative Technology Bachelor programme, for providing me with the knowledge and skills needed during the course of the design process.

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I – Introduction

Every year approximately 14.000 people are treated for a hip fracture in the Netherlands (VUmc Netwerk Acute Zorg, 2013). Most of these patients are often elderly patients. Hip fractures in elderly patients can have serious consequences and complications. According to Aarden et al. (2017), roughly 30% of the elderly hip fracture patients die within 12 months after being discharged from hospital, whilst many of the surviving patients sustain lasting disabilities. Rehabilitation of elderly people can be a slow and demanding process. This rehabilitation process generally includes physical therapy and clinimetric tests to assess progress of the patients. The goal of rehabilitation is for the elderly hip fracture patients to functionally recover and to return to their previous living situation. Within a year after surgery, 29 - 50% of these elderly patients are unable to do this (Aarden et al., 2017). As little is known about the rehabilitation process of elderly hip fracture patients, more knowledge has to be acquired. It is possible to gather more knowledge by using a way of remotely monitoring the rehabilitation process of elderly hip fracture patients.

For these reasons Ziekenhuisgroep Twente (ZGT), together with University of Twente's Biomedical Signals and Systems group (BSS), are researching ways to get more insight into the rehabilitation process of elderly hip fracture patients. They are currently doing this by continuously monitoring patients with the use of ambulatory monitoring devices, using a Fitbit Charge device (https://www.fitbit.com). The Fitbit can for example be used to monitor the heart rate, sleeping activity and number of steps of the wearer. The elderly hip fracture patients wear the Fitbit around their wrist, but since the patients often use certain aids to move around, it is unable to properly monitor the number of steps taken. To illustrate, elderly hip fracture patients might be assisted by a wheelchair to move around. A Fitbit device around the arm of a patient would then measure a quantity of physical activity, since the arms of the patient are moving, whilst the legs of the patient actually remain still. Oppositely, if a patient is assisted by a walker to move around, a Fitbit device would measure little to no physical activity since the arms of the patients remain relatively still, whilst the legs of the patient are in fact being used. This is why there is a need to develop a different wearable device capable of properly monitoring progress during the rehabilitation process of elderly recovering from a hip fracture. A smart wearable can prove to be useful for this. Smart

wearables are wearable computing devices capable of measuring certain signals from the user. Such a device possesses the potential of tracking and reporting on the physical recovery process of a patient. The successful implementation of a smart wearable could prove to be successful in remotely monitoring the rehabilitation process of elderly patients recovering from hip fractures. Therefore, this paper aims to find an answer to the following research question: "How can a smart wearable be designed to monitor the rehabilitation of elderly hip fracture patients?"

In order to do this, first a literature study will be conducted to get an understanding of smart wearables, their current utilization in healthcare monitoring and the monitoring of hip fracture recovery. Secondly, the methods and techniques used for the project will be listed, after which the ideation, specification, realization and evaluation of the project will be presented. Lastly, a conclusion concerning the research question and the scope of the project will be given.

II – Literature Research

In this chapter, a literature study will be conducted to get an understanding of the research question and its involved concepts. Firstly, a definition of the term 'smart wearable' will have to be formulated, together with providing examples of how smart wearables are currently being used to monitor physical recovery. Secondly, the capabilities of physiological monitoring and its parameters will be examined. Thirdly, the recovery process of hip fracture patients will be researched to get acquainted with the parameters involved with the rehabilitation process.

2.1 – Smart Wearable

In order to get an understanding of smart wearables and their capabilities, a definition of a 'smart wearable' has to be acquired. For a device to be called a smart wearable, it has to have certain characteristics. A first set of characteristics can be found in an article by Chan, Estève, Fourniols, Escriba and Campo (2012). They state that a smart wearable system encompasses a wearable computing device. It can be worn on the body or be implanted into clothing, while being capable of providing computational functions. Schneegass and Amft (2017) add to this, using the term wearable computers. They state that such a device has the characteristic of being able to collect and process data whilst the output is always perceptible, either on the wearable or on an external device, no matter where on the body the wearable is placed or what its particular function entails. Malmivaara (2009) agrees with this, adding that such a device has the characteristic of being constructed in such a way that it can fulfil one or more specific needs of a particular target group. Chan et al. (2012), Schneegass and Amft (2017) and Malmivaara (2009) all describe smart wearables as body worn computational devices, while also mentioning their capability of measuring physiological signals, which can enable smart wearables to monitor physical recovery. A smart wearable needs to have these characteristics to be able to monitor progress during the rehabilitation process of elderly recovering from a hip fracture.

There are multiple examples of these smart wearables being used to monitor physical recovery. A first example is mentioned by Appelboom et al. (2014) in a study in which a smart wearable, Mayo Clinic's "off-the-shelf" monitor, was used to assess the

mobility of elderly people after heart surgery. In this case, the smart wearable could keep track of the patient's heart rate and the number of steps taken, using ECG and accelerometer. Additionally, McAdams et al. (2011) state an example in which a 'smart glove' is being used to monitor a set of vital signs from patients. These vital signs include heart rate, respiration rate and skin blood flow. McAdams et al. (2011) also refer to a study conducted with a harness-like smart wearable. This device had the capability of continuously monitoring breathing rate, heart rate, body temperature, physical activity and posture. This smart wearable could make it possible to continually monitor a patient's vital signs, with minimal intrusiveness. Moreover, Chan et al. (2012) state multiple examples of smart wearables for physiological monitoring. These examples include diagnosing cardiovascular diseases through analysing changes in ECG patterns, aiding treatment of diabetes mellitus by continually monitoring blood glucose concentrations and aiding treatment of respiratory diseases by continually monitoring breathing rate. There are many different applications of smart wearables in recovery monitoring, indicating a vast amount of potential for future research, while also indicating their capability to monitor progress during the rehabilitation process of elderly patients recovering from a hip fracture.

2.2 – Physiological monitoring

To be able to monitor progress in rehabilitation, it needs to be clear what physiological signals play a role in measuring physical recovery. There are various physiological signals related to physical recovery. Coutts, Wallace and Slattery (2007) state several of these physiological signals in a study in which physical and mental changes during overreaching and recovery of male triathletes are monitored. In this study, in addition to hormonal and psychological signals, the maximum oxygen intake and blood and urine values of the athletes were measured to monitored, among other things, the level of recovery. On the contrary, Chan et al. (2012) mention a different set of physiological signals related to health monitoring. These include heart rate, body temperature, respiration rate, arterial blood pressure and blood oxygen saturation.

What is important for the physical recovery of elderly hip fracture patients can be more specific. For example, Appelboom et al. (2014) mention that measurements of body movement signals, primarily the number of steps taken, can also play a role in monitoring particular physical recovery. They mention that patients recovering from leg injuries need to use their legs during the rehabilitation process in order to the legs to functionally recover. This supports the case that measuring the number of steps taken by elderly hip fracture patients during rehabilitation can aid in monitoring the process in their rehabilitation. Additionally, Magaziner et al. (2000) discuss changes in functioning after a hip fracture. Here the dependency of patients performing physical activities was analysed to assess physical recovery. These physical activities included walking, climbing steps, getting in and out of a car, bed, chair or shower and putting on clothes. The patients were monitored to analyse these physical activities in order to obtain information about the physical recovery process of the hip fracture patients.

It is apparent that there are various physiological signals related to monitoring physical recovery, including heartrate and blood pressure. However, to measure physical recovery of elderly hip fracture patients, the set of physiological signals can be more specific. These signals involve physical activities such as walking, changing positions and climbing stairs. To be able to measure one or more of these signals can be useful in monitoring the physical recovery process of elderly hip fracture patients.

2.3 – Hip fracture recovery process

To get acquainted with the rehabilitation of elderly hip fracture patients, it needs to be clear what a standard hip fracture recovery process looks like. In an article by Folbert et al. (2012), the way of treatment for elderly hip fracture patients at ZGT in Almelo is described. It is a multidisciplinary treatment, wherein the trauma surgeon and geriatrician are highly involved during the whole recovery process of the patient in the hospital. This treatment uses a multidisciplinary clinical pathway, which already start at the hospital's emergency department. The multidisciplinary clinical pathway can be seen in Figure 1. All these processes, from admitting at the emergency room to discharging from the nursing home, are involved in the rehabilitation of elderly hip fracture patients and should be considered when designing and evaluating the intended smart wearable, since the output of the intended smart wearable needs to be made visible for the involved healthcare professionals.

It is also relevant to have an understanding of what is important in the recovery process of the elderly hip fracture patients. Ideally, surgery should take place within 48 hours after the injury to minimize the possibility of further issues (Cluett, 2018). After surgery, it is of great importance that the patients start getting up and moving around as soon as possible to prevent complications such as blood clots, bed sores or pneumonia (Cluett, 2018). Even sitting up straight or changing position in bed can aid in preventing such complications. The rehabilitation process is aimed at functional recovery of the patients so that they can return to their previous living situation. Cluett (2018) describes three important aspects the patients have to regain in order to functionally

recover. Firstly, the mobility of the patients has to be restored. In order for the muscles in a limb to function properly, the joints in that limb need to move. If the mobility of the joints does not get restored as soon as possible, the functionality of the muscles is impaired. Secondly, the restoration of muscle strength is of utmost importance. To prevent indefinite atrophy of muscle tissue, the muscles need to be working and moving as soon as possible after surgery. Thirdly, the recovery of balance is essential. Balance is an important aspect in physical activity and its restoration helps to regain functionality and to prevent potential further injury. Magaziner et al. (2000) also mention aspects involved with functional recovery of patients. They agree with Cluett (2018), stating that mobility, muscle strength and balance are important for patients to regain, while adding that the independence of the elderly patients has



FIGURE 1. MULTIDISCIPLINARY CLINICAL PATHWAY FOR ELDERLY HIP FRACTURE PATIENTS. ADAPTED FROM "GERIATRIC FRACTURE ... TREATMENT OUTCOMES," BY E. C. E. FOLBERT ET AL., 2012, *GERIATRIC ORTHOPAEDIC SURGERY & REHABILITATION, 3*(2), P. 61. COPYRIGHT 2012 BY THE AUTHOR(S)

to ideally be regained. Moreover, they mention that in elderly patients, social, cognitive and affective functioning are often important to be analysed and regained if necessary.

Overall, the rehabilitation process of elderly hip fracture patient is focussed on the functional recovery of a patient, for which physical activity of the legs is critical. The successful implementation of a smart wearable to monitor the physical activity of elderly hip fracture patients can provide more insight into the rehabilitation process, which might aid in accelerating successful rehabilitation.

2.4 Conclusion

For a device to be called a smart wearable, it has to be a computing device that can be worn on the body or be implanted into clothing. It has to be able to collect and process data whilst the output is always perceptible, either on the wearable or on an external device, no matter where on the body the wearable is placed or what its particular function entails. The intended end product of this project needs to possess these characteristics in order to be called a smart wearable. There are various examples of smart wearables being used to monitor physical recovery, including smart wearables to assess mobility in elderly patients, which indicate the potential of smart wearables for this project. To monitor the rehabilitation process of elderly hip fracture patients, the number of steps taken by a patient is an important signal to asses. Several other physiological signals, including heart rate, could also be measured to monitor physical recovery. The successful implementation of a smart wearable has the potential of assisting ZGT in properly monitoring the physical activity of elderly hip fracture patients during rehabilitation.

III - Methods & Techniques

In this chapter, an overview of various methods and techniques will be presented which will be used during the course of the project. Firstly, the Design Process for Creative Technology will be explained. Secondly, the Stakeholder Analysis will be described, leading to the PACT Analysis. Thirdly, the MoSCoW method will be presented. Then finally, the User Testing will be explained.

3.1 Design Process for Creative Technology

The design method to be used for the project is the 'Design Process for Creative Technology', as described by Mader and Eggink (2014). This design method is derived from two classical design approaches that provide essential aspects to the method, namely 'Divergence and Convergence Models' and 'Spiral Models', which will both be explained further in-depth.

The Divergence and Convergence Models describe creative design processes that have a divergence phase, followed by a convergence phase. The goal of the divergence phase is to allow creativity to flourish at its fullest, with the design space being open and boundless. The goal of the convergence phase is to deliberately limit the design space, reducing the amount of possible solutions to arrive at a definite solution. The Spiral Models describe the different design steps that professional designers take during a design process. These steps are presented in such a way that they do not necessarily require a logical order in which to execute them.

The Creative Technology Design Process integrates the Divergence and Convergence Models and the Spiral Models into a single way of addressing a design procedure, which can be seen in Figure 2. This Creative Technology Design Process consists out of four phases: Ideation, Specification, Realization, and Evaluation. These four phases will now be explained further in-depth.



FIGURE 3. DESIGN PROCESS FOR CREATIVE TECHNOLOGY (MADER & EGGINK, 2014, p. 270).

The Ideation phase starts off from the main research question. Different techniques like e.g. observations and interviews with potential users can be used to come up with or evaluate possible ideas, which can come in the form of e.g. sketches, mock-ups or storyboards. At the end of the Ideation phase the goal is to have a more detailed project idea that possibly contains a set of requirements.

The Specification phase is meant to refine the possible solution that was generated in the previous phase. At the end of the Specification phase the goal is to have an even more specific project idea, ideally with all different aspects evaluated and refined into a grounded and full-fledged design solution. In the Realization phase, the design solution and specifications generated in the previous phases are used to create the actual product. The different components of the product are realized and integrated into a single system. The previously specified requirements and specifications are used to assess the viability of the end product.

The Evaluation phase is meant to address multiple aspects. The functional and non-functional requirements of the end product, specified in earlier stages, will be tested and evaluated by performing user tests. This way it can be verified whether the design decisions correspond with the intended user experience and satisfaction. After evaluating the end product, a conclusion can be drawn concerning the design solution, together with a reflection on the design decisions made.

3.2 Stakeholder Analysis

In order to have a clear understanding of the project and its involved aspects, possible stakeholders have to be identified, as stated by Sharp, Finkelstein, and Galal (1999). These stakeholders can include any person or group that can have an interest in the end product of the project. This can for example include the intended primary users of the product, but also secondary users and involved clients and organizations. By clearly identifying these stakeholders, the different interests of each stakeholder can be analysed to identify a set of requirements for the end product.

3.3 PACT Analysis

For a successful design process, it is important to have a clear overview and understanding of the context in which the intended product is to be implemented. To identify and analyse this context, the PACT Analysis method can be used. PACT is an abbreviation for People, Activity, Context and Technology, which will all four be analysed.

The People section focusses on the involved stakeholders, which have been identified in the stakeholder analysis. In this section, stakeholders will be analysed more in-depth by identifying aspects such as the age, cultural background and motivations of the stakeholders. Personas can be used to get an even better understanding of the stakeholders. Personas detailingly describe fictional people that fit the within the identified stakeholders. The fictional people in the personas are created as truthfully as possible by implementing the previously acquired information and details about the stakeholders.

The Activity section focusses on the activities being undertaken within the target context. Scenarios can be used to depict activities in a comprehensible way. In a scenario, a short story is presented wherein identified end users undertake activities in the current context, after which a way the intended end product can influence these activities is presented.

The Context section further builds on the activities identified in the Activity section. Here a larger image of the environments and backgrounds in which the activities take place is presented and analysed. Again, scenarios can be used as an aid to depict the context to be analysed.

The Technology section focusses on the different technologies within the context. Literature findings can be used as background knowledge to build upon in this section. Several technologies that are currently being used for the activities within the context are identified and analysed, together with a possible overview of technologies that might be used in a later stage.

3.4 MoSCoW Method

In order to adequately design the intended end product, it needs to be clear what kind of requirements are of importance for the product. The MoSCoW method is a helpful tool for identifying and analysing these requirements. MoSCoW stands for Must have, Should have, Could have and Won't have, which are the four sections into which the requirements are divided.

In the Must have section, the most important requirements for the product are listed. This includes functions and features that are necessary for the product to function and fulfil its intended goal and user experience. These requirements are often the first to be implemented into the realization of the end product.

In the Should have section, requirements are listed that are of great importance to the intended end product, but are not vital to the functioning of the product or its core intended user experience. However, these requirements are often all fully implemented into the end product.

In the Could have section, requirements are listed that have a chance of improving the overall product quality. These requirements are often not of vital importance to the functioning or intended user experience of the product, but can have a chance of refining and enhancing these aspects. These requirements can often only be implemented into the product when the amount of time and resources available permit it.

Finally, in the Won't have section, requirements are listed that are not of importance to the product or cannot be implemented with the amount of time and recourses available. The goal of this section is to have considered all possible requirements of the product and to be able to have a full and open perspective of the product. It can also generate aspects that are required to not be implemented in the design. It is possible for a requirement in the Won't have section to be reconsidered in a later stage of the design process.

3.5 User Testing

In order to adequately evaluate design decisions and the end product, user testing has to be done. Ideally this is done on potential users, but it can also be done on other available test subjects or on the designer himself. By testing the product or certain aspects of the intended product on potential users, unfiltered feedback can be gathered regarding the product. Unexpected design flaws and imperfections can be identified, which can then be addressed to improve the product. During the project, two kinds of user testing will be done. The first one is done during the Ideation phase, wherein certain aspects of the design will be tested to improve the overall functionality and user experience of the design. Observations and open feedback will be the main source of output for this kind of user testing. During the earliest stage of the Ideation phase, observations will already be done of the target user group in their context environment. This is meant to give inspiration and understanding for the first designs of the intended end product. Interviews with stakeholders can also help with this. The second type of user testing will be done after the end product is complete. Here the product will be tested on its overall user experience and satisfaction from the users. The System Usability Scale will be used to evaluate the usability of the product. This is a form of a questionnaire that focusses on the usability of the product, wherein the users can rank usability aspects on a scale of 1 to 5. These scores are then calculated into a formula, resulting a score ranging from 0 to 100 which indicates the overall level of usability.

IV – Ideation

The following chapter will cover the first phase of the Creative Technology Design Process: the Ideation phase. Firstly, the stakeholders involved with the project will be identified and analysed. Secondly, a PACT Analysis will be conducted to get a clear understanding of the context in which the intended product is to be implemented. Personas and scenarios will be integrated into the PACT Analysis. Finally, after having observed potential users in the target environment, the MoSCoW method will be implemented to acquire an initial set of requirements for the intended product.

4.1 Stakeholder Analysis

To get a clear understanding of the different motivations and interests that are involved with the project, the different possible stakeholders have to be identified. As stated before, these stakeholders can include any person or group that can have an impact on or interest in the end product of the project. Multiple stakeholders have been identified and will be introduced in the following.

The primary stakeholders are elderly hip fracture patients. They form the primary user group of the intended end product and thus have a great amount of possible interests toward the project. The motivation of these stakeholders is to have a rehabilitation process which is as short as possible. They want to functionally recover as quickly as possible, with as little intrusiveness and discomfort as possible.

The second group of stakeholders contains the healthcare professionals that are involved with the rehabilitation process of the elderly hip fracture patients. This includes the trauma surgeon and the geriatrician, but most importantly the physiotherapist, since this person forms the secondary user group. The physiotherapist wants to receive the data collected from the elderly hip fracture patients by the intended product. Together with the trauma surgeon and the geriatrician, they want their patients to have a rehabilitation process which is a short and comfortable as possible.

The third stakeholder is ZGT, which is the external client of the project. Since ZGT is supervising the project, they are involved with the design process and the end result

of the project. They want the intended end product to be successful in monitoring the physical activity of elderly hip fracture patients during rehabilitation, while it also satisfies the interests and needs of the intended users of the product.

4.2 PACT Analysis

In the following section a PACT Analysis will be presented which is aimed at obtaining a clear overview and understanding of the context in which the intended end product is to be implemented. Personas and scenarios will be used to aid the PACT analysis in reaching this goal.

4.2.1 People

- Hip fracture patients

The patients of the project are mostly 65+ years of age. They are of Dutch nationality and speak the Dutch language. They want a rehabilitation process which is as short as possible, with as little intrusion and interruptions as possible. They can often have cognitive disabilities and/or physical impairments. They are commonly unfamiliar with technological devices and software applications.

– Therapists

The therapists are mostly aged between 20 and 65. They are mainly of Dutch nationality and speak the Dutch language. They want their patients to have a quick and successful rehabilitation process. They are medical professionals with an affinity for technological devices and software applications.

– Trauma surgeons

The trauma surgeons are mostly aged between 30 and 65. They can have different nationalities, though in the Netherlands most are of Dutch nationality and speak the Dutch language. They aim for a successful surgery and a quick recovery process for the patients. They are somewhat less involved with the dayto-day rehabilitation process compared to the therapists.

– Geriatricians

The geriatricians are mostly aged between 25 and 65. They are mainly of Dutch nationality and speak the Dutch language. They want the patients to recover from all afflictions and complications, or help them cope with them, as smoothly and inconveniently as possible. They are also somewhat less involved with the dayto-day rehabilitation process compared to the therapists.

Acquired information and details about the stakeholders and target group will be used to create personas that describe fictional target end users of the intended product. This is aimed at providing a better understanding of the target user group and their motivations. These personas can be found in Appendix A.

4.2.2 Activity

- Supervised exercises

Under supervision of a therapist, the patients perform daily exercises to maintain and recover functionality of the body after a hip fracture. This can be leg exercises concerning the movability of the legs in multiple direction, but also exercises involved with getting in and out of bed. The therapists assist the patients when necessary, but the goal is for the patients to eventually be able to independently perform these actions.

- Unsupervised exercises

The therapists assess each patient's ability to perform certain exercises and determine the patient's progress in independence. The patients then get assigned certain tasks like walking around that they can perform when the therapist is not there. The goal of these exercises is for the patients to actively keep up with the recovery process in the absence of the therapist, to make more progress during rehabilitation.

– Clinimetric tests

In order to monitor indications of progress in the patients, clinimetric tests are performed on them. These tests are aimed at determining progress in the functionality and mobility of the patients.

4.2.3 Context

- Rehabilitation centre

The patients and therapists all interact within a rehabilitation centre. Patients have their own rooms with basic bedroom and bathroom equipment. There are common dining halls wherein the patients eat breakfast, lunch and dinner, exercise rooms wherein the patients practice their exercises and rooms for staff members. The rehabilitation centre is equipped with all sorts of equipment to assist the patients and to test and assess the patients' physical abilities and recovery progress.

A fictional scenario is created to illustrate the activities being performed by the target users in the target context. The goal of this scenario is to get a better understanding of the activities of the intended users, together with their motivations and needs within the target context. This scenario can be found in Appendix A.

4.2.4 Technology

– Fitbit Charge

A Fitbit Charge is used to monitor various signals from the patients during their rehabilitation process. This device presents the output of these signals in an application for the therapists to analyse.

– Hometrainer

A Hometrainer cycling device can be used to train the patients' leg strength and mobility. An application with cycling visuals, such as landscapes, can be used as an experience enhancement for the patients.

4.3 Observations & Interviews

On the May 8, 2019, an orientation day was conducted at the residential care complex Het Borsthuis in Hengelo, the Netherlands. At this facility, among other patients, elderly hip fracture patients are admitted for rehabilitation after hip fracture surgery. The goal of this day was to obtain a better understanding of the target users, so that inspiration could be gathered for the first design options. Observations of the elderly hip fracture patients in the target context were done. These observations were done to observe the average day of an elderly hip fracture patient during rehabilitation. Unstructured interviews were held with both patients and their therapists. First the scope of the project was introduced to them, after which they were free to give their unfiltered feedback and opinions about possible design solutions. The most important knowledge gained from the observations and unstructured interviews is as follows:

- The patients indicated that a body-worn device around the leg should have to have a relatively soft inner material, since it might otherwise hurt their bodies.
- The interaction between elderly patients and technological devices can be stiff, so the design solution should not incorporate much interaction with the patient.
- The therapists indicated that the design solution should ideally have an accessible way of presenting the acquired data to the therapists.
- A body-worn design solution should have an attachment mechanism that is not too difficult to open or close. The ankle is the preferred location, since it is a relatively accessible part of the user's legs.
- A body-worn design solution around the leg can make the patients feel like they are wearing an electronic ankle bracelet. If such a device is e.g. clearly visible with a black colour, it can, for the patient, feel like a stigma of having to be tracked.
- The therapists indicated that, in possible future version, the sleep activity of the patients might also give them more insight into the rehabilitation process.

4.4 Initial concept ideas

After having performed the Stakeholder Analysis, PACT Analysis, observation and interviews, the following initial concept ideas were generated. These ideas can be refined at a later time in the Ideation phase. To recap: in order for a quick rehabilitation process, elderly hip fracture patients get assigned to keep moving their legs when the therapists are not around. The prototype design solution will be a device worn around the ankle or upper leg of the user so that it will be able to measure the activity of the legs of the user. The ankle has a preference since is a more accessible place on a patient's body and it allows for earlier detection of leg activity. The device will have to have a relatively easy way of attaching it to and detaching it from the user's body. This device will have to have a soft inner material in order for it to provide comfort to the elderly users. Since elderly patients tend to lack an affinity with technological devices, the interaction between the device and the elderly patients will be kept at a minimum. On the other hand, the interaction between the device and the therapists will have to be proper by presenting the acquired data in an accessible way. A Bluetooth connection to a smartphone application can be used for this. Since a device around the ankle can feel like a stigma of having to be tracked, the outer design of the device needs to account for this. At the moment, the outer colour will be the main focus in preventing this. Since electronic ankle bracelets are mostly of a black colour, the prototype design solution should not have this colour. A mild beige skin colour can be more discrete and prevent the stigmatizing feeling.

4.5 MoSCoW Method - Initial Requirements

Based on all the previously acquired knowledge concerning a possible design solution, the MoSCoW method will be implemented to identify initial requirements that are of importance to the potential prototype. Every requirement will be divided into a Must have, Should have, Could have or Won't have section.

Requirement #1	Requirement type: Functional	
Value: Measure leg activity	Attribute: Accelerometer	
Description: The device must be able to mea	asure the activity of the user's legs	
Rationale: To aid in monitoring the rehabilitation process of elderly hip fracture patients, the activity of the legs is considered to be an important aspect to measure		
Source: Ziekenhuisgroep Twente, Appelboom et al. (2014), Interviews		
Fit criteria Usability testing: The device can be tested on the measurement of activity.		
Priority: Must have	Conflicts: None	
History: Created 20-5-2019		

Requirement #2 Requirement type	: Functional
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Attribute: Programmed interface or application

Description: The device must present the acquired data in an accessible manner

Rationale: The therapists must be able to have easy access to the data that is acquired from the patients

Source: Interviews, Schneegass and Amft (2017)

Fit criteria

Acceptance testing: The therapists should find the manner of data presentation acceptable.

Priority: Must have	Conflicts: None
History: Created 20-5-2019	

Requirement #3	Requirement type: Non-functional	
Value: Attaching and detaching the device	Attribute: Attachment mechanism	
Description: The device must include a way of attaching it to the body of the user		
Rationale: The therapists must be able to attach and de-attach the device to the patient with relative ease		
Source: Observations, Interviews		
Fit criteria Acceptance testing: The therapists should find the manner of attaching and detaching the device acceptable		
Priority: Must have	Conflicts: The mechanism should not be too big	
History: Created 20-5-2019		

Requirement #4	Requirement type: Non-functional
Value: User experience	Attribute: Outer colour of device
Description: The device should have an outer design that does not warrant the unwanted user experience of feeling tracked	

Rationale: E.g. a black device on someone's body can feel like an unwanted electronic tracking bracelet, this can carry a certain stigma

Source: Interviews, Observations, Ziekenhuisgroep Twente

Fit criteria

Acceptance testing: The patients should not feel like the device carries the stigma of an electronic anklet

Priority: Must have

Conflicts: None

History: Created 20-5-2019

Requirement #5	Requirement type: Non-functional	
Value: Comfort and safety of elderly users	Attribute: Soft material	
Description: The device's inner material should be relatively soft		
Rationale: The elderly users can be frail, so the material touching them should be relatively soft so that it will not hurt their bodies		
Source: Observations, Interviews		
Fit criteria Acceptance testing: The patients should find the inner softness of the device acceptable		
Priority: Must have	Conflicts: The casing around the electronics should be solid	
History: Created 20-5-2019		

Requirement #6	Requirement type: Non-functional
Value: Adapt size to user	Attribute: Feature on attachment mechanism
Description: To be able to adapt to different users, the attachment mechanism should include a way of adjusting the size of the device	
Rationale: Different user have different body sizes	

Source: Observations, Interviews	
Fit criteria Usability testing: The device can be tested on how well it adapts to different body sizes	
Priority: Should have	Conflicts: The mechanism should not be too big or intrusive
History: Created 20-5-2019	

Requirement #7	Requirement type: Functional	
Value: Measure sleeping activity	Attribute: Heartrate sensor, accelerometer	
Description: The device could have the ability to monitor sleeping activity of the user		
Rationale: Sleeping activity can rehabilitation process in elderly	also be considered to be an important aspect in measuring the hip fracture patients	
Source: Interviews		
Fit criteria Usability testing: Were this to be implemented, then it could be tested on the accuracy of the measurements of activity		
Priority: Could have	Conflicts: A lack of time might make it difficult to implement this feature	
History: Created 20-5-2019		

Requirement #8	Requirement type: Non-functional	
Value: Interaction with elderly users	Attribute: Elaborate interface on body-worn device	
Description: The device won't have an elaborate interface on the body-worn device itself		
Rationale: Since elderly users often lack an affinity with technology, the interaction between the device and the elderly users should be kept at a minimum		
Source: Interviews, Observations		

Fit criteria Acceptance testing: The patients should be able to use the device without having complicated interaction with it	
Priority: Won't have	Conflicts: Some form of interaction with the elderly users might be needed
History: Created 20-5-2019	

4.5 Initial sketches

Based on all the previously acquired knowledge and requirements regarding a possible design solution, sketches have been made to illustrate possible ideas. These sketches can be seen in the following.



FIGURE 5. INITIAL DEVICE SKETCH 1



FIGURE 4. INITIAL DEVICE SKETCH 2, INCLUDING POSSIBLE ATTACHMENT MECHANISM



FIGURE 5. INITIAL DEVICE SKETCH 3

In Figure 3 and Figure 5, two possible outer designs of ankle-worn device are presented. The round design in Figure 5 is preferred since it contains less edges and has less chance of hurting the skin of the elderly patients. In Figure 4, a possible outer design for a device worn around the upper leg is presented. Even though the device is preferred to be around the ankle, a visualization of a device around the upper leg can be helpful. Figure 4 also contains a first idea regarding the attachment of the device. Velcro is presented as a way of attaching and detaching the device with adjustable size.



FIGURE 6. INITIAL ATTACHMENT SKETCH 1



FIGURE 7. INITIAL ATTACHMENT SKETCH 2



FIGURE 8. INITIAL ATTACHMENT SKETCH 3

In Figure 6, a possible way of adjusting the device's size is presented. A standard strap buckle could prove to be useful for this. This could be combined with the possible attachment mechanism presented in Figure 7. Here a standard belt buckle is presented with which the device could be attached and detached from the user's legs. In Figure 8, an alternate way of possibly attaching and detaching the device with a click system belt buckle is presented. These mechanisms could also allow for adjustability of the size of the device.



FIGURE 9. INITIAL ELECTRONICS SKETCH

In Figure 9, a first possible electronics overview is presented. Possible components, necessary for achieving the functional requirements, are indicated with a possible outer casing.

4.6 Supervisor Meeting – Refined Concept Idea

On May 10, 2019, a meeting was held with the supervisors from Ziekenhuisgroep Twente. Based on this meeting, certain alterations had to be made concerning the focus of the possible design solution. It was decided that the design solution had to be more novel, by implementing the device into a garment. This also connects to the previously identified requirement stating that the device should not give the user a stigmatizing feeling of having to be tracked. The solution to this problem previously involved the outer colour of the device, by having e.g. a mild beige skin colour instead of black. However, since the device would still resemble an electronic ankle bracelet, the device should be more discrete and inconspicuous. By implementing the device as a garment, the design solution becomes novel and the stigmatizing effect can be prevented. Some useful input for such a refined design solution has already been acquired during the observations and interviews. However, in order to successfully implement this design solution, some additional research has to be done regarding a possible garment for elderly hip fracture patients. The results of that research can be found in the following.

4.7 Additional Research

To implement the intended design solution into a garment for elderly hip fracture patients, possible garments need to be considered. A garment is needed that is suitable for all elderly hip fracture patients. During the observations and interviews, it was noted that the patients wore specific pieces of clothing around their legs. Most of the female patients wore support stockings, usually combined with standard socks underneath step-in loafers. Male patients were less likely to wear support stockings. Since the intended garment needs to be unisex, the support stockings might not be the most viable option for implementation of the device. Literature concerning the post-hip surgery clothing of elderly hip fracture patients gave scarce results. However, Burcea et al. (2017) mention hip fracture patients wearing cushion boots for heel protection to prevent bedsores.

The intended device will contain an accelerometer that can detect activity of the legs in the form of steps taken, only when the accelerometer is pointed in a specific direction. The device will contain the electronics, including the accelerometer, in a way similar to the simplified way depicted in Figure 9. For the accelerometer to be able to detect activity, the device would then have to be attached to either the right or left side of a leg. This is because the sensor will have to be placed parallel to the leg in order to properly measure the acceleration in the x and y direction. If a sock, support stocking or shoe would be used as a garment to contain the device, the device would then have to be implanted either on the right side or left side of the garment. The accelerometer would then only perform its function if it is placed on the corresponding leg. Since a sock, support stocking or shoe is usually designed to fit either on the left or the right leg, the user would not have the option to choose on which leg to wear it. However, since elderly

hip fracture patients can be frail with additional ailments complicating the use of their legs, they might want the option to choose on which leg to wear the garment. Thus, a garment that can be placed on either the left or the right leg of a patient is preferable.

A standard sportswear sweatband, such as depicted in Figure 10, can be ideal for this. This garment can be placed on either the left or the right leg of the user. The stretchiness of such a garment allows for it to adapt to different leg sizes, whilst also allowing it to be attached and detached by sliding it over the foot of the user. Its material is soft, allowing for comfort and safety of the user. If the device is implanted into or onto this garment, it will not look like an electronic ankle bracelet, reducing the change of it giving the user a stigmatizing feeling of being tracked. Additionally, this garment is fully washable. This way is can be easily cleaned for reuse.



FIGURE 10. STANDARD SPORTSWEAR SWEATBAND

4.8 Refined Requirements & Sketches

After having to refine the concept idea, most requirements gathered using the MoSCoW method stayed the same. Only requirement #4 is adjusted, since the not the outer colour, but the whole outer appearance is now the resolution to the problem concerning the stigmatizing feeling. This refined requirement can be seen in the following.

Requirement #4	Requirement type: Non-functional
Value: User experience	Attribute: Outer appearance, device implanted into garment
Description: The device should have an outer design that does not warrant unwanted user experience results	

Rationale: E.g. a black device on someone's body can feel like an unwanted electronic tracking bracelet, this can carry a certain stigma		
Source: Interviews, Observations, Ziekenhuisgroep Twente		
Fit criteria Acceptance testing: The patients should not feel like the device carries the stigma of an electronic anklet		
Priority: Should have	Conflicts: None	
History: Created 20-5-2019 Adjusted 3-6-2019		

To illustrate the refined concept idea, additional sketches have been made. These rough sketches can be seen in Figure 11 and Figure 12.



FIGURE 11. ROUGH SKETCH OF GARMENT AND DEVICE CASING



FIGURE 12. ROUGH SKETCH OF GARMENT WITH OUTER COMPARTMENT

In Figure 11, a rough sketch of the sweatband around a leg is presented, together with the probable shape of the device which is to be implanted into the garment. The device will either be implanted into the double-layered fabric of the sweatband, or into an external sewn-on compartment, which is roughly presented in Figure 12. For more comfort and better usability, the external compartment in Figure 12 is preferable.

4.9 Conclusion

After having performed Stakeholder Analysis, PACT Analysis, interviews and observations, an initial concept design solution was established. This concept incorporated an ankle-worn device able to monitor leg activity of elderly hip fracture patients. This device would have a soft inner material, an attachment mechanism and would accessibly present the data for the therapists. The data can be presented through a smartphone application. The MoSCoW method was used to identify and categorize a set of requirements for the product, after which initial concept sketches were made. On May 10, 2019, a meeting with the supervisors from Ziekenhuisgroep Twente concluded that the concept needed alterations. To prevent a stigmatizing feeling for the user and to make it into a novel concept, the device is to be implemented as a garment for the user. The device will be able to monitor the leg activity of the user, in the form of a number of steps, whilst being imbedded in a standard sportwear sweatband. This idea will be further specified in the following Specification phase.

V – Specification

In the following chapter, the previously established design solution will be further elaborated on. The different aspects of the concept idea will be refined and specified into a full-fledges design solution.

5.1 Components

In order to realize the intended design solution, it needs to be clear what components are needed for this realization. These components will be divided into sections concerning electronic and non-electronic components.

5.1.1 Electronic components

In order for the device to be able to fulfil its different functions, several electronic components are needed. The main component of the device will be the Arduino Lilypad, which can be seen in Figure 13. This microprocessor enables the device to process data acquired from different sensors. Since this Lilypad model is relatively small and thin, it is designed for wearable devices such as this one.



FIGURE 13. ARDUINO LILYPAD



FIGURE 14. MMA7361 ACCELEROMETER

The device will need to be able to detect activity of the legs of the user. This activity can be detected by measure the acceleration of the legs. An accelerometer sensor is designed to measure this acceleration. The MMA7361 accelerometer, which can be seen in Figure 14, will be used so that the device can measure the leg activity of the user. In order for the device to accessibly present the acquired data to the physical therapist, a smartphone application can be used. Arduino Bluetooth Terminal is a smartphone application designed to receive and present data from an Arduino board. In order for the device to send the data to the application, a HC-05 Bluetooth module will be used, which can be seen in Figure 15. This Bluetooth module allows for a Bluetooth connection between the Arduino and any Bluetooth device, so that the data can be transferred.



FIGURE 15. HC-05 BLUETOOTH MODULE



FIGURE 16. LIPO MINI BATTERY



FIGURE 17. USB LIPO CHARGER

In order for the device to independently function, a power source is needed. A lithiumion-polymer battery, or lipo battery, can be used for this. This battery can be seen in Figure 16. This battery delivers the current necessary to power the device, whilst its small design requires less space in the design. In order for this battery to not run dry, a way to charge the battery is needed. A USB lipo charger, such as depicted in Figure 17, can be used for this. This charger allows for the battery to be charged through a USB Micro-B port. A standard old smartphone charger cable can be plugged in to charge the battery.
All these components will have to be connected in such a way that the battery powers the device and the data can be acquired and transmitted to an external Bluetooth device. The connection layout for the all the electronics can be seen in Figure 18. Since the program used to create this layout (Fritzing) does not contain all of the previously specified components, similar components are presented in the layout. The way of connecting the components remains identical to the way depicted in Figure 18.



FIGURE 18. ELECTRONICS CONNECTION LAYOUT

5.1.2 Non-electronic components

In order for the electronic components to be held together and presented in a desirable manner, an outer case is needed. This case will have to have a mechanism with which to open and close it with relative ease, since the electronic components might still need alteration and calibration after enclosing them in the case. The case will also need an opening for the micro-USB charger port, so that the device can be charged whilst enclosed within the case. A 3D-model of the bottom part and top part of the case can be seen in Figure 19 and Figure 20, respectively. Indents on the inside of the parts will allow for them to be clicked on and off each other. In Figure 19, the opening for the micro-USB port is also clearly visible. These 3D-models can be directly used to print the parts using a 3D-printer.





FIGURE 19. BOTTOM PART CASE

FIGURE 20. TOP PART CASE

The case containing the electronic components will have to be imbedded into a garment. A standard sportwear sweatband was first considered to be a suitable garment for this. However, such sweatbands are mostly designed to be worn around the user's wrist. This does not provide for a large enough garment to be worn around the user's lower leg, whilst also having the case of the device embedded into it. Additionally, such a sweatband does not provide for a lot of support for either the leg of the user, or the embedded case. For these reasons an alternate garment, pictured in Figure 21, is considered to be more suitable. This Tarmak calf support brace provides the user's leg with compressing support, whilst also providing enough support for the case of the device to be embedded into it. This brace is especially designed to be worn around the ankle and to provide support to the muscles and tendons of the user. It is also designed for comfort in that it is made out of a soft material which is stretchable enough to be easily put on and off of the user's leg. This makes it an ideal garment for the purpose of this prototype.



FIGURE 21. TARMAK CALF SOFT 300

This calf brace can be placed on either leg, so that the device can properly measure the data no matter on which leg it is placed. To be able to embed the casing of the device onto the garment, a sachet will be attached to the side of calf brace. This sachet will have to be comprised out of a stretchable material, since it needs to be able to stretch with the calf brace when being put on and off of the user's leg. Cotton can be considered a proper material for this sachet, since it is soft, breathable and stretchable, whilst also providing the strength to support the casing of the device. Moreover, the resulting garment is completely washable, enabling it to be easily used between different elderly users.

5.2 User Interface

The Bluetooth module will send the data that was acquired from the patients to an external device so that the therapists can easily access these data. Arduino Bluetooth Terminal, a public Android smartphone application, is considered to be ideal for this. This application has been specifically created for HC Bluetooth modules, when used with an Arduino microprocessor. Since the intended prototype will be using an HC-05 Bluetooth module to send the data, an external Android device, with a Bluetooth connection and the Arduino Bluetooth Terminal application installed, can receive the data. Additionally, the application allows for the Android device to accessibly present the acquired data with relative ease. No extra programming is needed for the application to properly function. This makes for an ideal user interface for the therapists to easily perceive and analyse the data that was acquired from the users.

5.3 Conclusion

The previously identified concept idea has been specified into a full design solution. Electronic and non-electronic components that are needed to achieve the previously specified product requirements have been identified. The electronic components include an accelerometer to measure the leg acceleration, a Bluetooth module to send the data to an external device, a lipo battery and lipo charger to keep the device powered, and an Arduino Lilypad to run the device. The non-electronic components include a 3D-printed case to contain the electronics, with a charging port on the side of the case. This case will then be embedded onto a calf brace within a cotton sachet. The Arduino Bluetooth Terminal application will be used to receive and present the acquired data on an external Android device. These are all aspects that aim to provide a prototype that takes into account the previously specified product requirements. This product idea will be realized in the following Realization phase.

VI – Realization

In the following chapter, the realization of the previously specified design solution will described. The integrated of the different components into a single device will be presented, after which the calibration and refining of the created prototype will be described.

6.1 Integration of electronic components

The electronic components specified in chapter 5.1.1 have been integrated into a single device, as previously described in Figure 18. The resulting device can be seen in Figure 22.



FIGURE 22. INTEGRATION OF ELECTRONIC COMPONENTS

On the bottom, the lipo battery can be seen, which is connected to the USB lipo charger on the top right. On the left the Bluetooth module can be seen and the accelerometer can be seen on the top left. All these components are connected to the Arduino Lilypad microprocessor, which can be seen in the middle.

6.2 Integration of all components

After the electronic components have been integrated into a single device, they have to be enclosed inside a case. The case presented in Figure 19 and Figure 20 has been 3D-printed, which can be seen in Figure 23 and Figure 24.



FIGURE 23. BOTTOM PART OF 3D-PRINTED CASE



FIGURE 24. TOP PART OF 3D-PRINTED CASE

In Figure 23, the bottom part of the 3D-printed case is presented, wherein the charging port on the side of the case is visible. This bottom part can be easily clicked on and off of the top part of the case, presented upside down in Figure 24. The electronics have been secured on top of each other inside of the case, with the battery charger secured to the charging port of the case. This can be seen in Figure 25. The closed case containing the electronics can be seen in Figure 26. The case is 3 centimetres in height and 7 centimetres in width and length, which is the smallest size to still fit the electronics inside.



FIGURE 25. ELECTRONICS INTEGRATED INTO CASE



FIGURE 26. CLOSED CASE CONTAINING ELECTRONICS

This case has been embedded onto the calf brace that was previously identified in Figure 21. A cotton sachet was sewn onto the side of the calf brace, together with two snap buttons to open and close the sachet. The resulting garment, including the case, can be seen worn on a lower leg in Figure 27 and Figure 28.



FIGURE 27. SIDEVIEW OF FINAL PROTOTYPE WORN ON LEG



FIGURE 28. FRONTVIEW OF FINAL PROTOTYPE WORN ON LEG

In Figure 27, a sideview of the prototype is presented, worn on a lower leg. In Figure 28, a front view of the prototype worn on a lower leg is presented. Here all the parts are integrated into a final product.

6.3 Programming and calibration

In order for the electronic components to perform their respective functions, the Arduino Lilypad has been programmed using the Arduino integrated development environment (IDE), which is a platform with which Arduino microprocessors can be programmed. The resulting code can be seen in Appendix B. The code has two main purposes. It makes sure that accelerometer is able to measure acceleration and translate it to a number of steps and a distance, additionally, it makes sure that the Bluetooth module is able to send the data via Bluetooth to an external Android device.

The accelerometer code works as follows. When the accelerometer is moved in the x-, yor z-direction, the corresponding values change accordingly. For example, in a resting position the accelerometer might return a value '0' for x, y and z. If the accelerometer is moved into the x-direction and then moved back to the resting position, the value for x will go up to a certain value and back down to the starting value which in this case was '0'. The same goes for the values for the y- and z-direction. In the prototype, the accelerometer is places with the x-direction pointing forward and the y-direction pointing upward, as one would expect. When the user takes a step, the values for x and y will go up to a certain value and go back down to the starting value on which they began. In the code, prerequisites are set so that the device will detect a step when the x and y values change to the values corresponding with a step, which were determined during calibration tests.

During these calibration tests, the prototype was attached to the leg of a test person who was then asked to slowly walk a certain amount of steps. This way the range of x- and y-values corresponding to a step taken could be identified. However, it quickly became apparent that the accelerometer sensor was extremely sensitive. The slightest movement could already have a large impact on the returned values of the sensor. To account for this, an additional function was written into the code. This function calculates a walking average for every 10 values returned by the accelerometer, and returns these averages as a new value. This was done for both the x- and y-values, so that the device also returns a smooth x- and y-value. The step detection prerequisites were then adapted to use the smooth values of x and y as input values, so that it made for a smoother and more accurate step counter. Even with these adaptations, it proved to be difficult to get a precise measurement of the number of steps taken by the test person. Ten tests were performed in which the test person was asked to slowly walk 100 steps, the results of these tests are presented in Table 1. As can be seen, the amount of steps measured differ from the actual amount of steps taken. The amount of steps measured have a calculated mean average of 99.9 steps. Due to time considerations, it was decided to not further invest time into making the step detection more accurate. However, further research and calibration might provide for more accuracy. During the Evaluation phase, the accuracy of the step counter will be statistically tested.

Test number	Amount of steps taken	Amount of steps measured
1	100	97
2	100	98
3	100	105
4	100	96
5	100	104
6	100	98
7	100	98
8	100	102
9	100	104
10	100	97

TABLE 1. ACCELEROMETER CALIBRATION TEST RESULTS

After the accelerometer code for step detection was calibrated, the code was equipped with a function to calculate the travelled distance. This function takes the value returned from the step counter and multiplies it by the step length to calculate this distance. In order for this function to work, an average step length of the user is needed. Articles by

both Lindemann et al. (2008) and Hollman, McDade and Petersen (2011) mention step length in older adults with mobility issues. In both cases the average step length is mentioned to be approximately 60 centimetres. Therefore, in order for the code to return the distance travelled in meters, the value returned from the step counter is multiplied by 0.60.

After the accelerometer code had been completed, the calculated values were to be send to an external Android device via Bluetooth. The inbuilt SoftwareSerial library of the Arduino IDE allowed for this to happen. This library allows for Bluetooth modules to send their acquired data, without additional programming. This allowed for the Bluetooth module to transmit the acquired values of x, y, z, smooth x, smooth y, number of steps and distance in meters to be transmitted to an

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← HC-05	() 🌣	
X Acceleration:	723	
Y Acceleration:	647	
Z acceleration:	379	
Smooth X:	664	
Smooth Y:	664	
Steps:	70	
Distance (m):	42.00	
	B	

FIGURE 29. ARDUINO BLUETOOTH TERMINAL INTERFACE

external Android smartphone with the Arduino Bluetooth Terminal application installed. The resulting interface is presented in Figure 29. After this connection proved successful, the prototype was considered to be fully functional.

6.4 Conclusion

The design solution specified in the Specification phase has been realized. Firstly, the electronic components were integrated into a single device. Secondly, this device was integrated into a 3D-printed case which was then embedded onto a calf brace via a cotton sachet. The resulting device was programmed to measure and calculate the data from the user and transmit it via Bluetooth to an Android device. The Android device, with the Arduino Bluetooth Terminal application installed, is able to receive and present the acquired data. The fully functional prototype will be evaluated in the following Evaluation phase.

VII - Evaluation

In the following chapter, the functional prototype will be evaluated. Firstly, the evaluation plan will be described. Secondly, the results of the evaluation tests will be presented. Thirdly, a conclusion concerning the course of the evaluation tests will be given.

7.1 Evaluation plan

In order to evaluate the prototype, it will be assessed on whether it meets the product requirements stated in chapter 4.5, of which the refined requirement #4 is stated in chapter 4.8. Requirement #1 can be tested on the accuracy of the step counter. The calibration results presented in Table 1 will be used for this. A statistical T-test will be used to determine if there is a statistically significant difference between the average number of steps taken and the average number of steps measured. Requirement #2 to #8 can be evaluated on end-users, since all these requirements are mostly related to the user experience of the prototype. Requirement #2, #3 and #6 involve the user experience of the therapists, so these will be evaluated on them. Requirement #4, #5 and #8 involve the user experience of the patients, so these will be evaluated on them. However, since some requirements can be considered to have overlap with patients and therapists, they will be evaluated on both users. Since the 'Could have' requirement #7 has not been implemented in the prototype, this will not be evaluated. Before starting the evaluation tests, the users will be asked to sing an Informed Consent form, which can be seen in Appendix C. Note that the form is in Dutch, since all participants will be of Dutch nationality. This form is meant to give full disclosure about the tests to the users, so that they can voluntarily provide informed consent to participate in the tests. Additionally, they give permission to possibly be photographed during the tests. The tests will take place in the context environment of the users, which is the residential care complex Het Borsthuis in Hengelo. This is the same location as where the initial observations and interviews with the users were held. During the test, the therapists will be asked to use the prototype. This means that they will have to attach the prototype to the leg of a patient, after which the patients will perform their regular activities with the therapists. If possible, the patients will also be asked to walk around

and act as usual whilst wearing the prototype. The therapists will then have to use the Android application on a provided Android smartphone to perceive the data acquired from the patients. The therapists will then have to detach the prototype from the leg of the patient, which will mark the end of the test. The number of participants, for both therapists and patients, will depend on the available staff and wellbeing of the available patients. After a test has been completed, the therapists and the patients will be asked to fill in their respective questionnaires, which contain questions concerning their user experience involving the respective product requirements. These questionnaires can be seen in Appendix D. Note that the questionnaires are in Dutch, since all participants will be of Dutch nationality. To be able to evaluate the results of the questionnaires, the System Usability Scale (SUS), as stated by Brooke (1996), will be used. Using the SUS, the questionnaires will contain statements about certain user experience aspects. The users will then have to rate these statements on a scale of 1 to 5, with 1 being low and 5 being high. The resulting scores will be configured using the SUS-associated formula, so that the result will be a score ranging from 0 to 100. This score is not a percentage, but a clear way of visualizing the score. A score of 68 is considered to be average, whilst a score below 68 is considered to be below average.

7.2 Evaluation results

7.2.1 Step counter evaluation

Firstly, product requirement #1 has been evaluated using a two-tailed one sample Ttest. The values presented in Table 1 have been used for this. The null hypothesis H_0 of the test stated that there is no statistically significant difference between the average number of steps taken and the average number of steps measured. The alternate hypothesis H_a stated that there is a statistically significant difference. The 6 steps of the T-test and its results can be seen in the following.

- 1. $H_0 = 0$
- 2. $H_a \neq 0$
- 3. Sample mean $\bar{x} = 99.9$ Population mean $\mu = 100$ Sample standard deviation s = 3.45

Observations n = 10

- 4. T-value t = $(\bar{x} \mu)/(s/\sqrt{n}) = -0.0918$
- 5. Consulting the t-table at alpha level 1%, with the degrees of freedom being n 1 =
 9, the resulting two-tailed critical t-value equals 3.250
- 6. Since the calculated t-value t = -0.0918 falls within the critical t-value range of -3.250 to 3.250, the null hypothesis H₀ is not rejected.

This means that with 99% confidence, it can be said that there is no statistically significant difference between the average number of steps taken and the average number of steps measured. Conclusively, the step counter can be considered to be accurate.

7.2.2 User experience evaluation

On 26 June 2019, the user experience evaluation tests with therapists and patients were conducted at residential care complex Het Borsthuis in Hengelo. The evaluation tests were conducted as described in chapter 7.1. The questionnaires, presented in Appendix D, were used to evaluate the user experience concerning the involved product requirements. For the therapists, n = 2 participants were available for testing and answering their respective questionnaire. For the patients, n = 5 participants were available for testing and answering their respective questionnaire. In Figure 30, a patient can be seen wearing the prototype.



FIGURE 30. PATIENT WEARING PROTOTYPE

The raw results of the questionnaires are presented in Table 1 and Table 2. In Table 1, the raw results of the patients can be seen. In Table 2, the raw results of the therapists can be seen. The intersecting numbers are the scores, between 1 and 5, that a patient or therapist gave to the corresponding question in their questionnaire.

Question	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
number					
1	5	4	4	4	5
2	1	1	2	1	2
3	5	4	4	5	5
4	2	2	2	1	1
5	5	4	4	5	5
6	1	2	2	2	1
7	5	5	4	5	4
8	2	1	1	1	2

TABLE 2. RAW QUESTIONNAIRE RESULTS PATIENTS

Question number	Therapist 1	Therapist 2
1	4	5
2	2	1
3	5	5
4	1	2
5	4	5
6	1	2
7	5	5
8	1	1

TABLE 3. RAW QUESTIONNAIRE RESULTS THERAPISTS

After applying the SUS formula to these scores, resulting scores from 1 to 100 are created. These scores can be seen in Table 4.

Test person	Resulting score
Patient 1	75
Patient 2	67.5
Patient 3	62.5
Patient 4	75
Patient 5	72.5
Therapist 1	72.5
Therapist 2	75

TABLE 4. RESULTING SUS SCORES

As stated in chapter 7.1, a score of 68 is considered to be average. As can be calculated from the data in Table 4, the overall system usability score for the patients has a mean value of 70.5 out of 100. This means that on average, the prototype delivers an above average usability score for the patients. It is notable however, that for 2 out of 5 patients the score fell slightly below 68, meaning that they rated the overall usability of the prototype below average. The overall system usability score for the therapists has a mean value of 72.25, which means the usability of the prototype scored above average for the therapists. For both patients and therapists, it is notable that if more participants had been available for testing, the results might have been more divergent.

Moreover, from the raw results of the questionnaires certain notable aspects can be deducted. Question 1, 3, 5, 6 and 7 of the patient questionnaire relate to product requirement #5, concerning the comfort and safety of the patients. As can be seen in Table 2, these question yielded positive scores from the patients, with the scores being above the average score of 3 (in which a 1 in the even numbered questions indicates a high score). The prototype can be considered to provide comfort and safety to the patients. Question 2 of the patient questionnaire relates to the 'Won't have' product requirement #8, concerning the interaction between the prototype and the patients. As can be seen in Table 2, this question yielded positive results, again with the score being above the average score of 3. The prototype can be considered to not have elaborate interaction with the patients. Question 4 and 8 of the patients questionnaire relate to requirement #4, concerning the stigmatizing feeling of having to be electronically tracked. Again, with the score being above the average score of 3, the prototype can be considered not to give the patients a stigmatizing feeling of having to be electronically tracked. The therapist questionnaire focussed on requirement #2 concerning the presentation of the data, requirement #3 concerning the attachability of the prototype onto the patient's leg and requirement #6 concerning the size adaptability of the prototype. As can be seen in Table 3, these score resulted above the average score of 3 (in which a 1 in the even numbered questions again indicates a high score). The prototype can be considered to meet these product requirements.

7.3 Conclusion

The prototype has been evaluated to test whether it meets the specified product requirements. The reliability of the step counter has been statistically evaluated, which concluded that the prototype delivers reliable and accurate data. The remaining product requirements were evaluated in user tests with actual end-users. These user tests resulted in positive scores using the System Usability Scale. The prototype proved to be successful in providing a positive user experience and in meeting the product requirements.

VIII - Discussion

There are certain aspects concerning the project, the created prototype and its evaluation that provide room for discussion. Firstly, the evaluation can be discussed. During the evaluation tests of the prototype, a relatively low amount of test participants was available, with five patients and two physical therapists participating. The evaluation tests yielded a set of results regarding the prototype. However, had there been a larger group of participants, these results might have been more divergent. Additionally, having a larger group of participants can provide for more reliable results since it allows for a larger indication on the opinions of the target end-user group.

Another aspect that can be discussed is the size of the prototype. Ideally, the device would have been smaller in size compared to the created prototype. If the device were smaller, it would be less visible to the patients, which could result in a better user experience result. They could have a lesser feeling of being tracked. However, due to budget considerations, the components used for the prototype result in a relatively large device. Smaller components would have been too expensive to realize.

A third aspect to be considered is the design process of the project and how this could have alterations in possible future work. The prototype has now been designed as a device that is somewhat universal for all elderly hip fracture patients. However, it could be further personalized to better the user experience of each patient. For example, female and male patients have a slightly different set of possible garments in which the device could be embedded. For possible future work, research could be conducted to identify a better possible garment, for female and male patients separately, in which the device could be embedded. This could result in a better user experience.

IX – Conclusion

To answer the research question: "How can a smart wearable be designed to monitor the rehabilitation of elderly hip fracture patients?", particular aspects related to user experience need to be taken into account. To monitor the rehabilitation of elderly hip fracture patients, the activity of their legs is monitored. These patients have needs, goals and motivations that yield a set of product requirements for a design solution. The comfort, safety and feelings of the patients need to be considered during the design process. Additionally, the needs, goals and motivations of the physical therapists need to be taken into consideration. To successfully design a smart wearable to monitor the rehabilitation of elderly hip fracture patients, these user experience requirements need to be considered and met by the created device.

The created prototype proved to be successful in meeting the identified product requirements. It yielded positive user experience results and showed to be adequate in monitoring the rehabilitation of elderly hip fracture patients. However, possible future research might result in an improved design solution which can provide improved user experience results.

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Appendices

Appendix A - Personas & Scenarios

Sarah - Patient

Sarah is a 75-year-old retired woman living in Almelo, the Netherlands. Her husband passed away a couple of years ago and she has had to get by on her own ever since. She has two children who occasionally help her out with certain errands, but since they have children of their own, they are often too preoccupied to help. Sarah is aware of the importance of regular physical activity, so she tries to take a long walk every day in the park close to her house. She likes to be able to get around and enjoy the outside air, however, due to her age she often has to take it easy and rest inside her house. Her children have made sure that her house is equipped with technology that helps her get around the house, but she does not really use it much since she feels unaccustomed to all these technological devices.

Two weeks ago, Sarah decided not to use the stairlift to get down the stairs in her house. Upon reaching the second to last step, Sarah slipped and hit the ground with the side of her body. She was unable to get up by herself. Luckily, she knew where the nearest emergency button in her house was located, so she informed the emergency services. She was taken to the nearest hospital, where she was diagnosed with a hip fracture. Surgery was needed as soon as possible, so she was operated on within 24 hours. Four days later she was discharged from hospital and admitted to a rehabilitation centre in Hengelo. Every day, she has to perform certain exercises with her therapist to regain full functionality. She appreciates the efforts made by her therapists, but she does not like being in the rehabilitation centre and would like to return home as quickly as possible. She was told to keep moving even when the therapist is not there. She tries to do this, but she sometimes also skips it because she feels that it is a bit much and she does not feel as confident as when her therapist is assisting her. She just got a new walker with which she can walk around the rehabilitation centre. This gives her a little more freedom, which makes her slightly more cheerful and gives her some more courage to perform her individual exercises. She would like to successfully recover and return home knowing that she is able to return to her normal way of life.

Barbara – Therapist

Barbara is a 42-year-old physical therapist living in Hengelo, the Netherlands. When she was still in high school, she was already interested in the functioning of the human body, but she was not sure what to study. She realized that she enjoyed helping people who are in need of help, so she decided physiotherapy was a great direction for her. After having completed her study, she went to work at a rehabilitation centre in Hengelo, where she has now been working for 20 years.

Every day she has a certain set of hip fracture patients whom she sees for their scheduled physical exercises. She often has to work with patients who are cognitively impaired, or who have other age-related complications. Barbara always remains patient and motivated to help her patients reach their goal of functional recovery. All her patients receive a set of exercises that they can perform when she is not there. She believes that most of them perform those exercises, however, it is hard for her to know for certain which patient performed how many exercises. Barbara wishes to have a full understanding of the physical wellbeing and recovery of her patients. She desires to be able to track the actual activity of her patients when she is not around, to get a clear overview of her patients' progress. This way she can better assess the overall rehabilitation process of her patients and adjust the amount and variety of exercises for each individual patient. She hopes that this way she can be able to offer her patients a quicker and less inconvenient rehabilitation process.

Scenario

After Sarah broke her hip two weeks ago, she has had surgery and has been placed in a rehabilitation centre in Hengelo. She has been assigned to a physical therapist, Barbara, who is helping her during her rehabilitation process. Every morning Sarah wakes up and gets to eat breakfast with other patients in the dining hall. She is first assisted out of her bed and into her wheelchair, after which she is escorted to the dining hall. After having eaten breakfast, she meets up with Barbara in the exercise room to perform certain physical exercises. These exercises include raising the legs in multiple directions, walking with assistance and squatting. Barbara assists Sarah when necessary, but the overall goal is for Sarah to be able to do it by herself. When the leg exercises are done, they practice for Sarah to get in and out of bed by herself. After having completed the exercises, Sarah gets escorted to her bed again to rest. Later in the afternoon, after

having lunch, Sarah is given a walker to replace the wheelchair. Now she can walk around the rehabilitation centre by herself, giving her more freedom and allowing for more physical activity. When Barbara has to go see other patients, she gives Sarah a set of exercises which she can perform in the absence of Barbara. These exercises are mostly leg exercises. After Barbara has left, Sarah feels tired and rests some more. She then performs some of Barbara's exercises. She does not feel as confident as when Barbara assists her and thus does not complete the full set of exercises. Sarah feels a bit bad about not completing the exercises, but she does not dare to risk anything, even though she knows that it can shorten her stay at the rehabilitation centre. After having had dinner, Sarah has some interaction with the other patients until she feels tired and is escorted to her bed again.

Appendix B – Arduino Code

```
/*
```

Accelerometer with Bluetooth output

Reads x, y and z values from accelerometer, makes for smoother x and y values, determines whether a step is taken and calculates distance in meters. All the values are send via Bluetooth to an available Bluetooth device.

```
created 14 June 2019
by Thijs van Vliet
modified 16 June 2019
by Thijs van Vliet
```

```
Inspired by and adapted from:
https://www.youtube.com/watch?v=vTz6oJrhqpM&t=38s
https://www.arduino.cc/en/Tutorial/Smoothing
*/
```

#include <SoftwareSerial.h>

SoftwareSerial MySerial(10,11); //pin 10 connects to TX of Bluetooth module, pin 11 to RX of Bluetooth module

```
int x, y, z, smoothx, smoothy;
int steps = 0;
float distance;
int temp = 0;
const int Sleep = 2;
```

```
const int numReadings = 13;
int readings[numReadings];
int readIndex = 0;
int total = 0;
int average = 0;
```

```
void setup() {
    MySerial.begin(9600);
    pinMode(Sleep, OUTPUT);
    digitalWrite(Sleep, HIGH); //Turn on accelerometer
```

```
for (int thisReading = 0; thisReading < numReadings; thisReading++)
{readings[thisReading] = 0;}</pre>
```

}

```
void loop() {
    x = analogRead(A0); //Read x,y and z values from accelerometer
    y = analogRead(A1);
    z = analogRead(A2);
    smoothx = xSmooth();
    smoothy = ySmooth();
```

```
//Calibrate the step detection using the moving average of the x and y acceleration
//Very difficult to get an accurate step detection
if ( smoothx >= 678 && smoothx <= 700 && smoothy >= 690 && smoothy <= 710)
{ temp++; }</pre>
```

```
if (smoothx < 678 || smoothx > 700 && smoothy < 690 || smoothy > 705) { temp = 0; }
```

if (temp >=2) { steps++; }

distance = steps * 0.6; // Elderly step size is on average 60cm.

```
MySerial.print(x);
                       //Send all values via Bluetooth module to connected device
MySerial.print(",");
MySerial.print(y);
MySerial.print(",");
MySerial.print(z);
MySerial.print(",");
MySerial.print(smoothx);
MySerial.print(",");
MySerial.print(smoothy);
MySerial.print(",");
MySerial.print(steps);
MySerial.print(",");
MySerial.print(distance);
MySerial.print(";");
delay(150);
}
//Return a walking average for the x acceleration to create smoother data
int xSmooth(){
 total = total - readings[readIndex];
 readings[readIndex] = analogRead(A0);
 total = total + readings[readIndex];
 readIndex = readIndex + 1;
 if (readIndex >= numReadings)
  {readIndex = 0;}
 average = total / numReadings;
 delay(1);
 return average;
}
//Return a walking average for the y acceleration to create smoother data
int ySmooth(){
 total = total - readings[readIndex];
 readings[readIndex] = analogRead(A1);
 total = total + readings[readIndex];
 readIndex = readIndex + 1;
 if (readIndex >= numReadings)
  {readIndex = 0;}
 average = total / numReadings;
 delay(1);
return average;
}
```

Appendix C – Informed Consent Form

Studie administrator: _____

Deelnemer naam:

Deelnemer nummer: _____

Het doel van deze studie is het evalueren van een prototype dat is ontworpen om de fysieke activiteit van heupfractuur patiënten te meten. Het prototype zal worden getest op functionaliteit, gebruiksgemak en gebruikerservaring. Het uiteindelijke doel van het project is om meer inzicht te geven in de voortgang van heupfractuur patiënten tijdens hun rehabilitatie. Uw deelname aan deze studie zal ons helpen dit doel te bereiken.

Tijdens deze studie zal u gebruik maken van een werkend prototype onder toezicht van een studie administrator. De studie zal ongeveer 15 minuten bedragen, waarna u gevraagd zult worden een enquête in te vullen over uw ervaring met het prototype.

Het kan zijn dat er foto's van u gemaakt zullen worden tijdens de studie. Deze foto's, samen met al de van u verkregen informatie, zal alleen gebruikt worden voor de doeleinden van dit project. De verkregen informatie zal verwerkt en gedocumenteerd worden, waarna het gepubliceerd kan worden. Alle gedocumenteerde informatie zal compleet anoniem en vertrouwelijk blijven.

Deze studie is bedoeld om het systeem te verbeteren en zo dichter bij het uiteindelijke doel van het project te komen. Het is niet bedoeld om u op welke manier dan ook te analyseren. Mocht u zich tijdens de studie niet comfortabel voelen, dan mag u aangeven te willen stoppen met de studie wanneer u wilt.

Verklaring van geïnformeerde toestemming

Ik heb de omschrijving van de studie gelezen en ik ben bewust van mijn rol en rechten als deelnemer. Ik doe vrijwillig mee aan de studie.

Handtekening: _____

Datum: _____

Appendix D – Questionnaires

Therapist Questionnaire

Erg mee Erg mee oneens eens **1.** Het apparaat was makkelijk te gebruiken. 2. Ik had hulp nodig bij het gebruiken van het apparaat. **3.** De manier waarop de data werd laten zien was toegankelijk. 4. De data was irrelevant en onduidelijk. 5. Het apparaat was makkelijk aan en uit te trekken bij de patiënten. 6. Het was onduidelijk hoe het apparaat aangetrokken moest worden door de patiënten. 7. Het apparaat paste goed op verschillende maten enkels van patiënten. 8. Ik moest veel dingen leren voordat ik het apparaat goed kon gebruiken.

Patient Questionnaire

