



PROCESS REPORT

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Title page



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Abstract

Preface

The purpose of this project is to research, find, analyze and create a solution for a design problem within a post- stroke condition area. Based on the data gathering and research it was found out that patients affected by stroke suffer from post stroke problems in upper body such as arm immobility, inactive muscles, muscular atrophy, and torso collapsing, chronic back pain. These problems affect the overall performance in daily life and lead to decrease of life standards. These findings led to the research and market analysis of how are these post-stroke problems curretnly solved, which resulted in finding out a gap in the market. Therefore an opportunity for a new product emerged. To solve the patients problems, the areas of FES stimulation and body suits are investigated and tested. The process of development of the device is based on the design thinking, where concepts of FES unit, suit pads and bands are created, tested and evaluated. The result of the development process is a compact, intuitive design solution of a product that will help the stroke patients regain the muscle strenght in upper body, correct the posture, avoiding loosening of body while training, and monitor life functions. The device would help the patients from stage 1-4, whereas it can be used with or without the supervision of rehabilitation staff. The device is a personal medical equipment designated for rehabilitation training sessions, municipality training, ADL training and home wearing. The device is expected to solve the most common upper body problems, that current medical equipment fails to solve. The device is expected to cover the gap in the market, since the rehabilitation centers seek for product that yet do not exist, but is necessary to be developed.

The project was developed as final project for 10. semester of education program Industrial Design at Aalborg University. The project begun 1. February and ended 15. of August 2018. The result of the project is a Process report, Product report and Technical folder.

The project was developed based on the data gathering in the initial phase-from February until April. During this phase the key data were gathered, therefore the project group would like to thank Allan Lu for his contribution in finiding the area and topic data gathering (page 14-20). Furthermore, the group would like to express gratitude to the main supervisor Thomas Arvid Jaeger and co-supervisor Ewa Kristiansen for their valid inputs and advices during overall project duration.

Furthermore, the group would like to thank following:

- Wellfare center Aalborg
- VR Rehab Aalborg
- Brønderslev Rehabilitation center

Reading guide

The project consist of 3 main documents- Process Report, Product report and Technical folder. It is recommended first, to read the Product report to see the final product, its functions and properties. Then it is recommended to read the Process report to see how was the project developed over the 5 months period. The process report consists of four main chapters-Focus area, Concepts development, Product development and Business. In the begining of each chapter, there is a flowchart which briefly explains the sequence of further analysed information.

In the end of the report (page 62-65) are located the requirements for the final product. These requirements were being found during the whole process. The requirements are based on the findings and are labeled with an icon. These are distributed all over the Process report according to the phase, where they were found.

After reading the Process report, it is recommended to read the Technical folder to understand the technical details of the final product.

Requirement finding icon:



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FOCUS AREA

METHODS:

RESEARCH

INTERVIEW



INTERPRETED CUSTOMER NEED





The process of gathering the information in different ways from trustworthy sources. This involves desktop research or field studies. Then the results are documented and refined.

Interviews are used to gather the information from different sources that are related to the topic. It may include users, stakeholders or academic profesionals.



Framing is a continuous process throughout the whole project. It serves to corrdinate the coming information and data gathered during the research and development phase. This methos helps in overall understanding of the problem scope and the focus area.



This method serves to identify and specify the needs and requirements collected during the interviews and analysis of the data. These are dicussed and selected based on the frame of the problem.

STAKEHOLDER MAPPING



Stakeholders are mapped and identified in order to get a better understanding of the user and end customer. The requirements are aimed to satisfiy the stakeholders expectations.

Focus area flowchart:



INTRODUCTION: STROKE

Brain is the body organ that requires a constant source of a blood flow, that transports the most important supplies- oxygen and sugar. If the supply is inhibited, the brain is not able to perform its function [2]. Stroke is a clinical diagnosis concerning a brain blood supply blockage. The blockage of the blood flow results in damaged cells in a specific brain area, which is consequently reflected in stroke symptoms such as numbness, weakness, involuntary movements, aphasia and more [5]. This cardio-vascular condition is characterized as a brain injury, that a person experience as a sudden shock by being struck [2]. Stroke can be devided in two main types- Ischaemic and Hemorragic. Ischaemic stroke is caused by a blockage that cuts off the blood flow in the brain. The blockage is aresult of a clot in an artery leading to the brain or vessel in the brain. The clot causes the restriction of a blood supply and thereby the oxigen does not get to the designated areas. Thereby the brain presents a deficiency of nurishemnts transported in the blood. The Hemorragic stroke is characterized by

the rupture of a blood vessel in or above the surface of the brain. Because the blood leakage in the brain, and bleeding into the skull occurs. This type of stroke reffers to a redundance of a blood within the brain [2]. Both types of strokes results in not proper functioning of the brain and thereby consequences are present. The main 5 skills are influenced depending on the severness of the stroke and area of the brain that was affected. The 5 skills are Mobility, Motor skills, Speech and Communication, Perception, Memory and Thinking. A patient can suffer from several function disabilities, while some of them can be gained back, some endure for long period of time, others can not be restored. The most common consequences after the stroke involves physical disfunctions in arms and legs, weakness, loss of corrdination or sensory malfunctions [2]. The cognitive abilities of a stroke patients might be affected at the same time as the physical disabilities are present. Thereby a patient can lose orientation senses, jugment, memory or undercome personality changes.



III. 1-Two types of stroke

III. 2- Human brain

5 abilities:

MOBILITY



Mobility is the ability of freely move the body in desired direction without any internal obstacles. The mobility activity affected by the stroke decreases and results in spasmatic movements, partial or overall paralysis, that may emerge to be permanent. Mobility is performed with a foundation of group of muscles that join to execute a concrete movement. To perserve the mobility of the body at functional level, the muscle group needs to be kept in a passive-active status.

Motor skills are defined as a ability to operate the single fine movements in order to carry out accurate and precise practical tasks. Motor skills include the movement of smaller muscle groups as in hands and feet, that a person exhibits in synchronization and complex control

MOTOR SKILLS



SPEECH AND COMMUNICATION



Verbal communication serves as a tool for sharing information. 50% percent of stroke patients suffer from speech problems. The incapability of expression, talking, comprehension or problems in leading a conversation is called Aphasia. Speech problems occures due to the impairments in the brain and therefore the patients are not able to formulate or articulate. Aphasia also influences visual language, writing, auditory comprehension and can possibly lead to a complete paralysis of speech muscles. To treat the disorder, the patients currently use SCA method, which is a technique to ease and train the speech and communication.

MEMORY AND THINKING



Failing in memory and thinking is a result of coginitive imapirment in the brain. When a patient's memory and thinking is perturbed, he can no recall memories or remeber things correctly. There comes a lot to misunderstanding of the different realities or difficulties in problem solving can appear. He can overestimate himself and consequently ijnure himslef, thereby a constant presence of a third person is needed.

PERCEPTION



Recognition and understanding of the world around. It is the ability to see and hear, generally being aware of the surrounding. Perception is closely connecte to the nervous and sesnory system. When the brain is affected by stroke, the perception of a patient changes and he is not able to recognize the information that was previously comprehended. The behaviour and even personality in the stroke patients can be changed to a level when the patient perception of life is not coherent anymore.

Stroke facts- Cardiovascular

disease figures (CVD)

• CVD is responsible for 3.9 million deaths in Europe [1].

of action.

- 45% of all deaths in Europe and 37% of all deaths in the EU are assigned to CVD [1].
- CVD costs €210 billion a year the economy of European Union [1].
- Every 45 sec. a stroke occures, and every 3.1 min., someone dies because of a stroke [2].

A stroke is a medical emergency that effects primary neurological functions and may cause advancedhealth complications and consequently death. Stroke is of major importance for public health internationally, as it is the second most common cause of death globally and is a major cause of disability worldwide. The number of strokes in Denmark alone is around 15.000 a year. Stroke victims cost the government 2.030 mio. kr. in treatment and nursing.

Stroke Rehablitation Progressive delvelopment



III. 3- Stroke stages

Treatment

Treatment of patients depends on the type of the stroke and the area of the damaged brain cells [2]. Medical and surgerical methods are used to treat the stroke survivors, however the stroke condition has a progressive development, thereby the time and patience is needed to recover. The Hemorragic and Ischeic stroke have different timing, structure and degrees of recovery. For example, in the case of Ischemic stroke , the blood flow needs to be radically increased [2]. Generally, most of the stroke patients are recommended to participate in rehabilitation. The goal of rehabilitation is to help the patients to return as close as possible to normal life and regular activities. The rehabilitation process consists of four stages, through which the patients goes, while recovering.

Four stages of the stroke:

1. stage- Acute treatment: In the first stage of a stroke, the patient gets right away the treatment for the emergency accident and is diagnosed the severeness of the stroke. The patient is under strict control in the hospital to ensure the intense care. After establishing the patient's vital functions and primary cognitive and physical skills, a proper rehabilitation plan is designed for the patient.

2. stage- Rehabilitation under hospitalization: If the patient needs a rehabilitation during hospitalization, the hospital will, depending on the needs of the person, rehabilitate at the main function level, regional level or highly specialized level. The hospital plans a rehabilitation plan within the hospital region. The patient has established the basic functions and is ready to participate in the active rehabilitation process.

3. stage- Rehabilitation after discharge: It is essential that the hospital, municipality and general practicioners cooperate on the overall rehabilitation process. The patient lives at home and he participates in the rehabilitation sessions in the municipality. In this stage the patient gets less monitored by hospital and more dependent on his relatives and himslef.

4. stage- Stable maintanance: The patient is stable and he is able to train by himself. He can still participate in the rehabilitation process, though there is involved more independency. In this stage, the relatives present a big role for the patient as a moral support. The patient does not recover to the status as before the stroke, however there is a high chance to reach a good life standards.

TREATMENT IN DENMARK

Stroke patient rehabilitation process						
	stage 1	stage 2	stage 3	stage 4		
Hospital	X	X				
Hammel		X				
Bronderslev		X	Х			
Hobro/ Frederkishavn			х			
Municipality/Home			Х	Х		



Table 1- Stroke patient rehabilitation process

Life after stroke

A person's life can be changed a lot after a stroke incident. All stroke victims goes through changes that affect their daily life. These changes can be hard for the patient, especially in the early stage, as the symptoms are most severe right after the stroke. This makes it hard for the patient to see the future without the consequences. However, there is hope to recover and get back to the lost life standards the person once had. After stroke not only the patient

is involved, but also family and friends can feel misplaced and unsure how they can help and ease the rehabilitation process of the patient. However, majority of stroke patients are able to return back to their lives and regain lost phyical and cognitive functions [2].

MOBILITY

Finding a tangible problem

The Mobility is one of the most affected abilities at the post-stroke conditions. Thefore the rehabilitation centers focuses on the training and recovery of physical abilities by creating a special conditions for the patients. The mobility is trained on daily basis and covers rehabilitation of limbs, corpse and body balance.

VISIT AT BRONDERSLEV REHABILITATION CENTER

Bronderslev rehabilitation center is a residential hospital, that recieves patients from all over the northern Jutland for shorter or longer period of time. The purpose of the stay at Brønderslev Neurorehabilitation Center is to rehabilitate and compensate for the physical, psychological and social functions lost due to the brain injury, such as stroke. The goal at the center is to get the patients to former life as close as possible. Bronderslev Rehabilitation Center provides daily care, treatment and training for the resident patients by ensuring complete continuity of hospitalization and rehabilitation [7].

Who treats and takes care of the patient during the rehabilitation phase?

- Nurses -takes care of health condition, such as daily regimes, pain and diets
- Physiotherapists -works with the patients mobility, movement and muscles analysis.
- Occupational -works with patient's daily problems and is responsible for ADL (activities of daily living)



III. 4- Helle photo

Helle

Helle is a Occupational therapis and head of the research and development department at Brønderslev rehabilitation center.



III. 5- Carina photo

Carina

Carina is a Physiotherapist and head of the arm training session at Brønderslev rehabilitation center.

"We have a big need for a product for stroke patients that would support their upper body and work properly. There isn't anything on the market that we can use. "

"Stroke patients life is affected on the level of everday activities and basic daily routines. It is a long process to get them back, where they were before. Anything that would ease and accelerate that process would be very useful. "

The rehabilitation is individually adapted and takes place in close cooperation between the patient and the staff. The training sessions takes 5-6 times a week for a duration of 1 hour. After the discharge patients should continue with the training for 2-3 times weekly. The rehabilitation staff makes 3 weeks overview plan for each patient and 1 week plans are made for specific part of the body to be trained. The plan contains usually 3 goals. The training sessions are formed to reestablish patient's physicall abilities and retrieve the muscle memory.

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Participation in the arm training session

In the arm traning session at Brønderslev, 4 patients were observed performing variety of exercises focused on the upper body. Each patient was adressed individually having his proper equipment, exercise set-up and pace. Generally the patients have one common goal- to be able to move and use their arm again. To achieve that goal, the body position is set-up first. The training sessions are dynamical, as every week the patients tends to make a improvement and the level of the work out rises until the patients are released for home care.

POSTURE CORRECTION

The starting point for performing the rehabilitation exericses properly, a correct body posture needs to be established. The body of a stroke patient is loose and tends to lean or drop. The body position needs to be rebuild, as the muscles don't know where they belong and how to maintain an upright pose. The correct body position is very important since the patient adopts certain body behaviour and keeps it for the rest of the life. In the Brønderslev rehabilitation ceneter single stripes are used to guide the patients posture and attitude towards not collapsing in holding the body upright. The patients are guided to maintain straight back either by themselves or are being helped with a customized tools.



Ill. 6- Rehabilitation training



III. 7- Rehabilitation training

TRAINING TOOLS

When the correct body position is established, different exercises take place,.The exercises are designed to reestablish the patients muscle strtucture and initiate the movement of upper body. Patients use baloons, balls, straws, wooden sticks or boxes of milk to perform extension, rotation or twist of the arm. The variety of exercises leads to full performance of 3 basic movement- shoulder flexion, external rotation and elbow extension. During these exercises, customized tools are used to train the basic movements. The tool needs to be easy to understand in usage and also very intuitive for the patient. The therapist makes several rounds in the team and corrects the patients position and performance.



III. 8- Patient training



Ill. 10- Patient training



Ill. 9- Patient training



Ill. 11- Patient training

Post-stroke problems that patients are suffering from:

- Arm immobility
- Upper body muscles inactivity
- Dead arm syndrome
- Loose upper body and back
- Ligament shortgage
- Muscular atrophy
- Chronic back pain
- Torso collapsion

TRAINING EXERCISES

When reaching for a object a person executes a group of upper body movements called Reaching phase. Reaching phase is consisted of three sub-phases: Transport phase, Pre-shaping phase and Grasp phase. These are the most trained movements at the rehabilitation centers as it forms a basis for any complex movements that a patient would to execute in higher level of recovery. Transport phase is a action of movements composed of 3 dispacements of the arm. Transport movement is represented by a trajectory of the arm from point A to point B. Essential movement components consist of shoulder flexion, elbow flexion and external rotation for moving the arm towards a certain object. During the action of transport phase, not only arm is moving, but also trunk displacement is performed [6].

ļ

Not being able to paticipate in life

Not performing in ADL (activities of

Failing in municipality and home

daily living)

Lost of life standard

training

Muscles trained while performing Transport phase:

External rotation: Shoulder flexion: Elbow flexion: Infraspinatus, Supraspinatus, Teres minor, Posterior deltoid, Anterior deltoid, Pectoralis major and minor, Coracobrachialis, Biceps brachii Biceps brachii, Brachialis, Triceps brachii, Brachioradialis



III. 12- Training exercises

ACTIVITIES OF DAILY LIVING

The ADL are activities of daily living that are the most common actions a person does during a day. These are trained at rehabilitation centers to simulate the variety of activities that a person would do real life. The rehbilitation centers assesses the patients based on their performance at ADL. Depending on the scores, the patient is continually given harder taskes and more challenging goals, unitl released from the hospitalization.

Stroke patients may be affected in very different ways, so they might not recognize what is right, wrong or what to do when encountered in a certain situation.For example when a patient gets clothes, he might not now what to do with it or how to put it on. Thereby in the rehabilitation centers the ADLs are trained to help them understanfd the world around and tackle everday situations the patient might encounter in. The most commonly trained ADLs at rehabilitation centers:

- prepare and eat food
- reaching for objects
- put the clothes on
- brushing teeth
- sorting out groceries



Table 2- ADL

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MOBILITY

Finding a tangible problem



Mobility problems are not only sovled in classic rehabilitation centers, such as Bronderslev. Currently, the topic of stroke rehabilitation is stariting to merge with innovation and new technologies. The new approaches are looked into and new technologies are used in order to ease post-stroke traumas and make the rehabilitation more effective. One of the examples is VR Rehab.



Daniel Christiensen

Daniels Christiensen is a CEO of a newly established business VR Rehab that emerged from a university project. Their main focus is to treat patient's physical problems after stroke with a unique approach. They build a virtual reality software for rehabilitation. Currently, they are focuing on the stroke patients with immobility in upper body and training of ADL. They use their own developed software and are searching for an inhouse developed hardware.

"The patients are very keen to get better, especially, when they are motivated and encoureged."

III. 13- Daniel photo

VISIT AT VR REHAB

The VR Rehab platform treats patients on the municipality level- that means they train after the discharged from the hospitalization. The main contribution to the patients life is that they are getting into the every day life again. The training in VR Rehab is not a mandatory rehabilitation process, though it is highly recommended if the patient feels incompetent in mobility performance. The training is being hold as a group formation of around 10 patients and is composed of several activities and tasks that aim to regain the muscle memory and neuroplasticity. The training is based on the software and hardware equipment, where the patients wear VR glasses and is able to see a setting of a regular kitchen. The patients hold a pair of hand sesnors to be able to operate in the software, seen on the III 15.-17. His task is very concrete, such as sorting the groceris into the fridge or prepare a cup of coffee. This exercises has a goal to simulate the ADLs, so to patient challenges himslef and is able to repeat the tasks afterwards in the daily life. The key point for the patient to be able to get better is a very intuitive approach regarding the software. After each session the patients achievements are sum up and are compared with the previous scores and also with other patients, which creates a competitive motivational environment. According to Daniel motivation is an important factor for stroke patients as it drives them towards the progress. The patients wants to learn and be independent, they just need to be little encouraged.



III. 14- Daniel VR Rehab



III. 15- VR Rehab training

The VR rehabilitation is also clamied to increase the overall mobility and cognitive perception. The rehabilitation shows 12.4% of improvement in fine motor skills. Patients overcome the fears that may appear as a big barrier in real life. The software is therefore a safe space, where no mistake is seen as a failure. The physical position of the body is established and trained progressively until the patients regain the strength and are being able to participate in everday life.



III. 16- VR handles



III. 17-VR training



III. 18- VR training



Ill. 19- VR training

MARKET ANALYSIS

How are the upper body and arm post-stroke problems currently solved?

For mostly seeing the big need for a product for the upper body, the upper body devices were researched. Market analysis in the upper body area can vary as the consequent stroke effects often overlap and depend on each patients needs. Currenlty the market for post-stroke patients offers several soultions for a upper body and problems. The market analysis shows products most commonly used in the rehabilitation centers and for post-stroke patients in stable maintance phase. The products vary in focus on patient's problems and needs and also in functions and solution space.

ADL assistive device



provides comfort and security for patient



III. 20- ADL device

Ill. 21- ADL device

ADL assistive device is a complex machine composed of joints and springs to provide a arm support for a post-stroke patients in eating. The device comes in a form of a chair or adjustable to a table.

helps in the basic ADL- eating

not transportable (fixed to a selected place)
 complicated operating with the device

Active responsive arm training



III. 22- Responsive training

III. 23- Responsive training

10

Machines for active responsive training are designed to entertain the patient while training and thereby come to a better results and enjoy the exercise. It is designated to patients that suffer from major arm immobility. The training consist of robot assisted arm and a software training.



Shoulder supporter and arm holders



III. 24- Arm holder



Ill. 25- Arm holder



III. 26- Arm holder



III. 27- Arm holder

Arm supporters are used for the patients that suffer from dead arm or shoulder dislocation. The supporter is composed of two detechable sleves and bands to adjust for proper wearing comfort.



good for patients with complete immobility in arm and low chance of recuperation



does not actually hold the arm and shoulder in the desired position



good for early stage of post-stroke arm disfunction

Stimulation of inactive muscles



kick-start of the muscle movement

improves blood circulation

Exercise equipment



III. 30- Exercise tools



III. 31- Exercise tools

At the rehabilitation centers, the patiens uses various kinds of soft exercising tools ranging from balls, baloons to weights. The equipment offers wide possibilities for exercises, where patients selects the type of the tool his physical ablities allow to use.



the avalaibility of exercise variety



the avalaibility of tools variety

Posture correction



III. 34- Posture bands

III. 35- Posture bands

Posture correctors are used to strenghten the body position for the patients who's upper body tends to collapse. The cross form on the back side of the posture correctors allows the patients keep the back upright and shoulders are being pushed backwards.



the cross on the back impedes upright position

not every supporter works



Blue Ocean Canvas

The Blue Ocean strategy is a method used to measure the performance of chosen products on the market in certain area. The products are chosen based on fullfilling one goal or group of goals. These products are compared amongst each other by using key criteria. The blue ocean canvas tool shows the ability of a product to fulfill the criteria [4]. For this case, 6 products used in upper body stroke recovery were selected to measure its performance and see a possibility for developing a new product.



Table 3- Blue ocean canvas

The figure shows that each product perfroms differently for different criteria. Each product has its strenghts in one or two features, but does not cover globally the patient's most crutial pains. Therefore a blue ocean appears to be present. A possibility for a development of a new product is visible, so it could fullfill more criteria and cover more features.

STAKEHOLDERS

STROKE PATIENT

Stroke patients are very vulnerable, both physically and psychically after they suffer a stroke. They need a immediate support from the first stage and full atendance of doctors, nurses and rehabilitation staff. After they pass the accute state, they focus on recuperation and getting back to previous life. It can present a big challenge for the patient to encounter himself in the old enviroment, that he might not recognize. The life of a stroke patient is changed radically and the new life style is set up to reinteract with things the person has left behind. The rehabilitation starts to be the principal focus of the patient. He might feel isolated, too dependent and disencouraged. During the rehabilitation, the patients follow the exercises and routinesof the residential hospital. The patients learn to perform by themselves, though usually use a help of the caretaker. The patients would find usefull a product that would be developed specially for them and would aid them in the recovery process. They would also like to bond more with the family, since the stroke accident and rehabilitation isolates them from family members. The patients expressed a wish that it would be very encouraging to see their own progress. Currently, the data of the patients are accessed only by caretakers and the patient himslef does not have an overview.

FAMILY

The family of a stroke patient is a very much affected group of stakeholders. They might not be completely included in the recovery process, since the recovery is focuses primarly on the stroke patient himself. In the first stage of the stroke accident the family is informed about the patient's current situation, but the interaction between the stroke patient and family is scarce. It is the second and on ongoing stages, the patient and family interact more, though not as much as they would wish. The family's need is to reconnect with the patient on everday basis and know more about his status. They expressed a need to be part of the recovery process of the patient and monitor his progrees. They care about him more than ever and want to present every time it is possible.

REHABILITATION STAFF

Rehabilitation staff present a big role in the patients life, as they interact with patients on everyday basis. The patients might see the rehabilitation staff more often then family, as the rehabilitation staff knows how to tackle with casual patient's problems. The staff is needed while exercising, performing ADL or just being around, depending on the patient's condition. During the rehabilitation, the caretakers lead and help the patients to perfom correctly. The rehabilitation staff takes care not only of physical state of the patient, but also of pshychical state. That means that the patients are encouraged. Hoerever, this encouragemnet might not always work, as the patient needs to work on his own. On the physical level, the rehabilitation staff often has to correct the patients body and movement and assist them. They have confessed that they might find usefull to make the patient more independent and make him rely on himself. The rehabilitation staff would find handfull to have a device specially for stroke patient that would correct their body and guide them and help them in recovery. The rehabilitation staff would also like to have more acces to the patient, during the situations where they are not present. During the fourth stage, the patients are released from the supervision of caretaker and are no longer present at their everday life. The rehbailitation staff expressed a need to be able to monitor a patient, while the patients are at home alone and still vulnerable.

PROBLEM STATEMENT

HOW CAN WE DESIGN A COMPACT SOLUTION FOR POST-STROKE PATIENTS THAT WOULD HELP THEM REGAIN MUSCLE ACTIVITY IN UPPER BODY, ASSIST IN RETURNING INTO THE DAILY LIFE STANDARDS AND MONITOR PATIENT'S LIFE AFTER THE DISCHARGE?

CONCEPT DEVELOPMENT

METHODS:

SKETCHING

STIMUL





Sketching serves as a tool for visualisation of ideas and helps in the communication when working witin the ideation process. It also provides a wider range of diferent ideas that can be thought upon.

Pictures, photos and objects stimulate the creative process to help covering the framing area. It is used to create more solutions for a concrete problem scope.



SYSTEMATIC

A sketching method where different ideas overlap and combine various solutions. Sketching is systematic and provides

a better overview of

the possibilities for the

concept.

MOCK-UPS



Mock-ups are 3D physical representations of the 2D ideas. It helps to understand the dimensions and shapes. They are used to verify how the further development should be designed and executed.

Act-it-out



Act it out is a phenomenological process where acting and simulation of specific situation gives an insight into the aspects of what the user would do or feel i. This includes usage of mock ups and models.

CAD-modelling



Creation of a design in 3D programme gives a real and concrete understanding of the concept and helps in the development of the product with details. It is a 3D representation in a real or minimized scale.

Concept development flowchart:



First ideation

The first ideation was a very broad exploration of what ways the product should be directed through. The first ideation shows different brief concepts, drawings and mock-ups, seen on ill. 36-41. The main purpose of the ideation was to find a way, the solutions should be executed and how they should be developed further on.



Ill. 41- Ideation 2

III. 40- Ideation 2

Vision



III. 42- Ideation skecth

| 11

FES

FES (Functional Electrical Stimulation) is a currently the widest used technology to stimulate muscles in the post stroke conditions. Patient's body does not perform the same way as it did before the stroke, thereby a external stimuli is used to generate the activation of different muscle groups. The technology is applied to different body parts depending on which area is impaired. The critical areas such as upper and lower arm muscle groups are stimulated. The technology tacles the arm immobility, dead arm syndrome, problems in activation of certain muscle groups. The FES stimulation is also prevalent in treating joint/muscle injuries, back pain, stretched tendons or it is used while training and bodybuilding to enhance the muscle activity. FES is a method using electrical impulses with low energy input to activate muscle movement.



The technology is applied to different body parts depending on which area was damaged. For post-patients with arm immobility, the muscles such as biceps, brachialis, brachioradialis and extensors are stimulated. FES uses electrical current to cause the muscle contractions in a group of muscles. Besides the muscles strenghtening, the FES stimulation fastens the blood supply into the area, which resluts in faster healing of the damaged muscle. The contractions develop the strenght and establishes the muscle pattern needed for the muscle memory creating the muscle structure.



III. 44- Blood circulation

III. 45- Blood circulation

How does the FES technology work?



III. 46- FES technology

Neurons (nerve cells) are cells that are electrically operating. The information in neurons is coded and transfered as a sequence of electrical impulses that are called action potentials. These stand for changes in cell electric potential. An electrical stimulation are able to artificially evoke the action potential by changing the electric potential in between the nerve cell membrane- covering also the nerve axon. FES technology benefits of this property in order to electrically activate nerve cells, which consequently activates the muscles and other nerves. [9]

As seen on the III 47., the information recieved from dendrites and delivered to the cell nucleus is being synthetized and selects whether or not to create signals. After suffering from a stroke, the group of muscles are impaired, as the motor neurons are not able to obtain enough information from central nervous system anymore. (b) The FES technique system inserts electrical current inside the cells. (c) The axon receives the stimuli and produces an action potential to (d) the neuromuscular connection. (e) Related muscle fiber constricts and (f) muscle force is initiated. (g) A sequence of negative episodes is generated and (h) depolarization happens where negative current comes into the axon at the "active" electrode. [9]

The electric stimulator work on the base of the flow of cations and anios, where the stimulator has a special character as the cathode is the negative pole (discharging anions) and the anode is the positive pole (discharging cations). Depending upon the configuration of the polarity, the stimulator discharges either cations or anions into stimulated muscle. In cathodal stimulation, the anions are being discharged as current runs from cathode, through tissue, and back towards the anode. In anodal stimulation, cations are being discharged into the muscle as current runs from anode, then through tissue going back to cathode, seen on III 46.



The FES stimulation device is composed of conductive pads and a controller connected by cables. The composition of the FES pads is generally a conductive material, such as conductive polymere, gel or water medium that tranmits the electric stimuli.



III. 48- FES non-adhesive electrode

The current FES device is usually composed of two or more electrodes of size between 20-30 mm, wiring cables and a control unit. Currently, there are several types of devices on the market varying in size. One can find a device with several modes, such as muscle activation, instensive stimulation or a massage programme, or interval mode or even special modes for proffesional athletes.



III. 49- FES adhesive electrode

FES parameters for 10 minutes of stimuli

- Pulse duration: 400 microseconds
- Frequency: 50 Hz
- On time: 12 seconds
- Off time: 50 seconds







III. 52- FES controller



Ill. 51- Electrodes on skin



III. 53- FES controller



The FES unit test has an objective to find out how to incorporate the FES unit into the bodysuit and how should be the working prinicple of the FES unit within the suit. Thereby a demands has been set up for the testing. The test is conducted first by desiging 3 concepts that would be tested by wearing and manipulating with the suit in order to satisfy the test criteria. The results would be represented in Table 4.

TEST criteria:

- 1. The FES unit needs to be a integrated part of the suit
- 2. The FES unit needs to maintain a stable position and fixed to the skin
- 3. The FES unit should not be in the way while putting the suit on
- 4. The FES unit should be easily accesible

CONCEPT 1

The first concept was based on making the apperture in the cloth, so the stimulation from the electrode can pass through the skin directly. The soultion was meant to be an integrated part of the suit. Thereby the electrode is connected on one side to the suit.





III. 55- FES concept 1 test

sticky surface of the electrode adheres to the skin, but tends to slip off

III. 54- FES concept 1 sketch



III. 56- FES concept 1 test

the cut is too wide open

CONCEPT 2

The second concept was developed from the first concept, however this time, it was made more fixed to the skin. The electrode adheres well to the body, but it is harder to acces it. It this case, it was a big problem to put the suit on, since the sticky surface of the electrode was adhering to the body, when not necessary.



Solution

II. 58- FES concept 2 test

II. 58- FES concept 2 test

II. 58- FES concept 2 test

II. 59- FES concept 2 t

disturbing
CONCEPT 3

The third concept presents an integrated solution where the electrode adheres well to the skin from each side, thanks to the velcro stripes around the verge of the cloth of the suit. It it also wraped in a tight cloth which hold the position of the electrode secure. It is easy to access the electrode, as the apperture on the suit can be opened.



III. 60- FES concept 3 sketch



RESULTS

	CONCEPT 1	CONCEPT 2	CONCEPT 3
test demand 1	satisfy	satisfy	satisfy
test demand 2	did not satisfy	satisfy	satisfy
test demand 3	did not satisfy	did not satisfy	satisfy
test demand 4	satisfy	did not satisfy	satisfy

Table 4- FES results

Conclusion:

The third concept was able to fullfill the test criteria, thereby the solution will be used further in the product development, prototyping and consequently detailing.

BANDS

The correct posture is a basis for development of correct movement. The rehabilitation center at Brønderslev solves the problem of correct posture with bands, where according to Carina, the cross on the back is a key to maintain and giude the upright back posture. The main aim is to keed the upper body steady, upright without leaning the shoulders forward.



Ill. 65- Training bands

III. 66-Training bands

The aim for the experiment is to find out how to design the postue correcting bands. The criteria are set up to fulfil the desired effect on the upper body. It needs to be also found out whether the bands should be part of the suit or be detachable.

Concept testing criteria:

- 1. cross on the back
- 2. pushing the shoulers backwards
- 3. maintain the body upright and compact
- 4. inhibit bending forward



CONCEPT 1

The first concept was based on two crossing straps on the back attached to the strap of lenght of x mm. The crossed bands guide the body to stay upright. The bands are a separate item and the x mm strap is being pushed too much upwards, which interferes with the overall effect.



CONCEPT 2

The second concept was derived form the first concept. Since the big band around the waist was pushing the suit too much upwards, another smaller band was added. It was placed under the main band and they were connected. The bands has a good effect on holding the body compact. The cross on the back seems to be to much on the top, so the effect on the shoulders is not present.



III. 69- Bands test concept 2

III. 70- Bands test concept 2

CONCEPT 3

The third concept is composed of a crossed bands attached in the back side of the neck and cross section attached to the main vertical band. The main vertical band is sewed to the suit and, the other bands are not sewed to the suit. The bands keep the body upright. The whole effect of keeping the body straight is reinforced by adding another band on the lower back. The forces are distributed, thereby the straps are not being pushed in wrong directions.



III. 71- Bands test concept 3

III. 72- Bands test concept 3

CONCEPT 4

The fourth concept is being derived from the third concept. It shares the same component structure. It is also part of the suit, as it is sewed to the suit. Howerver it differs in the location of the stiches. The fourth concept has the stiches around the front shoulder, which appear to be a point where the pushing the shoulders backwards takes real effect. Also, it is easier to put the suit on if the bands are being sewed at the shoulder area.



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	CONCEPT 1	CONCEPT 2	CONCEPT 3	CONCEPT 4
test criteria 1	satisfy	satisfy	satisfy	satisfy
test criteria 2	did not satisfy	did not satisfy	did not satisfy	satisfy
test criteria 3	satisfy	sarisfy	satisfy	satisfy
test criteria 4	did not satisfy	did not satisfy	satisfy	satisfy

Table 5- Bands results

Conclusion:

The fourth concept was able to fulfill the test criteria, thereby the solution will be used further in the product development, prototyping and consequently detailing.

PADS-inspiration from hockey suits

Hockey suits served as a inspiration for the concept creation as they are known to provides a certain degree of restriciton in the body, so the person is forced to move in the way that the suit allows to. The hockey suits components are the main body vest and pads on the thorax and abdomen, that maintain the upright posture. The main suit provids a very firm fixation of the upper body thanks to the distribution of forces.





TEST hockey suit

III. 75- Hoceky suit

III. 76- Football suit

The objective of the test of the suit was to find out what are the factors in the suits that make a person to be upright, not bending forward and maintain a stable positon of the body. To find out those factors, 5 students were asked to try it out and describe the suits. First the suit was put on and adjusted. Then the 5 participants were asked to describe the effect of the suit while standing and then while moving around.



III. 77- Person A



III. 78- Person B



III. 79- Person C



III. 80- Person D



III. 81- Person E

PERSON A.:

"It feels tight around the chest, like the body is carried by the suit. The suit makes we want to stand straight more with my back, because leaning forward make it uncomfortable. It's better to be straight. The sides do not feel super tight, but when I'm breathing and taking in a lot of air I can feel it's tight. I can't really lift my shoulders, without lifting the whole suit. The comfort in general is fine, but it has little tight on my neck. I feel big and wide with the suit on. "

PERSON B.:

"It feels like its stretching my back out, so I have better posture. The pads in the front forces me to keep my back backwars and not bending too much forward."

PERSON C.:

"I feel like pulling it down, it's to small in the length but to width of the shoulders. So, I feel like pulling it downwards. It feels a little tight at above the chest area, below at the Velcro it feels quite nice. I think it feel very flexible for movement, it doesn't lock me. The suit is not hurting, it is not really a hrad force. I think its okay. I general I like to comfort, it feels so mobile to have on and it follows my body movement.

PERSON D.:

"It feels like its stretching my back out, so I have better posture. Depending on what purpose I'm wear it, when doing sport, I won't mind it's tighter. When it's tight, it feel like my body in a more correct placement and also it feel more solid to wear. I get some restriction around the chest with the pads, but I am still able to have full movement.

PERSON E.:

"Not uncomfortable, doesn't mind. Doesn't position the body directly, but when i want to move i am too restricted. The vest is making me want to be straight up, abut at the same time it is kind of comfortable. It feels like it is straightening up the body, also nice to wear. "

Results: Trying out the hockey suits led to the findings of the parts that influnce the most body posture. Those are the pads in the thorax and abdomen. These were the criticall areas that 5 correspondents desribed as inhibitors of bending forward. For a proper understanind of the placement, dimensions and ergonomical attributes, the single pads will be tested out.

TEST PADS



The objective of the test pads is to find out the functional solution to constrain bending the upper body forward, which is the consequence of a bad posture habit. The test is set up with the limitation of not bending forward beyond 20°, as for the difference from the correct 90° (possition while sitting). Three concepts were developed to be tested. The test begins with putting the pads on and bending forward until the pads are in the way and a person gets a external feedback. The person stops bending forward when hitting the pads with lower thorax, then the angle of displacement is measured. The expected results are to find out a solution that would inhibit the bad posture habit and give the person a feedback to remind straight posture.

The concepts will be tested out with the criteria of:

- 1. not bending forward beyond 20° and maintain a stable position of the body
- 2. ergonomical form fitting form for lower thorax and middle abdomen
- 3. relative flexibility while performing ADL on the scale 0-10



III. 82- Muscle figure

The test of the bending had an objective to simulate the upright position compared to naturally loosen position of a stroke patient.

For measuring the angle of displacement (bending forward) the following indications were set up:

- the refernce point set up to hip joint x
- the axis of shoulder in 90 ° y1
- ${\boldsymbol{\cdot}}$ the axis of bended shoulder of $\,\,{\boldsymbol{\beta}}^{\circ}\,{\boldsymbol{y}}2$
- the angle of bending forward ß



III. 83- Pads test criteria 45

CONCEPT 1

The first concept is composed of a 4 soft cardboard plates with 4 extended cardboard pads and foam cushions on the top part of the concept. The dimensions of the concept are 28x16x3 mm. The spaceing between the single pads is of 20 and 15 mm.



CONCEPT 2

III. 84- Pads test concept 1

The second concept is composed of 7 pads in totall. The three main pads have a vertical orientation. These padshave dimensions of $40 \times 110 \times 8$ mm. There are 4 side pads with oblique external edges. The oblique pads have dimensions of $30 \times 14 \times 8$ mm. The spaceing is of 15 mm.



III. 86- Pads test concept 2



III. 85- Pads test concept 1



III. 87- Pads test concept 2

CONCEPT 3

Third concept consist of a cardboard plate of thickness of 15 mm, longitude of 170 mm and width of 250 mm. The concept includes in totall 18 pads of two kinds. The bigger one is of dimension 70x30x10 mm. The pads are placed on six flexible plates, which allows the movement while beiing constricted. The distribution of the pad is in 4 columns and 5 rows. The spaceing between the single pads is of 20 and 5 mm.



III. 88- Pads test concept 3



III. 89- Pads test concept 3

CONCEPT 4

Fourth concept is derived from the third concept. There are four main pads of dimensions of 50x30x10 mm and side pads of dimension 35x30x10 mm. These pads are sewed into a polyesther fabric to provide a ergonomic and comfortable wearing experience.



III. 90- Pads test concept 4



III. 91- Pads test concept 4

	Concept 1	Concept 2	Concept 3	Concept 4
test criteria 1	did bend over 20 °	did not bend over 20°	did not bend over 20°	did not bend over 20°
test criteria 2	did not fit	fit	fit	fit
test criteria 3	4/10	6/10	8/10	10/10

Table 6- Pads results

Results concept 1: The first concept did not succeeded in not bending over 20 °, since the pads were not thick enough to realize to not to bends. The form for the middle abdomen did not fit well as the pads were too wide and to flexible. The overall movement while performing ADL activity (sorting out groceries) was not satisfying due to the discomfort and not ftting pads. The pads and plate were not allowing to perform the activity properly-the pads were too muc h in the way. However the foam cushions provided a positive user experience. The score was set to 4 out of 10.

Results concept 2: The second concept succeeded in not bending over 20°. The form of the plate for lower thorax and middle abdomen fitted due to its ergonomical shape. The overall movement, while performing ADL activites was smooth thanks to the flexibility of the pads, though the 3 middle padsprooved to be too long. The evaluation of the concept was set to 6 out of 10.

Results concept 3: The third concept succeeded in not bending over 20°. The form of the plate fitted for middle abdomen, though did not fit for the lower thorax. The performance of the concept during ADL activity was evaluated to 8 of 10 due to the satisfing combination of flexibilility while being restricted. The pads were thick enough to give a feedback to to user not to bend forward.

Results concepts 4: The fourth concept showed to be the most efficient way of inhibit the bending, where the person could notice the feedback from the pads. The performance during the ADL was set to 10/10.

Points to take for further product development:

- the dimensions of the pad plate should be of 130x180 mm for one side
- the pads should be of dimensions 50x30x10 mm
- the pads need to be a integrated part of the suit and sewed within a flexible fabric
- the pads need to be in 4 columns and 5 rows

PRODUCT DEVELOPMENT

METHODS:

SKETCHING







Sketching serves as a tool for visualisation of ideas and helps in the communication when working witin the ideation process. It also provides a wider range of diferent ideas that can be thought upon.

Pictures, photos and objects stimulate the creative process to help covering the framing area. It is used to create more solutions for a concrete problem scope.

SYSTEMATIC SKETCHING



Asketching method where different ideas overlap and combine various solutions. Sketching is systematic and provides a better overview of the possibilities for the concept.





Mock-ups are 3D physical representations of the 2D ideas. It helps to understand the dimensions and shapes. They are used to verify how the further development should be designed and executed.

Act-it-out



Act it out is a phenomenological process where acting and simulation of specific situation gives an insight into the aspects of what the user would do or feel i. This includes usage of mock ups and models.

CAD-modelling



Creation of a design in 3D programme gives a real and concrete understanding of the concept and helps in the development of the product with details. It is a 3D representation in a real or minimized scale.

Product

FES UNITS

FES area is a part of the device that includes electrodes to stimulates the inactive muscles.

ARMLET WITH CONTROLLER

The armlet with controller is a separate item. The controller can be connected by cables to the FES units. It is possible to track patients vital functions.

BANDS

Pads invoke the upright position and inhibit the tendency to lean forward. The back is pushing backwards and the upper body does not collapse.

PADS

The pads helps in maintain an upright position and correct the posture of the upper body.



III. 92- Product- Suit

Components exploded



III. 93- Exploded suit



III. 94- Exploded suit



III. 96- Exploded suit



III. 95- Exploded suit



III. 97- Exploded suit 51

MATERIALS- analysis of textiles

The material analysis will provide an understanding of textiles and the mechanical and physical properties of chosen materials. Generally, the textiles are devided in two main caterories based on what origin they come from. They are either man made or natural. The natural fibers are vegetable, animal or mineral menwhile the synthetic fibres are regenerated, synthetic polymeres or inorganic. [8] . The analysed materials are selected based on current usage in the sport idustry, thereby the properties such as flexibility, elasticity and resiliency and abrasion resistance were considered. **Flexibility** is an ability of a fibre that strongly depends of the thickness and cross section shape. To measure the flexibility of a fibre, the tensile modulus is calculated, where a force is applied per unit area. The fibres that posses a high tensile modulus are more likable to resist a force, meanwhile fibres with low tensile modulus shows less resistency. A generall modulus for textiles stands between 0,08-10 GPAa. **Elasticity** is an ability of textile to recover to its original position after being streched and the force is no longer applied. **Resiliency** is a property of a textile to be able to come to its original position after exposure to a distortion, such a compression. **Abrasion resistance** of a textile happens when fibers of the same or other fabric are rubbed against each other. The material with low abrasion resistance will wear of quickly by disrupting the toughness of the fibre. The following materials were suggested for the product development: Cotton, Nylon, Polyesther, Spandex, Polypropylene and Microfibres. [8]



III. 98- Polyesther cloth



III. 99- Cotton cloth



III. 100- Nylon cloth

Polyesther

Polyesther are sub-category of polymers, that is manufactured in two methods, when after the formation of the fiber is made with spinning and drawing. This allows creation of very thin filaments. The attribute of polyesther fibres are high tensile strenght, abrasion resistance, and resistance to strech and easy care properties thanks to its hydrophobic structure.

Cotton is one of the mot used natural fiber worldwide, whereas the biggest area for demand is the clothing sector. Cotton is mostly used for highquality end product. The cotton fiber presents physical properties such as uniformity of fibre lenght, strenght, elasticity and elongation. The type of cotton used for textiles is long-staple cotton, which presents the highest quality. Natural cotton is usually used for athletic dresses and prevents the sweat maintaing on the body. The cotton textiles are comfortbale, uniform and breathable.

Nylon

Nylon, more concretely Nylon 6 is a fibre widely used in the clothing, because of its excellent tensile stenght, elasticity recovery and abrasion resistance. Nilons are hygroscopic and present large extentions before breaking. Compared to polyester filaments, the nylon fibres present similar strenght, however are more extensible. Nylon textiles shows resitance in rupture, thanks to its strenght which is 0,5 N/ tex.



Ill. 101- Spandex cloth



III. 102- Polypropylene cloth



III. 103- Microfibres cloth

Spandex

Spandex is the most commercialy used synthetical fibre with, also known elastan. The testile has a major use in clothing ranging from cyclists jerseys, athetic sportswear, underwear, orthopedic braces, tights, swimwear or ski suits. The fibre presents high elasticity performance, strenght and great resiliency. The elasticity of Spandex accounts for the ability of the cloth to expand twice its original size. Spandex present a low tensile modulus

Polypropylene

Polypropylene are sythetic fibres with very low production cost and overall cost. First the monofilaments are extruded, that could be formed into multifilaments. Polyproplyene fibres presetns hydrophilic properties, high strenght, toughness. Polypropylene textiles are most commonly used for sports clothing (diving suits), underwear and warm weather clothing. The hydrophylic attribute accounts for transporting sweat from the skin. The disadvantage of polypropylene the textiles are hard to dye.

Microfibres are also known as microfilaments are fibres with very small diamerer, less than 10 micrometers. They are of a sythetic origin, that present high performances in flexibility, filtering capabilities and ability for threading dense structures. The textiles of microfibers are usually composed of acrylic, polyester or nylon. Microfibers can make textiles with tough and very sof to the touch properties.



Table 7- Modulus of fibres

Detailing of the components- materials and composition BANDS





III. 107- Pads zoom



III. 109- FES

WIRING







III. 111- FES wires

ARMLET WITH CONTROLLER AND SOFTWARE





The controller monitors the heart beat and sends it directly to the paried phone or computer through an application. III. 112- Controller

The device is intuitive to use just with few buttons and two functions- stimulation mode or monitoring mode.





Ill. 114- Display monitoring



Ill. 116- Display set-up

III. 113- Display BPM



III. 115- Display set-up

BUSINESS ASPECT

THE GOLDEN CIRCLE- WHY, HOW, WHAT

Golden circle is a value proposition method used in businesses to achieve an innovation within a specific industry in modern economy. The value proposition has three main components- WHY, HOW and WHAT. [3]

WHY-WHY factors is a core and a 'driver' component of the circle standing for a reason, value, purpose and cause.

HOW- HOW factor stands for the way of achieving the set up goal or value proposition.

WHAT-WHAT stands for the product itself representing the value proposition and provides the service for customer.



How can one buy the product in Denmark?

As the product would be considered as a medical device, there are two ways how a patient could get it-through a public or private way:

Private- People go to the welfare center to the showroom to see and try out the product. The trust between the customer and the product is build through the welfare center. If people do not fulfill the service law, then they buy the product by themselves.

Public- The service law §85- The municipal council shall offer assistance, care or support as well as training and assistance for the development of people with decreased skills, because of considerably reduced physical or mental functioning or special social problems.

The patient has to fulfill the criteria set by the government of the disease, before the municipality can grant him any kind of support (aids, products, etc.)For the government to even consider buying the product for patients to use, the product needs to reduce the time and cost (Example- SOSU worker cost 384.000 DKK a year and spend around 37 hours a week working with the patients. If the SOSU spends 2 hours on a patient, then she can handle 18,5 patient a week. If we can reduce this to 1.5 hours per patient and save half an hour per patient, the SOSU would be able to handle 24,6 patients per week.) A senior patient goes through the elderly department of the municipality to get granted the support.

STAKEHOLDER MAPPING



REQUIREMENTS

Label

bel	Requirements
! 1	1. The device should be designated for the upper body and mobility
! 2	2. The device should ease the patients recovery process
. 3	3. The device should be applicable in the stage 2,3 and 4
4	4. The device should cut the rehabilitation staff's time spent on each patient by monitoring the patient's life functions
! 5	5. The device should guide the patient to be independent and autonomous
6	6. The device should support the body during the exercises and ADL activities
! 7	7. The device should help regain patients the muscle activity and avoid the post stroke problems such as arm muscle immobility, muscular atrophy, ligament shortgage, dead arm syndrome, chronic back pain, tourso collapsion, loose upper body and back.
8	8. The device should hold the patients upper body compact, upright and avoid bad postue habits
9	9. The device should encourage the patient to train and be interested in the recovery process
10	10. The device should fill the gap in the market for a proper device for stroke patients
! 11	11. The product should be in the form of a suit incorporating the technology inside of the suit
ļ 12	12. The suit should incorporate FES electordes
! 13	13. The FES electrode pads should be easily accessible
! 14	14. The FES electrode pads should maintain a stable position and be fixed to the skin.
ļ 15	15. The FES unit should not be in the way while putting the suit on
ļ 16	16. The FES electrode should be a part of 40x40 mm
! 17	17. The FES unit are should be of maximum 80 mm in width and maximum of 280 mm in lenght.
! 18	18. The suit should incorporate bands for correcting the upper body posture.
ļ 19	19. The bands should be in the form of cross on the back.
20	20. The bands should push the shoulers backwards.

nr.	Quantitative	Qualitative	Fullfilled
1.		х	YES
2.		х	YES
3.		х	YES
4.	х		YES
5.		х	YES
6.		х	YES
7.		х	YES
8.		х	YES
9.		х	YES
10.		х	YES
11.		х	YES
12.		х	YES
13.		х	YES
14.		х	YES
15.		х	YES
16	х		YES
17.	х		YES
18.		х	YES
19.		х	YES
20.		х	YES



21. The bands should maintain the body upright and compact

22. The bands should inhibit bending forward.

23. The suit should incorporate pads for the abdomen part to avoid bending forward and maintain a stable position of the body.



one side



25. The number of pads should be of 2x5 and 2x4 of dimensions 50x30x10 mm and 35x30x10 mm

24. The dimensions of the pad plate should be of 130x180 mm for



26. The FES electrode controller needs to be wearable and being able to connect easily with the suit.



27. The controller of FES electrodes should be intuitive and easily understandable.



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28. The controller should have a build-in monitoring function.

29. The materials of the suit should be of flexible material with a elastic modulus minimum of 1 GPAa.

30. The cables of the FES units should not be in the way while wearing the suit.

21.		х	YES
22.		х	YES
23.		х	YES
24.	x		YES
25.	x		YES
26.		х	YES
27.		х	YES
28.		Х	YES
29.	х		YES
30.		х	YES

Conclusion

The FORTFES project is a result of development of a design solution for post stroke patients to help them in regaing muscle activity and assist in returning into the daily life standards. The design of the final solution is based on the prior data gathering in rehabilitation centers, research and interwies with patients and therapists. The opportunities in the market were analysed for the framed problem and a gap in the market was found, which created a opportunity for a development of a new product in the area. Therefore, relevant segments, such as FES electrodes and back correctors were investigated to be able to provide anwsers for the problem statement. The requirements for the product were chosen based on the findings through across the whole project to establish the attributes and features of the future product. During the concept development phase, the framing of the solution features were find out and sorted out by testing the concepts exposed to test requirements and limitations. The results of the tests provided the concrete solution for integration of FES unit within the suit and the working principle of the pads and the body vest. With these results a product development was initated to bring the functional and formal solutions into one final product. It is concluded that the estimation of working principles of the product - FOREFES suit, would provide the patient activation of the muscles in upper body, correcting and maintaing the correct posture, avoid arm post-stroke problems and monitor life functions. Moreover, providing a proper assistance in returning into daily life standards by wearing the FORTFES suit.

Perspectives

The perspectives of the project include further development of the final product in terms of detailing, moreover the business cases and implementation to the market. First, the product needs to be tried out with stroke patients under the supervision of doctors and a proper feedback will need to be given. A different sizes of product will need to be developed for different sizes of bodytypes. Regarding the materials, a maintanance factors will be considered, such as washing, cleaning and resistance of the materials.

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PRODUCT REPORT

ANDREA MIRETINSKA MSc04- ID, August 2018

Title page



Title:	FORFES
Type of project:	Master thesis
Project semester:	MSc04- ID
Project period:	01.02.2018- 15.08.2018
Theme:	Stroke patients
Supervisor:	Thomas Arvid Jæger
Co-supervisor:	Ewa Kristiansen
Pages:	20

Andrea Miretinska
Abstract

The purpose of this project is to research, find, analyze and create a solution for a design problem within a post- stroke condition area. Based on the data gathering and research it was found out that patients affected by stroke suffer from post stroke problems in upper body such as arm immobility, inactive muscles, muscular atrophy, and torso collapsing, chronic back pain. These problems affect the overall performance in daily life and lead to decrease of life standards. These findings led to the research and market analysis of how are these post-stroke problems curretnly solved, which resulted in finding out a gap in the market. Therefore an opportunity for a new product emerged. To solve the patients problems, the areas of FES stimulation and body suits are investigated and tested. The process of development of the device is based on the design thinking, where concepts of FES unit, suit pads and bands are created, tested and evaluated. The result of the development process is a compact, intuitive design solution of a product that will help the stroke patients regain the muscle strenght in upper body, correct the posture, avoiding loosening of body while training, and monitor life functions. The device would help the patients from stage 1-4, whereas it can be used with or without the supervision of rehabilitation staff. The device is a personal medical equipment designated for rehabilitation training sessions, municipality training, ADL training and home wearing. The device is expected to solve the most common upper body problems, that current medical equipment fails to solve. The device is expected to cover the gap in the market, since the rehabilitation centers seek for product that yet do not exist, but is necessary to be developed.

PROBLEM STATEMENT

HOW CAN WE DESIGN A COMPACT SOLUTION FOR POST-STROKE PATIENTS THAT WOULD HELP THEM REGAIN MUSCLE ACTIVITY IN UPPER BODY, ASSIST IN RETURNING INTO THE DAILY LIFE STANDARDS AND MONITOR PATIENT'S LIFE AFTER THE DISCHARGE?

Helle

Helle is a Occupational therapis and head of the research and development department at Bronderslev rehabilitation center.



Carina

Carina is a Physiotherapist and head of the arm training session at Bronderslev rehabilitation center.



"We have a big need for a product for stroke patients that would support their upper body and work properly. There isn't anything on the market that we can use. " "Stroke patients life is affected on the level of everday activities and basic daily routines. It is a long process to get them back, where they were before. A product, that would ease and accelerate that process would be very useful. "





FOREFES is a compact, intuitive design solution of a product that will help the stroke patients regain the muscle memory in upper body, correct the posture, avoiding loosening of body while training, and monitor life functions. The device would help the patients from stage 1-4, whereas it can be used without the supervision of rehabilitation staff. The device ia a personal medical equipment designated for rehabilitation training sessions, municipality training, ADL training and home wearing. The device is expected to solve the most common upper body problems, that current medical equipment fails to solve. The device is expected to cover the gap in the market, since the rehabilitation centers seek for product that yet do not exist, but is necessary to be developed.



4 stages of the stroke

1. stage- Acute treatment: In the first stage of a stroke, the patient gets right away the treatment for the emergency accident and is diagnosed the severeness of the stroke. The patient is under strict control in the hospital to ensure the intense care. After establishing the patient's vital functions and primary cognitive and physical skills, a proper rehabilitation plan is designed for the patient.

2. stage- Rehabilitation under hospitalization: If the patient needs a rehabilitation during hospitalization, the hospital will, depending on the needs of the person, rehabilitate at the main function level, regional level or highly specialized level. The hospital plans a rehabilitation plan within the hospital region. The patient has established the basic functions and is ready to participate in the active rehabilitation process.

3. stage- Rehabilitation after discharge: It is essential that the hospital, municipality and general practicioners cooperate on the overall rehabilitation process. The patient lives at home and he participates in the rehabilitation sessions in the municipality. In this stage the patient gets less monitored by hospital and more dependent on his relatives and himslef.

4. stage- Stable maintanance: The patient is stable and he is able to train by himself. He can still participate in the rehabilitation process, though there is involved more independency. In this stage, the relatives present a big role for the patient as a moral support. The patient does not recover to the status as before the stroke, however there is a high chance to reach a good life standards.

Stroke patient rehabilitation process				
	stage 1	stage 2	stage 3	stage 4
Hospital	X	X		
Hammel		Х		
Bronderslev		Х	Х	
Hobro/ Frederkishavn			х	
Municipality/Home			Х	х

In which stage should the patient to use FORFES bodysuit?

Post-stroke problems that patients are suffering from

•

- Arm immobility
- Upper body muscles inactivity
- Dead arm syndrome
- Loose upper body and back
- Ligament shortgage
- Muscular atrophy
- Chronic back pain
- Torso collapsion

- Not being able to paticipate in life
- Not performing in ADL (activities of daily living)
- Failing in municipality and home training
- Lost of life standard

Where to use FORFES bodysuit?







Exploded -components

PADS and BANDS

Pads and bands invoke the upright position and inhibit the tendency to lean forward. The back is pushing backwards and the upper body does not collapse. The pads and bands help in maintaining an upright position and correct the posture of the upper body.





FES UNITS

FES area is a part of the device that includes electrodes to stimulates the inactive muscles..

ARMLET WITH CONTROLLER

The armlet with controller is a separate item. The controller can be connected by cables to the FES units. It is possible to track patients vital functions.





How to use FORFES bodysuit?





4.

Repeat the step 2 and 3 on all four bands on the arm, so all the four electrodes adhere to the skin.

5.

Wear the armlet with controller. Connect the cables from the suit with the armlet.





6.

Turn on the controller on the side button. Choose the intensity of stimulation and press GO button. Let the stimulation transfer for 10-20 minutes.

7.

Turn off the stimulation by pressing END button. Open the FES area and paste the foil to the sticky electrode. Close the FES area.

8.

Wear the suit during the ADL or municipality training or casually at home, to enhance the correct posture habits and ease the post-stroke consequences.



3.

Wear the single armlet whenever needed or desired to monitor your life functions and let your family/ caretaker know you are all right. The sofware in the controller automatically sends your data directly to paired phone or computer.

Implementation of FORFES - go-to-market strategy



Break even diagram [DKK]

70.000.000





Total revenue over time

Business model canvas

