



Design and evaluation of a wearable system to increase adherence to rehabilitation programmes in acute cruciate ligament (CL) rupture

George Kordatos¹ · Stavrakis Modestos¹ 

Received: 25 April 2019 / Revised: 22 October 2019 / Accepted: 19 November 2019

Published online: 16 December 2019

© Springer Science+Business Media, LLC, part of Springer Nature 2019

Abstract

Smart wearables for health monitoring, prevention, and patient support play a significant role in today's treatment and home rehabilitation. The effectiveness of rehabilitation in acute cruciate ligament (CL) rupture is dependent upon patient adherence to personalised Home Exercise Programmes (HEPs) and development of self-efficacy. This paper presents the research, preliminary design stages and a formative evaluation of a digital wearable system for monitoring, tracking, guiding and motivating users during HEP. The aim of the prototype is to support patients' rehabilitation program by reducing the risk of re-injury during the process and motivate them to adhere to their HEPs by monitoring, providing constructive feedback, encouraging understanding and thus promoting self-efficacy. The digital infrastructure is composed of three main parts, a physical product of two smart bracelets for sensing data from the patient's knee, a smartphone application for the user to interact with and a web-based service for collecting, storing, analysing, and sharing data. The evaluation of the wearable system was based on a randomised group of 15 subject participants.

Keywords Wearable health technologies · Smart wearables · mHealth · Cruciate ligament rupture · Rehabilitation · Monitoring · Self-efficacy · Home exercise programmes

1 Introduction

Smart wearables have attracted much attention in recent years for their capabilities in fitness monitoring and other health-related metrics. The importance of bio-medical engineering and

✉ Stavrakis Modestos
modestos@aegean.gr

George Kordatos
kordatos.g@gmail.com

¹ Department of Product & Systems Design Engineering, University of the Aegean, Syros, Greece

wearable solutions for healthcare is growing during the decades thanks to the improvement and the availability of many devices and technological solutions, as well as their cost reduction. As a consequence, the interest in applying and combining those technologies to the monitoring and treatment of several kinds of diseases has increased [1]. A tear of Cruciate Ligament (CL) is a common knee injury that occurs mostly among athletes. A CL injury can last as long as a year and often includes physical therapy, strength exercises and frequent visits to physiotherapists and doctors.

The broader scope of digital health and health wearables is to provide patients with technologies (hardware devices, software tools/systems and online services) to better monitor, track and eventually manage their health and wellness related activities [2]. Wearable health monitoring systems integrated into telemedicine systems are novel information technologies that support early detection of abnormal conditions and potentially prevent serious consequences of non-adherence with physiotherapy treatment. Many patients can benefit from continuous monitoring as a part of a diagnostic procedure, optimal maintenance of a chronic condition or during supervised recovery from an acute event or surgical procedure. Wearable technologies and biofeedback systems appear to be a valid alternative, as they reduce the extensive time to setup a patient before each session and require limited time involvement of physicians and therapists [3]. Researchers have focused on three main areas of work to develop tools of clinical interest: the design and implementation of *sensors* that are minimally obtrusive and reliably record movement or physiological signals, the development of *systems* that unobtrusively gather data from multiple wearable sensors and deliver this information to clinicians in the way that is most appropriate for each treatment, and the design and implementation of *algorithms* to extract clinically relevant information from data recorded using wearable technology.

In this project, attention is given on people who experience CL rupture and are at the stage of recovery. The effectiveness of exercise programs for CL injuries is dependent upon patient *adherence* to HEPs and the development *self-efficacy*. *Adherence* can be defined as an active, voluntary, collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a desired therapeutic result [4]. *Self-efficacy*, refers to an individual's belief in one's own motivation and skill to execute a particular task [5]. In the case of CL rupture rehabilitation, this may be addressed by caregivers working with patients suffering from musculoskeletal conditions to improve adherence to HEPs. The use of exercise programmes, in clinical settings or at home, is described the standard rehabilitation method for musculoskeletal conditions. In these situations, patient adherence is considered a necessary milestone that increases and maintains self-efficacy. *Home exercise programs* (HEPs) lessen the number of visits required in a clinic, thus saving resources and unnecessary effort for patients, caregivers, and insurance companies. Also, researchers in the area have identified personal factors that support non-adherence to HEPs including, mental conditions such as depression or anxiety, weakness and increased musculoskeletal pain with exercise, the patient's subjective understanding of barriers that they encounter, reduced self-motivation and low self-efficacy [6].

In the following Sections, we analyse CL, the characteristics of a rehabilitation program, the need for improving users HEPs adherence through self-efficacy and processes of monitoring, tracking and guiding with wearable health technologies. We provide an overview of related projects, present our research, describe the design stages of the wearable system, outline the evaluation methodology followed and provide a detailed analysis of the formative evaluation with actual users and its results. Finally, we also outline some insights for future work.

2 Cruciate ligament (CL) and management

CLs are the key knee stabilisers, necessary for both static and dynamic stability. As presented in Fig. 1, CLs consist of the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL), and their purpose is to stabilise the knee especially during rotation, sidestepping and pivoting movements [7]. Knee injuries to young athletes make up 60% of sports surgeries and according to some recent studies, 50% of these include injuries to the ACL [8]. Ruptures of the CLs usually result either from the rapid deceleration of the lower limbs associated with the quadriceps or in a sudden change of direction or landing with slight knee overexposure. There are three mechanisms of the anterior cruciate ligament injury: direct contact, indirect contact and noncontact [9].

The patient who has a rupture of the CL usually has pain, premature swelling, knee fluid, limb in knee movement and difficulty in lifting weight [10]. Proper diagnosis is essential for a well-designed recovery program. The Dutch Orthopaedic Association's clinical guidelines for the diagnosis of rupture of the CL are the Lachman test, the Anterior Drawer Test, the Pivot Shift Test, and the MRI [7]. The Lachman examination is performed with the patient lying supine and the knee in 20° to 30° of flexion [7]. One hand stabilizes the femur while the other hand grasps the proximal tibia and pulls anteriorly, enabling the assessment of the anterior translation and the endpoint. The Lachman examination is regarded as the most reliable examination for evaluation of CL tears. The anterior drawer test is also performed with the patient supine but with the knee flexed to 90 degrees [10]. The examiner grasps the tibia just below the knee joint, with the examiner's thumbs placed on either side of the patellar tendon. The pivot shift test is performed with the patient supine and the knee extended. The examiner stresses the lateral side of the knee while gradually flexing the patient's knee. The pivot shift test is often difficult to perform with an acute knee injury because of pain and guarding. An MRI is usually not necessary to make the diagnosis of a CL tear, as a positive Lachman test result is sufficient. However, where physical examination is difficult to perform because of

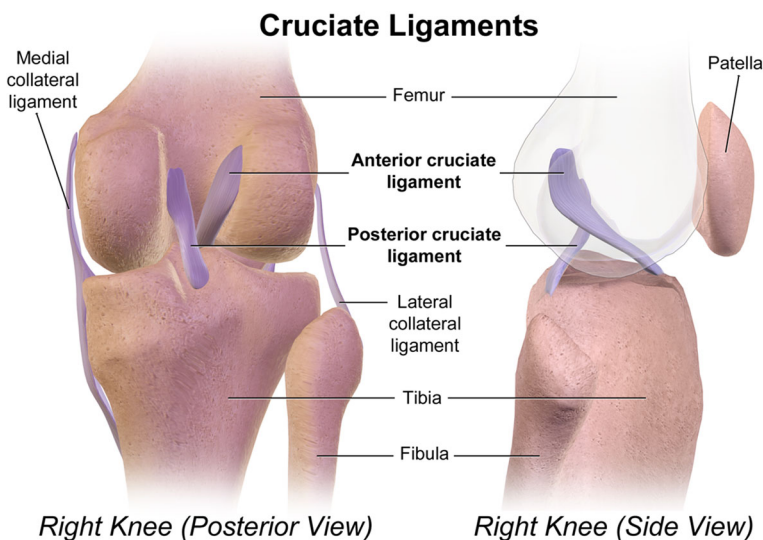


Fig. 1 Anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) [12]

pain and swelling or if there is a concern for associated injuries, an MRI may be a valuable ancillary tool.

Researchers at the University of Delaware have identified two categories of injured who appear to react differently to the CL injury [11]. The first category, which is the largest, is characterised as “noncopers” and the second as “copers”. Noncopers cannot return to a high-level sporting activity without having surgery to repair their CL, while copers can return to the activities they did before their injury after completing a well-designed rehabilitation program without being subjected to surgery.

The main treatment decision for the patient with an injured CL is whether to choose conservative or surgical management. The overall goal of treatment is to prevent recurrent injuries while facilitating the patient’s return to his or her desired or preinjury level of function. Defining each patient’s lifestyle goals is essential. Prospective studies on conservatively treated CL injuries have shown that up to one third of patients require late ligament reconstruction, approximately 20% return to their preinjury level of activity without restrictions, and 35%–68% require subsequent meniscal surgery [13]. With conservative treatment, the caregiver aims to reduce swelling, restore Range of Motion (ROM) of the knee as well as muscle strength. Knee stability can be improved by intensive rehabilitation exercises not only to strengthen the anterior muscles, known as quadriceps and hamstring muscles but mainly to improve knee balance and proprioception. The conservative program may also include bracing. Surgical management is usually offered as the treatment of choice for young patients with intact menisci, injured elite athletes, and patients with a very active lifestyle. Surgical treatment is expected not only to restore knee stability but also to protect the knee from further damage to the articular cartilage and the meniscus.

2.1 CL Rehabilitation protocol & benefits of monitoring

Structured rehabilitation for rupture of the anterior cruciate ligament is similar for injured patients treated with surgery or with conservative treatment. In general, the recovery program includes cold-therapy (ice), gravity-induced or continuous passive motion (continuous machine motion), brace, electrical neuromuscular stimulation and exercises (e.g. isometric, isotonic, isokinetic) with the aim of empowering, balancing, proprioception regarding the mitigation of the inflammatory reaction [9]. The above objectives can be achieved through a well-designed rehabilitation program divided into three phases, the acute phase, the recovery phase and the functional phase [11]. In the acute phase of rehabilitation, the goals include the reduction of pain and swelling, the achievement of full extension, mobilization of the patella to reduce postsurgical scarring, and early weight bearing. In the recovery phase of rehabilitation, the goals are to obtain the full range of motion, achieve quadriceps muscle control, work on the hip as well as other core muscles, improve proprioception and balance, and finally, integrate functional activities in 3 planes of motion. In the functional phase of rehabilitation, the goals include strengthening the complete kinetic chain, working on power, and returning to sports. Recent studies show that 70% of the people are quitting physiotherapy sessions when the acute pain disappears, and they regain confidence about their mobility. The reasons are multiple, and we mention a few of them: cost of treatment, the feeling that they recovered, no more time to dedicate for recovery and the loss of motivation. The worst part is that half of them are able to see the injury reappear in the course of 2–3 years [14].

The physical therapist (PT) is responsible for designing the recovery program, on the other hand, the patient is responsible for maintaining and completing it since most of the process will

take place at the patient's home. We see, therefore, that there is a need for regular monitoring, data recording and guidance during rehabilitation. Wearable devices have begun to focus on digital health and now are able to monitor accurately the recovery process according to each patient's treatment plan. Wearable sensors can provide a safer environment for successfully completing the rehabilitation protocol. The PT receives the captured data in order to analyse it and reconsider the effectiveness of the recommended program.

3 Adherence to rehabilitation programs

The effectiveness of a rehabilitation program is dependent upon patient adherence [4]. *Adherence* is defined by the World Health Organization as the degree to which the patient's behaviour and actions correspond with the agreed recommendations from a health care provider. The use of exercise programmes, in clinic settings and at home, is considered the standard of care for musculoskeletal disorders, with patient adherence being the number one factor to increase and sustain self-efficacy. Regardless of the fact that exercise programs are beneficial for patients' fast recovery, patients have been adherent only by 50% of the time when in a clinic setting [15] and even less when they are at home, away from caregiver supervision. According to Bassett, the lack of commitment to physiotherapy is a problem as 65% of patients are inconsistent or partly consistent in performing the home exercise program, and about 10% fail to complete the predicted physical therapy [16].

Systematic use of *Home exercise programs* (HEPs) reduce the number of clinic visits for participating in supervised sessions, saving resources and effort for the patients, the caregivers, the health institutions, and insurance companies. The degree of consistency with which patients adhere to the exercise program is considered to be significantly responsible for the successful completion of the program. Researchers have identified personal factors that contribute to non-adherence to HEPs including, mental conditions such as anxiety and depression as well as helplessness, increased pain with exercise, the patient's perception of barriers that they encounter, reduced self-motivation and low self-efficacy [6].

Self-efficacy, is a mechanism in human agency. According to psychologists it is defined as an individual's judgment of "how well one can execute courses of action required to deal with prospective situations" [17]. Self-efficacy refers to the overall belief that an individual has to achieve a goal and not as a measure of whether she/he can perform it. Low self-efficacy has various expressions in human behaviour including fear of taking risks and dealing with uncertainty, irrational fear of failure and low aspirations. Patients that exhibit low self-efficacy may also display reduced levels of confidence and hesitate to participate to activities they consider as threats. Moreover, when difficulties arise, they may reduce their efforts towards consistent completion of an activity, insist on shortcomings and failures and perform with a low level of commitment towards goals or personal desires [18]. Instead, those patients that exhibit a higher level of self-efficacy are characterised by a greater level of confidence, plan ahead by setting personal goals and work in a pro-active and intensive mode to achieve them, despite breakdowns and failures. Self-efficacy theory can be employed by caregivers as a means in suggesting HEPs to improve patient adherence to rehabilitation and, in turn, achieve patient outcomes in improving their health. According to research in this area, the perception of self-efficacy is related to four types of experience: mastery of experience (enactive mastery experiences or performance attainments), vicarious experience, verbal persuasion, and physiological state.

Mastery of experience is defined as repeated performance accomplishments and has been proven to be the most powerful for increasing self-efficacy. It functions as a mechanism for coordinating behaviour that evaluates previous experiences (successes or failures) of participation with present ones that are encountered during the current activity of the actor. *Vicarious experience* is obtained through observation of others performance and thus enables observing actors to direct their interpretation to someone else who completes a task (successfully or not). Depending on the similarity of the two actors (observer and performer) and the activity at hand, vicarious experience presents greater influence on the observer. When observers realise that another actor is accomplishing a task in a similar context, they potentially gain the self-confidence and empowerment to overcome that task as well. *Verbal persuasion* or exhortation is aimed at convincing an actor of one's capability of performing a task. Verbal persuasion may also affect motivation for the outcome of a task. Provided by caregivers, positive support and motivational communication, along with coaching and home communication programs as well as online educational material that present the benefits of exercise have been proven to eventually increase patients' self-efficacy for exercise especially in HEPs. *Physiological states*, and in particularly anxiety provide the grounds for the individuals to observe their own capabilities of performing or maintaining a give action or activity. Individuals make inferences about their abilities from emotional arousal and other physiologic cues experienced while enacting a behavior or anticipating its enactment. Positive interpretations of arousal, such as excitement or satisfaction, enhance self-efficacy, while negative interpretations like pain, fatigue, anxiety or stress, reduce one's sense of self-efficacy.

The rationale of self-efficacy can be employed by caregivers as a guide when defining home exercise programs in order to improve patient adherence and outcomes. In this paper, it is also used as a means to evaluate user/patient adherence to rehabilitation mediated by the designed wearable system.

4 Related work

Biosensor based Smart Health Wearables or Wearable Health Devices (WHDs) are emerging technologies that enable continuous ambulatory monitoring of human vital signs during daily life (at work, home, during sport activities, etc.) or in a clinical environment [19], with the advantage of minimising discomfort and interference with normal human activities [20]. The use of WHDs allows the ambulatory acquisition of vital signs and health status monitoring over extended periods (days/weeks), often 24 h a day in real time both inside and outside clinical environments [21, 22]. This functionality allows sensing and capturing of data during different daily activities, ensuring a better support in medical diagnosis and/or helping in a more appropriate and faster recovering compared to medical intervention, medical–pharmacological treatment or surgery [23]. This process of data collection is usually complemented by companion smartphone applications and/or desktop computer software for more sophisticated data analysis and visualisation, and lately stored in the cloud [24]. These devices can be used for both medical and fitness/wellness purposes, always targeting the monitoring of the human body. Wearable sensors are used to gather physiological and motion data thus enabling patients' monitoring their current status [25]. They can be extremely useful in providing accurate and reliable information on peoples' activities and behaviours, thereby ensuring a safe and sound living environment [26]. The technological revolution in the miniaturisation of electronic devices is enabling to design more reliable and adaptable

wearables, contributing to a worldwide change in the health monitoring approach. Body sensor network systems can help people by providing healthcare services such as medical monitoring, memory enhancement, control of home appliances, medical data access, and communication in emergency situations [27]. Continuous monitoring with wearable and implantable body sensor networks increases early detection of emergency conditions and diseases in at-risk patients and groups of people that need special attention, such as the elderly [28]. Moreover, provides a wide range of healthcare services for people who experience various degrees of cognitive and physical difficulties in their everyday life [29, 30] and even more mainstream conditions like stress and anxiety [31]. All these advances in wearable technologies and the various remote patient monitoring systems [32], provide a new ground for shifting from episodic to continuous patient care and thus better knowledge management around the relation of condition and treatment for both healthcare professionals and their patients.

4.1 Related projects

There is a large number of low-cost wearable devices, prototypes and smartphone applications used for monitoring, tracking and guiding in real time during knee rehabilitation as part of an in-home physical therapy program. Few of them focus on rehabilitation programmes after the ACL injury. In 2007 a research group from Australia developed a unique textile-based device, the intelligent knee sleeve (IKS), which uses conducting polymer technology to provide feedback on knee flexion angle for injury prevention programs [33]. The IKS contains minimal rigid components, conforms to body shape, is lightweight, does not impede human performance, is safe to be worn during physical activity and provides immediate, individualised biofeedback. The main function of this device is to reduce the risk of a non-contact ACL injury [34]. Another monitoring device prototype, in 2013, a wearable device for visualising knee rehabilitation exercises [35]. This device focuses on the recovery process at home for patients undergoing knee rehabilitation, specifically on the knee extension exercises. To better understand the needs of patients, they explored the design of a wearable electronic device that utilises an electroluminescent (EL) display as a feedback mechanism with patients who have or are currently attending physical therapy for knee rehabilitation. KneeHapp is a compression bandage that tracks patient's movements during different rehabilitation exercises and gives feedback to patients and orthopaedists about the quality of the performed exercises [36]. Developed in 2015, KneeHapp supports the entire rehabilitation of an ACL injury including the recovery of flexibility, muscle strength and coordination and is intended to be used by patients at home and unsupervised. Another category of projects aims at supporting patients in adhering to the long rehabilitation processes during their recovery by the use of motivational techniques that involve gamification and other engagement and persuasion mechanisms [37, 38]. The Fun-Knee prototype developed in 2017, a novel sensor-equipped knee support complemented by mobile device-supported games, is specifically designed for gamified Total Knee Replacement (TKR) rehabilitation [38]. A portable and low-cost sensor system has been developed to be mounted on a knee sleeve for knee angle measurement. The system consists of two inclinometers which are used to measure the knee angle as the main input to the developed game paired with mobile device-supported games. The game's target at training specific movement with evidence-based rehabilitation exercises. This system allows monitoring of knee position; providing real-time feedback as patients are guided through gamified rehabilitation exercises. Fun-Knee aims to improve exercise compliance, effectiveness and care continuity, while creating a more engaging and positive rehabilitation experience for patients.

These systems do not focus on guiding users in completing accurately their HEP, neither in supporting the development of self-efficacy, but rather focus on enjoyment and care continuity.

5 Design methodology

The design methodology used in this work is based on the Goal-Directed Design [39] and is mainly focusing on a user centered design paradigm. This method is a set of tools and best practices developed entirely through practice in the real world. It encompasses the design of a product's behaviour, visual and physical form. Based on Goal-Directed Design is also focussing on the design process, the steps and techniques involved in planning and conducting design research, using it to develop personas, scenarios, and requirements, then using those to develop and iterate a design solution. In this work, the methodology consists of six phases: project planning, research, modeling, requirements definition, framework definition and detailed design. In the project planning phase, a rough outline of the project is structured as well as expected results. While in the research phase is a systematic study to establish facts. By conducting research, the aim is not only to grasp new vocabulary and understand unfamiliar processes, but also to fathom the needs, views, and goals of the people buying, using and maintaining our product or service. Questionnaires and surveys aim at people who have suffered from CL rupture in the past, and physiotherapists in order to collect quantity and quality data. Throughout the modelling phase, data collected during the research is evaluated and personas with scenarios are created to generate and iterate specific solution ideas. By analyzing personas data users' requirements are defined. In the framework definition phase, the basic form and behavior of the product is laid out and will eventually lead to the detail design phase. This work focuses on how the design interacts with the mobile application and the physical industrial product (electrical circuits, sensors). Last, in the design phase comes the creation of iterative prototypes and Proof-Of-Concepts (POC) using equipment such as visual cards, development kit or 3D-printers, so that the feasibility of both the concept and technology choices can be confirmed.

6 Research

During this phase and following the Goal Directed Design Methodology we performed quantitative and qualitative studies, used research methods most importantly those of desktop research and literature review, contextual inquiry and online surveys [40].

A dedicated online survey was conducted, based on questionnaires, to collect quantitative data about people who suffer from CL injuries. Online communities, societies, and associations were identified that are related to CL injuries and a set of questions were prepared (demographic and rating scales) and were distributed to them through online social media. The aim of the questionnaire was to identify and evaluate data on the rehabilitation program of each injured person. The main goals of the questions were firstly to record if users found it useful to be able to monitor and capture data during the recovery process, and if they already use a device for monitoring. Moreover, if they successfully completed their program and if they were wearing a brace during the exercises.

Responses from injured patients ($n = 40$) were received, from which 89.2% (first bar on Fig. 2) had followed the surgical treatment. The main reason for this choice was that the knee

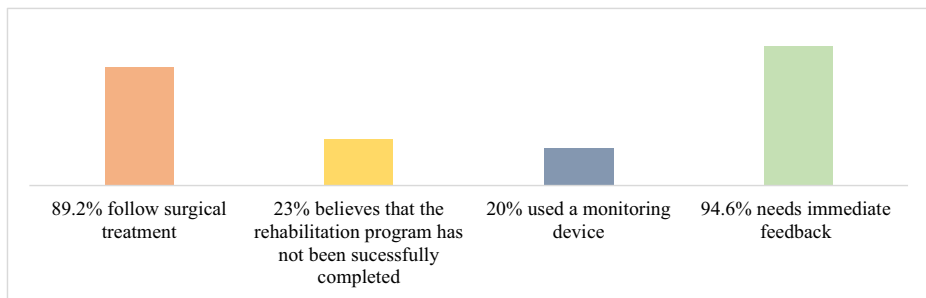


Fig. 2 Responses from patients regarding treatment, rehabilitation, monitoring and feedback

was unstable, and they wanted to return to sports activities they had done before the injury. The other 10.8% had either followed the conservative treatment because the knee joint was stable, or they had not been able to afford the other option. According to the answers, the physiotherapist designed the rehabilitation program in 83.3% of the respondents. The actual rehabilitation program was mainly conducted in a mix of sets: in the physiotherapy room (89.2%), at home (78.4%) and at the gym (64.9%). The duration of the program was between six months to a year. The 42.9% believe it has completed the rehabilitation program successfully. While the 22.9% believes it did not successfully or partially successfully complete the program. This is because 29% failed to fully return to the same level of activity as before the injury (second bar on Fig. 2). Most of them (69.4%) did not use brace support during the rehabilitation program. The other 30.6% who followed the conservative treatment approach used bracing which the protocol recommends. The rate of 80% did not use a device to monitor the recovery. Only 20% used a device to monitor the recovery (third bar on Fig. 2), with devices such as: activity trackers (37.5%), rehabilitation activity trackers (37.5%) and mobile applications (12.5%). However, 80% of the total responses believe that it is very useful to be able to monitor progress during recovery. When exercises take place at home, 60% consider it necessary to be able to see how the exercise is executed. The 94.6% find it beneficial to receive immediate feedback for the exercise execution (fourth bar on Fig. 2). Last, the 75.8% think that this kind of feedback should be provided through a mobile application, while 40% believe that receiving feedback from a wearable device you are wearing during the exercises was more helpful.

In addition, interviews with professional caregivers (physiotherapists and orthopaedics) were performed. The purpose of these interviews was to record the data of the rehabilitation program, the effectiveness of these programs and the choice of treatment. The caregiver would like to be able to see specific data on a patient's performance after each daily exercise program. The data could include, muscle activity, knee angle, time for each exercise execution, as well as patient comments.

Through this research, a noticeable need was found for improving patient's adherence during HEPs. A systemic review found that 14% of patients undergoing physiotherapy did not return for follow-up outpatient appointments and suggested that non-adherence with treatment and exercise performance could be as high as 70%. Poor adherence can compromise treatment outcomes and lead to the recurrence of symptoms [41]. The following items were found to be important for patients adherence: social support, guidance, number of exercises, self-motivation, self-efficacy, previous adherence behaviour, low level of physical activity, exercise attention, worsening of pain during exercises, and high degree of helplessness, depression and anxiety [42]. The most important factor of these seems to be the feeling of self-efficacy [5].

The results of the questionnaire present that about 30% believe they did not complete their program with complete success. The main reason for this seems to be the reduced adherence to

the rehabilitation program. According to the research and presented in Fig. 3, the functionality elements that the system should support to improve patient's adherence in HEPs are *prevention*, *monitoring of recovery*, *information for and education of the patient*, *measurement of the effectiveness of a program* and *communication enhancement with the caregiver*.

Prevention programs for avoiding CL injuries have shown that they play a very important role [10]. The goal for these programs is to reduce the risk of knee injury. This is accomplished with specific actions such as exercises for warming, stretching and empowering in order to deal with potential weaknesses in the strength and coordination of the stabilizing muscles around the knee joint. *Monitoring and tracking* data during recovery is a very important element for the patient. With the appropriate monitoring system, the patient will be able to see data from the beginning of the program, it is important to know the strength of quadriceps and hamstring muscles, but also the progress they are making. Another important factor is recording and collecting data from patients. Through this system, patients do not need to record daily data in calendars or special forms for caregivers. An important element of patient awareness is to *inform and educate* about the importance of these programs. Monitoring the rehabilitation program opens new horizons in the evaluation of a program. Measurements and data are automatically sent to the physiotherapist or the orthopaedic for patient evaluation and the follow-up of the program. The caregiver will be able to directly assess *the effectiveness of the program* according to the data received from each patient and adapt it accordingly. Good, direct *communication with the caregiver* is an important element for improving the patient's adherence to HEPs. The patient, when performing an exercise or a specific action at home and facing potential concerns or insecurities, needs the caregiver to give him immediate solutions. Creating a common system for the patient and the caregiver can greatly enhance this communication and the continuity of patient compliance in HEPs.

7 Design and prototyping

7.1 Design requirements

The word wearable implies the use of the human body as a supportive environment for the product. The human body is active, its form is diverse and changing. Wearable design that respects these dynamics results in product wearability [43].

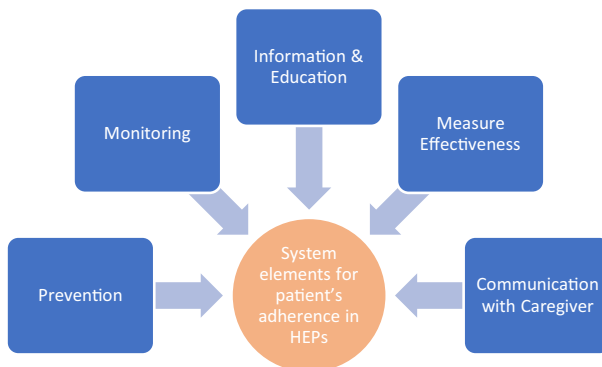


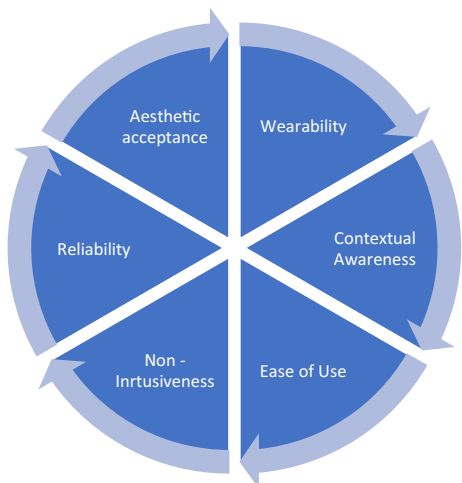
Fig. 3 Elements that a health wearable system should afford to improve patient's adherence in HEPs

A design process involves a set of procedures of problem solving where various types of information are collected and synthesised to generate a consistent concept followed by a visual form. As presented in Fig. 4, recent studies identify wearability principles which involve hardware and software aspects of devices as well as human and contextual aspects [44–47].

The design requirements for this study include: *Wearability* considers the physical shape of objects and their active relationship with the human form. It also includes principles such as comfort, affordance, aesthetics and ergonomics. These refer to the physical shape of the device and its functionality, user physiological and psychological characteristics. It is a key factor for the usability and effectiveness of a device and influences users' engagement and satisfaction. 'Dynamic wearability' occurs when the device is worn in action. *Contextual-awareness* refers to the scenarios in which the wearable device will be used must be clearly understood and considered during the design process. *Ease of Use* refers to a straightforward, simple and intuitive interface that enhances the usability of the device and further engages users with the underlying application. *Non-intrusiveness* is related to physiological sensors have various degrees of intrusiveness, where intrusion may involve using body tissue to diagnose a particular physiological state or condition. Devices should be transparent in use, enabling natural body movements and carefully considering anatomical characteristics and constraints of the human body. *Reliability*, refers to the level of confidence and trust that users have on the device, concerns safety, precision and effectiveness. *Responsiveness*, ensuring high responsiveness helps users to complete their tasks more efficiently and productively. *Aesthetic acceptance*, as an attempt to avoid social stigma and misperceptions of assistive technologies [48, 49]. People who use medical devices in their everyday life often feel uncomfortable in wearing them in public primarily because they might be stigmatised or socially discriminated.

The design of the wearable device, in addition to being aesthetically attractive, should also be able to adapt to the body of each user. This system can be used to strengthen and further maintain the prevention program in order to reduce the risk of injury to the CLs, as well as to monitor the recovery after CL rupture. It is very important for users, especially those with high daily sports activities, to understand the importance of maintaining preventive empowerment programs to avoid risks as well as the importance of the recovery program itself after such an injury.

Fig. 4 Design requirements the wearable system should afford



The main objectives of the product are intuitiveness and a non-intrusive design with targeted interactions, minimalistic aesthetics, customization, water and dust proof. Furthermore, a mobile application working in cooperation with the bracelets that give immediate feedback to the user, as well as being a tool for monitoring, tracking and guiding during the exercise process. The product applies both usable and ergonomic features to give the user the maximum experience. The bracelets with the mobile application aim at improving adherence and increasing self-efficacy during home exercise programs. Thus, the system includes mechanisms to increase user motivation and create personal goals with targeted alerts and personal achievements. To create the ideal conditions for the user to successfully complete the rehabilitation program, the system should provide a collaboration interface with the caregiver.

7.2 Industrial design

Design of the industrial product is considered important for a number of reasons. The designed product complies with the design requirements and fulfills the users' needs.

As presented in Fig. 5, the actual design consists of two bracelets made of special elastic fabric (hypoallergenic) mixed with a soft plastic bump for better grip that the user wears when performing the recovery exercises. The main bracelet is placed on the upper leg and in particular at the area of the quadriceps-hamstring muscles while the second part will be placed at the calf. In this way we can measure the angle of the knee and the muscle activity.

The width of each bracelet is 3 cm and the thickness is 2 cm while the diameter is adjusted according to the body mass of the user (different diameter between upper leg and calf). The bracelets will be in three number sizes, small, medium and large. The main bracelet has four surface electromyograph sensors (EMG) for tracking the activity of quadriceps-hamstring muscles. Both have an inertial measurement unit (IMU) sensor for tracking the knee angle, flexible PCB circuit accommodates the microcontroller unit (MCU), two vibrating disk motors (2 mm) on each bracelet and a flexible battery with wireless charging and a capacity estimated to be sufficient for 2 days (350mAh for the main bracelet and 150mAh for the second one, Li-Po). The BLE protocol ensures tiny power consumption and deep sleep modes when the device is not in use. A detailed overview of the bracelets and its components is shown in Fig. 6.



Fig. 5 Product design of bracelets

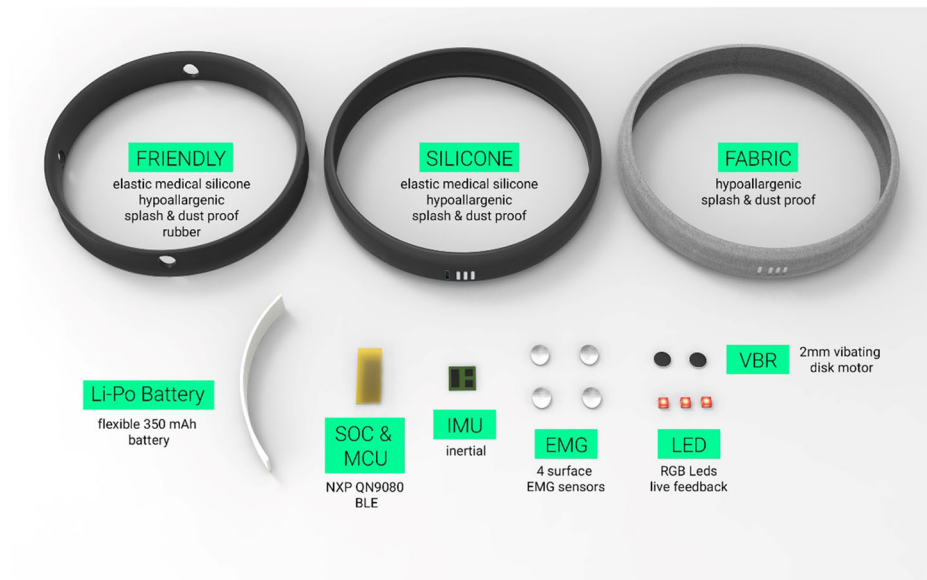


Fig. 6 Main bracelet and its components including: on the top left the rubber elastic medical silicone material, on the top middle the soft elastic medical silicone material, on the top right the hypoallergenic fabric material, on the lower left the Li-Po Battery, in the middle the SOC & MCU processor, the Inertial sensor, the four EMG surface sensors and on the lower right the three RGB LEDs and the two VBR motors

The material is mainly a skin-friendly elastic fabric combined with soft elastic bump plastic material and are dust and splash proof resistant, so the user can safely use it in indoor and outdoor exercises. In the following Table 1 we present how each component contributes to monitoring user's daily rehabilitation program (all the components except EMG sensor and USB-C charging are used on both bracelets).

Table 1 Electronic components and their relation on the bracelets

I/O	ID	Component type	Role
Input	EMG	<i>Surface Electromyography (on main bracelet)</i>	Valuating and recording the electrical activity produced by quadriceps-hamstring muscles. Monitors the strength of the muscles to reach the levels before the injury
	IMU	<i>Inertial Measurement Unit</i>	IMU sensor is a combination of accelerometers and gyroscopes. Real time knee angle tracking for avoiding the of risk of knee re-injury
Output	VBR	<i>Mini Vibrating Disk Motor</i>	Receive feedback alerts when knee angle becomes risky
	LED	<i>RGB LED</i>	Feedback to user interaction
	MC Unit	<i>System on Chip (SoC) Microcontroller Unit (MCU)</i>	Microprocessor with integrated Bluetooth Low Energy (BLE) chip
	Power	<i>Flexible Battery (Li-Po)</i>	Flexible battery with wireless charging and a battery life for 2 days
	USB-C	<i>USB-C charging (on main bracelet)</i>	Charge the main bracelet and through wireless charging charge the second one
	DOCK	<i>Charging dock</i>	Wireless power receiver located on both bracelets. When bracelets are in close proximity with the dock start charging them

7.3 Mobile application and user experience

The wearable device combined with the smartphone application, shown in Fig. 7, offers a digital service for both the patient and the PT. This application and hardware ecosystem provide a friendly context for the successful completion of the rehabilitation program and it significantly reduces the risk of possible re-injury. Through this system PTs will get smart insights and data about the current status of the patients. These will allow PTs to make personalised adjustments for each patient and monitor the process of rehabilitation program in order to speed up recovery. The end-users will also be able to monitor their recovery through the smartphone application in real time. By sending motivational notifications, the users will be informed about various events including the necessity of taking breaks during exercises and the appropriate intensity and repetitions for each exercise. The main focus here is to improve user adherence and to avoid injuries. Visualisation techniques including charts and infographics will be used to provide a friendly interface to the actual data.

The experience of using the final design proposal focuses on minimal possible user interaction with targeted interactions. The entire user experience takes place in the main bracelet. This bracelet has a main button which has two basic functions available: 1) the first function is to open and close the device by prolonged pressing and 2) refers to the indication of the three RGB Led. With the touch of a button, the user can see if the exercise is being performed properly, the 3 LEDs adjust their colour to indicate whether the exercise is being performed correctly or not. The colour scale is from green (correct execution/reduced risk of injury) to red (incorrect execution/high risk of injury). With double-tapping the user can see the muscle activity as the LEDs act as a bar graph, while by tapping three times the available amount of battery appears. Through the two mini vibrating disk motors located at specific points in both bracelets, the user receives immediate intuitive feedback when the exercise is performed incorrectly. The vibration function shows the user when he is performing the exercise incorrectly and at a frequency to prevent him from continuing to do so.

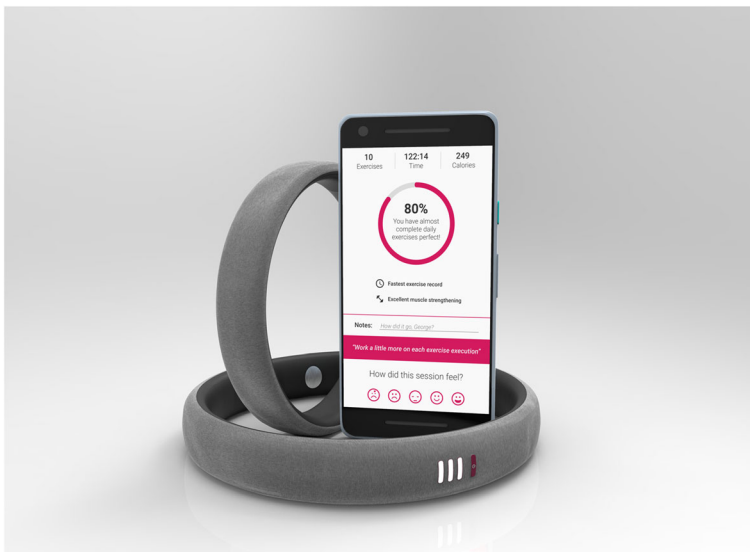


Fig. 7 Bracelets and smartphone application interface

The interface is intuitively designed following Google's Material Design guidelines to provide a reliable and pleasing user experience [50]. The main features of the smartphone application are: *Timeline* activity, in which the user can view the daily rehabilitation program, how many days are left for completing the program as well as the duration of the daily activities (UI1 in Fig. 8). All the activities/exercises must be performed in the order set by the PT. Exercise activity, includes all the necessary elements for tracking the execution of each exercise (UI2&UI3 in Fig. 8). Before each exercise execution, the user must perform the following protocol (UI2 in Fig. 8). First place the bracelets in the right place (on the upper leg and at the calf) with the guidance of the mobile application, wait for bracelet calibration and warm up. After the completion of patient's physical examination, the PT determines through the digital service: a) the initial and final position (knee angle degrees), b) repetitions and c) number of sets that the user can support for each exercise. Additionally, there is an interactive guidance (tutorial) for depicting the implementation of each exercise, live feedback for knee angle degrees and charts for illustrating the knee angle and the muscles activity throughout the duration of the exercise (gradient colours indicate the risk factor). After each daily exercise session execution, a Progress activity appears with exercise stats, tips and feedback collection for better results (UI4 in Fig. 8). Specifically includes, the total number of exercises performed by the user, the total time taken to perform these exercises as well as the total calories burned. There is a progress bar with the completion rate of the daily exercises, daily achievements/records and a motivational message with advice appears to enhance the feeling of self-efficacy depending on the user's performance. Finally, at the bottom of the screen, the user can evaluate the session and how it feels to have completed the daily exercise schedule. Journal activity presents the log of the recovery (daily, weekly, monthly data), how successfully the patient performed the exercises, what is the amount of muscle recovery (strength), the amount of time it took to execute the exercises, motivational feedback such as achievements record and calories burned (UI5 in Fig. 8). Other activities include functionalities such as: Personal Info, Treatment Plan, Virtual PT communication, Wearable settings.

8 Evaluation

The goal of this research is to experimentally evaluate the benefits of a wearable assisting system on the rehabilitation exercise programs. For this reason, a working prototype of the system was employed. The goal of the evaluation was to evaluate the different aspects of the

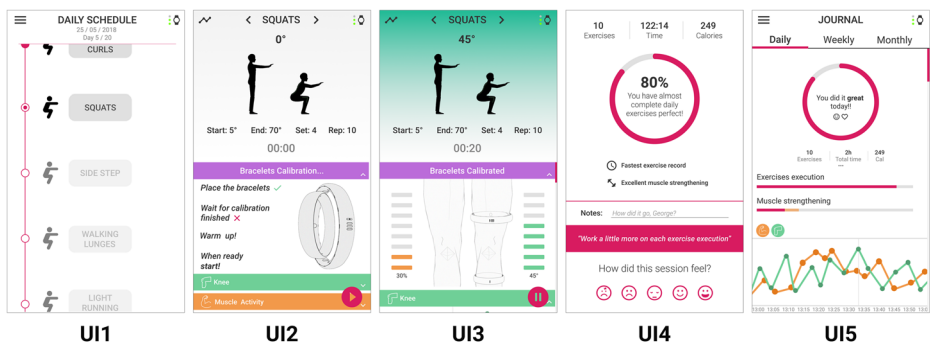


Fig. 8 Concept design of user interfaces

design and development, often iteratively, by detecting and eliminating usability, functionality and design problems. Two formative evaluation sessions were conducted during the different phases of system & product development lifecycle. A number of prototypes for both the wearable device and the smartphone application were designed and evaluated during the following two iterative design/evaluation phases.

8.1 Phase one: mockup preliminary evaluation

At this stage of the project, a fully functional mockup (with physical and digital objects) was developed to monitor the angle of the knee and muscle (quadriceps - hamstring) activity. A smartphone application also designed for digital data viewing. A knee bandage was used for adjusting all the physical components in one complete set. As presented in Fig. 9, the components used included *Arduino Micro*, *MyoWare Muscle Sensor Kit*, *Flex Sensor*, *Bluetooth Sensor HC-05*, *Battery Li-Po 450mAh*. The mockup collected data from the knee, angle and muscle activity, that where transferred to a smartphone application for the user to interact and observe.

The preliminary evaluation was based on a formative study with experts. The main objective was to examine the effectiveness of the preliminary design concept and collect information that will be used later on for the design of the actual prototype. We developed high-fidelity interfaces, running as a native application for Android, for the test subjects to evaluate. The usability testing process was informal between participants and test moderator. A total of seven ($n = 7$) user subjects were recruited to evaluate the prototype, one with anterior cruciate ligament rupture. User subjects performed a specific scenario with a number of tasks ($t = 20$) related to Factors and Features (FF) for wearables design [2, 45].

Evaluation findings showed that the user subjects believe the digital wearable assistive system is useful during the execution of a rehabilitation program. The system enhances the communication between patients and caregivers as the physical prototype helps in monitoring, tracking and disseminating results. The smartphone application motivates users to adhere in their HEPs, primarily because of its user-friendly interface, the non-intrusive interaction techniques employed and the detailed layout of the descriptions of the exercises. A number of issues related to the functionality and the form of the physical product of the early concept were observed. These include inaccuracies in angle calculation by the flex sensor which in turn distracted the users when they performed their exercises. Moreover, visualisation techniques of muscle activity during the exercises were not clear for most users. They requested a clearer interface compared to the summary graphs presenting the overall performance at the end of its program. Most of these issues were further investigated, a new set of design guidelines was introduced, and a redesign of the initial system was performed based on the aforementioned findings and consequent research that was performed. The two versions of the low-fidelity and high-fidelity prototypes are shown in Fig. 10.

8.2 Phase 2: prototyping of the system and evaluation

In this phase, a fully functional and improved prototype in terms of physical and digital form and functionality was developed. A smartphone application was also designed as a companion for guiding the user in setting up the system, controlling HEPs and visualising data. The aim of Phase 2 evaluation was to monitor a fixed rehabilitation scenario focused on specific aspects of the activity, and thus to evaluate the system in terms of its usability and extract information regarding the potential to improve adherence to rehabilitation and the development of self-efficacy.

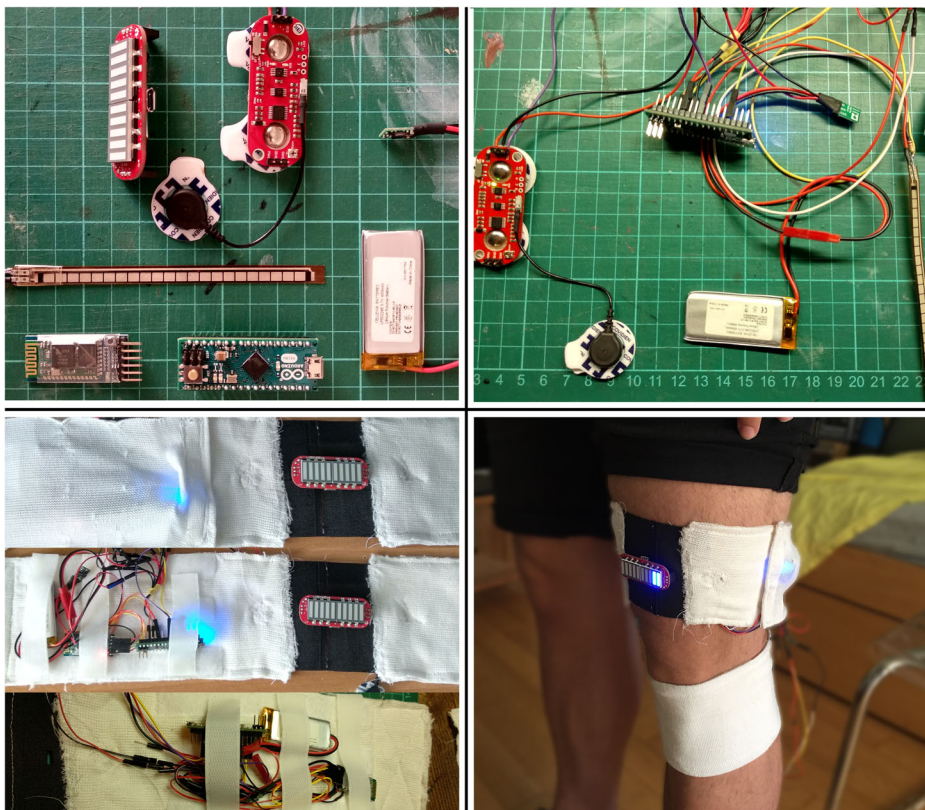


Fig. 9 Prototype assembly and its components including; Top left the MyoWare Muscle Sensor Kit, the Flex Sensor, the Li-Po Battery, the Arduino Micro and the HC-05 Bluetooth Module; Top right all the components connected; Lower left the bandage prototype assembly; Lower right the prototype placed on the user on the area around the quadriceps and hamstring muscles and at the calf area

8.2.1 Methodology of evaluation

To comprehensively understand participants' overall experience, workload and performance, acceptance for possible adoption and the user perspective about the quality of the wearable

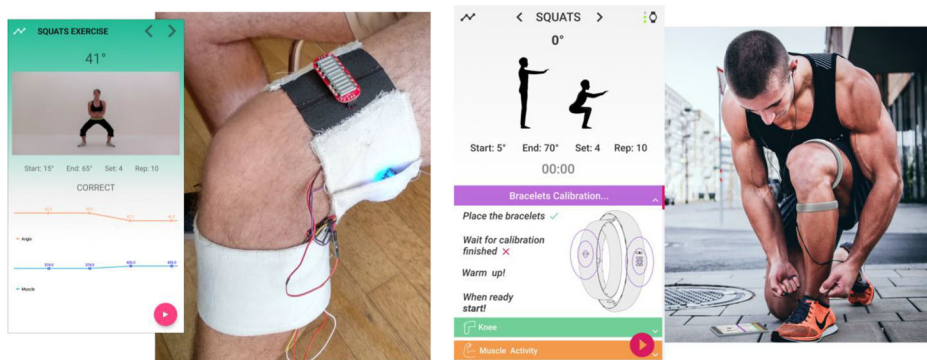


Fig. 10 On the left the low-fidelity prototype and its application interface, on the right the high-fidelity fully working prototype and its interface. (Image on the right is from [51])

prototype, an evaluation framework was developed that combined a set of models and tools as presented in Fig. 11. These included a *Users' Views and Emotions post-questionnaire* (Likert Scale 5) for collecting data regarding the current experience of the users about their interaction with the system, *Nasa TLX* for rating perceived workload and assessing performance in terms of mental demand, physical demand, temporal demand, performance effort and frustration. Based on the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) a post-test questionnaire (Likert Scale 5) was used to evaluate the acceptance and possible adoption while a System Usability Scale (SUS) 10 item questionnaire to provide a “quick and dirty” measurement of the usability of the prototype.

This was a mix of a usability evaluation based on Formative Evaluation, to improve the design of the product and service and refine the development specifications for future work, and an experiment on users' views, intentions, attitudes and emotions about the product and the potential to motivate their adherence to rehabilitation in HEPs through the possible development of self-efficacy.

8.2.2 Materials

Each user was seated on a chair by the moderator for attaching the wearable (two bracelets) to his/her body. The main bracelet was placed on the area around the quadriceps and hamstring muscles while the second one at the calf area. The MyoWare muscle sensor with the EMG (Muscle Sensor Development Kit) was attached to the quadriceps and an LED display positioned above it. On the left side of the bracelet there was the Arduino Micro with the HC-05 Bluetooth module and the Li-Po 450mAh battery. The flex sensor was placed at the back of the knee and between the main and the secondary bracelet. The skin area around the quadriceps was cleaned with rubbing alcohol for better adjustment of the main bracelet and for the more accurate collection of data from the EMG sensor. Then, a mobile phone was given to the users with the high-fidelity Android application installed for performing the two exercises, while another mobile phone was in charge for capturing photos during the session. After the completion of the rehabilitation scenario, a laptop was given to the users for completing the NASA Task Load Index (TLX) as well as the questionnaire for the System Usability Scale (SUS) and the Users' Views and Emotions post-evaluation questionnaire. A few days later an online post-evaluation study was launched for evaluating technology acceptance and adoption based on UTAUT2 for the specific group of users.

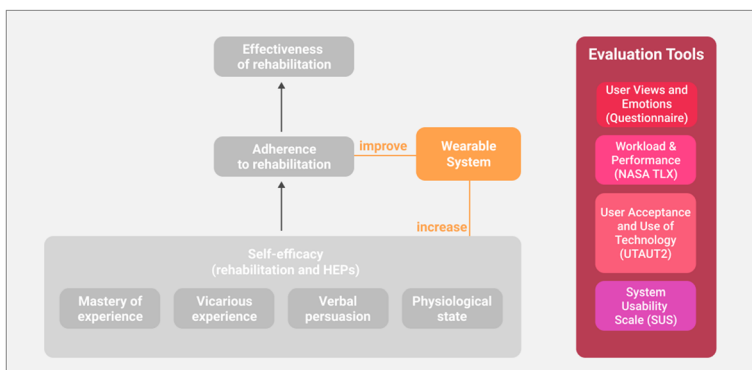


Fig. 11 Evaluation framework

8.2.3 Subjects

Fifteen random user subjects ($n = 15$, female = 4, male = 11) were recruited to participate to the evaluation of Phase 2. The participant group had a moderate to strong daily sports activity level and their ages were spread between 17 and 25 years. Ten of the users ($n = 10$) had previous experience with wearable technologies and used a device for monitoring exercise activity. Five ($n = 5$) had a modest level of experience, but neither of them owned a wearable health device or system in the past. Nine of the users ($n = 9$) had high self-efficacy and no hesitation to complete exercise/tasks presented to them. Six of them ($n = 6$) presented low self-efficacy and were hesitant to try new exercises/tasks. None of the users had used a similar or the system in the past, nor had ever participated to user tests regarding their health problem. In Table 2 we summarise participant characteristics.

8.2.4 Measuring instruments and data analysis

During the evaluation the moderator recorded users' views, intentions and perceptions towards wearables, bracelets, mobile applications and rehabilitation exercises. In addition, the moderator defined views as to how users perceived the rehabilitation program, regardless of their

Table 2 Participants' characteristics

Participants' characteristics	Number of participants
Type of participant	
Strongly active in sports activities	10
Moderate active in sports activities	5
Total number of participants	15
Frequency of sports activity	
Rare: 0–4 times per month	5
Frequently: 5–9 times per month	7
Very frequently: 10 or more times per month	3
Location of exercises	
Home	6
Gym	7
Outside	2
Use of a device for monitoring exercises	
Smartwatch	2
Activity tracker	3
Health wearable tracker	1
Smartphone	4
Self-efficacy	
High	9
Low	6
Age	
17–25	15
Gender	
Female	4
Male	11

evaluations of these perceptions. Furthermore, the moderator monitored and evaluated user attitudes towards the product in dimensions such as good/bad, harmful/beneficial, pleasant/unpleasant, and likeable/unlikeable. While at the same time considered motivational factors that influenced user behavior. To record the workload of each user the NASA-TLX was used. This subjective workload assessment tool allowed users to perform subjective workload assessments when using the various human-machine interface system. An overall workload score was derived from the NASA-TLX based on a weighted average of ratings on six subscales: mental demand, physical demand, temporal demand, performance, effort and frustration.

The SUS was used to measure the usability of the system. It consisted of a 10-item questionnaire with five response option for respondents, from Strongly agree to Strongly disagree. The participant's scores for each question were converted to a new number, added together and then multiplied by 2.5 to convert the original scores of 0–40 to 0–100. A SUS score above a 68 would be considered above average.

A Likert emotions scale was given to the users based on the following semantically differential emotions: happy-sad, confused-confident, bored-interested, disappointed-satisfied, and undetermined-determined to record views and intentions for the overall interaction.

The online post-evaluation survey based on UTAUT2 was administered a few days later to the specific group of participants. Based on their previous experience with the actual evaluation the participants were asked a set of questions identical to the ones presented by [52] for evaluating seven factors that affect user's intention to adopt wearable technologies. These include factors of *Perceived Benefit* such as *Performance Expectancy* and *Hedonic Motivation*, *Perceived Health Threat* such as *Perceived Vulnerability* and *Severity* and other factors such as *Effort Expectancy*, *Functional Congruence*, *Self-efficacy* (for using the system), *Social Influence* and *Perceived Privacy Risk*.

8.2.5 Procedure

In the beginning of the evaluation, the users were informed that they were going to participate in a voluntary activity about a health wearable assisting system. The evaluation protocol was based on the Greek National and European Code of Ethics approved by the Deontology Committee of the University of the Aegean (reference number for the approval: 2nd /16.10.2019). Before the conducted study, each participant was requested to complete a form of consent for participating to the study. Subsequently, an introduction of the project took place and then participants followed a structured rehabilitation scenario that consisted of two basic exercises. The first exercise was the side stepping (initial position = 5° , final position = 55° , set = 4, repetitions = 5) while the second one was the squats exercise (initial position = 2° , final position = 90° , set = 4, repetitions = 5). The scenario included specific tasks which involved interactions with the wearable health system: interact with the physical product, interact with the mobile application, reach the final position, evaluate system feedback, check the accuracy.

After the completion of the rehabilitation scenario the NASA-TLX was given to the users. Next a SUS questionnaire was answered by all participants followed by the Users' Views and Emotions evaluation test. Some participants were unable to answer all questions without assistance from the moderator, especially those that involved empathic readings and technical skills. The duration of each evaluation session was about 20–30 min.

9 Results and discussion

Most of the users participated for the first time in a controlled evaluation environment and that played an important role in their commitment to complete the evaluation. All of them found the tests interesting and completed them in the planned timeframe. Most users ($n = 13$) had no issues in grasping the main concepts related to the system's functionality and scenario related terminology while two users ($n = 2$) needed further assistance with specific scenario tasks (training exercises execution in relation to system functionality).

The evaluation procedure collected statistical data from each different tool. For the Users' Views and Emotions questionnaire as shown in Table 3, the participants exhibited positive emotions and expressed constructive comments about the system usage.

For most cases ($n = 14$) the immediate feedback from the relation between the physical product and the mobile application made them feel more happy ($M = 4.13$, $SD = .640$), confident ($M = 3.93$, $SD = .884$), interested ($M = 4.33$, $.617$), satisfied ($M = 4.40$, $SD = .632$) as well as more determined ($M = 3.47$, $SD = .640$) to complete the rehabilitation scenario successfully (100% for $n = 15$).

However, in a specific execution of the evaluation scenario, data transfer rates related to muscle activity and knee angle were lower than expected (greater than 1 s) due to connectivity issues. This made the specific user subject ($s = 12$, in Fig. 12), feel less confident and undetermined as he could not make a concrete decision in time, of whether he was doing the exercise correctly.

It is obvious from answers given that the subject exhibited such emotions and lowered his expectations about using the system. Subject's confidence score was 2 (outlier), when the mean value for the group was $M = 3.93$ with a std. deviation of $SD = 0.884$ while satisfaction was 3 (outlier) when the mean value for the group was $M = 4.40$ with a $SD = 0.632$. This has been verified through triangulation with the SUS score where on most critical statements (2, 4, 6, 8 and 10) the specific user answered negatively (lower than 2 out of 5), and the UTAUT2 score was lower (mean 3.2) compared to the group average (mean 3.593). All other users expressed satisfactory feelings after completing each rehabilitation scenario. This means that performance issues and failure of the wearable system to archive performance expectancy is heavily associated with individuals' appreciation of wearable technologies as it is shown in Fig. 13.

The overall SUS score was ($SUS = 80.3$) with a standard deviation $SD = 3.763$. The average scores for each statement of the questionnaire was $St1 = 3.86$, $St2 = 1.4$, $St3 = 4.26$, $St4 = 1.33$, $St5 = 3.6$, $St6 = 2$, $St7 = 4.46$, $St8 = 1.33$, $St9 = 4.06$ and $St10 = 2.06$. The strongly active in sports activity users ($s2$, $s6$, $s7$, $s10$, $s11$) were positive about the usefulness of such an assistive device for monitoring and being a companion for their rehabilitation programs.

To calculate the workload of each user, the NASA-TLX was used and measured mental demand (md), physical demand (pd), temporal demand (td), performance (pe), effort (ef) and

Table 3 Mean and standard deviation of users' views and emotions questionnaire

Participants views and emotions	Mean	Std. deviation
Happy	4.13	0.640
Confident	3.93	0.884
Interested	4.33	0.617
Satisfied	4.40	0.632
Determined	3.47	0.640

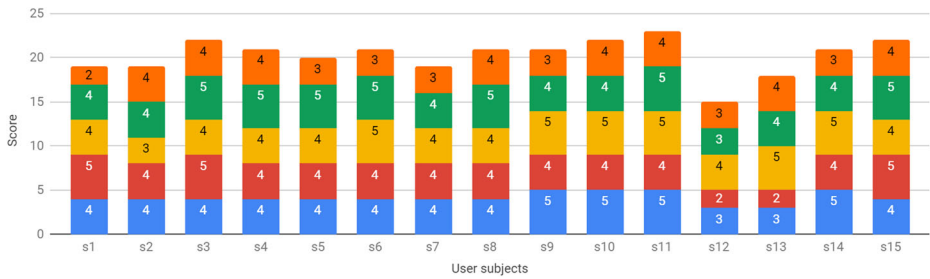


Fig. 12 Users' views and emotions questionnaire answers

frustration (fr). The mean values for each factor was: $M_{md}=15.6$, $M_{pd}=26.3$, $M_{ld}=18.6$, $M_{pe}=27$, $M_{ef}=22.3$ and $M_{fr}=12$. The average subjective task load is shown in Fig. 14. Participants had an average task load of $M=22.993$ ($SD=10.07$). It is important to note that from qualitative feedback we revealed three significant subgroups of users within the main sample, those ($n=5$: s2, s6, s7, s10, s11) that have been training frequently (more than once a week) and thus maintain a very healthy overall lifestyle, those ($n=5$: s1, s3, s5, s14, s15) that exercise occasionally and try to maintain a relatively healthy overall lifestyle and those ($n=5$: s4, s8, s9, s12, s13) that do not exercise and do not systematically maintain a healthy lifestyle. It is also important to identify that the latter subgroup had a number of participants (s4, s8 and s9) that had performed significantly lower in terms of performance, physical demand and scored much higher on effort and frustration (Overall Nasa TLX score with $M=31.168$, $SD=5.467$).

This subgroup of users also had the lower UTAUT2 score in terms of wearable technology acceptance and intention to adopt ($M=3.553$). On the other hand, the first subgroup had a higher overall Nasa TLX score with $M=17.88$, $SD=5.467$, and a better UTAUT2 $M=3.673$ score but not significantly different. This possibly means that participants that maintain a healthy lifestyle and exercise frequently are more likely to adopt a wearable health system and are much more determined to adhere to their HEPs and potentially achieve self-efficacy. Surprisingly enough participants with low self-efficacy although they scored low in terms of workload and their performance was almost half compared to the other subgroup, they also exhibited strong interest in adopting a wearable health system and strongly believed that such a system can potentially assist them to adhere to their rehabilitation program (HEPs) and potentially achieve self-efficacy.

Supported also in terms of qualitative feedback, most user subjects ($n=13$) stated that had, still have or currently feel low in terms of self-efficacy in fully completing a rehabilitation program and believed that this system could increase their self-efficacy as well as improve their adherence to HEPs.

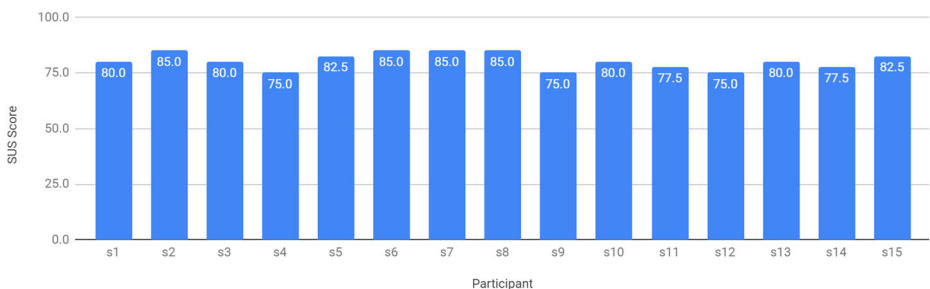


Fig. 13 SUS score for each participant

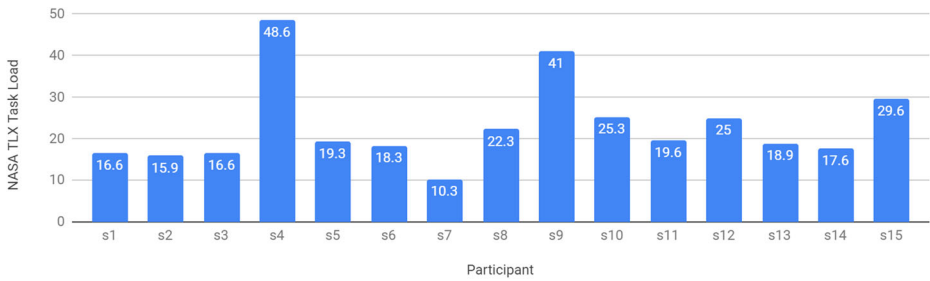


Fig. 14 NASA TLX task load values

10 Conclusion and future work

In this paper, we described the design, the formative evaluation and an experiment based on a wearable health system that aims to assist people with CL rupture during their rehabilitation in HEPs. We presented a set of requirements, the design decisions, the prototype of both the physical product and its software ecosystem and an evaluation with users. Throughout the iterative process of design and evaluation, we identified a set of new issues that need to be improved, are related to the physical product, the interactions, and the smartphone companion application.

In this early version of the wearable system, we identified that system performance is closely related to user anticipation of personal performance expectancy in terms of their rehabilitation progress. The hedonic motivation that derives from the pleasure or satisfaction to interact or own a wearable health system that can potentially assist users in achieving their health goals, positively affect individuals' intention to first adopt and consequently use for rehabilitation. Usability also plays an important role in the adoption and later use in such scenarios.

It still remains an important task to better identify the role of the caregivers and the interface components and functionalities for them to participate remotely in the rehabilitation program by managing, observing and assessing patients' activities. It is important to further investigate motivational techniques and educational mechanisms for supporting self-efficacy and improving adherence during HEPs.

In further longitudinal research, the intention is to repeat the experiment based on an improved version of the wearable system and with a larger group of participants with various conditions related to cruciate ligament injuries and in collaboration with caregivers. We plan to implement a dynamic engine for creating and customising HEP scenarios and do better data analytics based on machine learning. Moreover, we need to further study the effects of the wearable health system in post-injury scenarios and in combination with gamification techniques to better engage users in a healthier and more active lifestyle. To conclude, our plans are to investigate data privacy and security issues, explore different types of hardware in terms of sensors and microcontrollers, energy efficiency for battery-powered devices, and networking technologies for low-bandwidth scenarios.

References

1. Pastorino M, Arredondo M, Cancela J, Guillen S (2013) Wearable sensor network for health monitoring: the case of Parkinson disease. *J Phys Conf Ser* 450:012055. <https://doi.org/10.1088/1742-6596/450/1/012055>
2. Partheniadis K, Stavarakis M (2018) Designing a smart ring and a smartphone application to help monitor, manage and live better with the effects of Raynaud's phenomenon. In: Guidi B, Ricci L, Calafate C et al (eds) *Smart objects and technologies for social good*. Springer International Publishing, pp 1–10

3. Bonato P (2005) Advances in wearable technology and applications in physical medicine and rehabilitation. *J NeuroEng Rehabil* 2:2. <https://doi.org/10.1186/1743-0003-2-2>
4. Peek K, Carey M, Mackenzie L, Sanson-Fisher R (2018) Patient adherence to an exercise program for chronic low back pain measured by patient-report, physiotherapist-perception and observational data. *Physiother Theory Pract* 0:1–10. <https://doi.org/10.1080/09593985.2018.1474402>
5. Picha KJ, Howell DM (2018) A model to increase rehabilitation adherence to home exercise programmes in patients with varying levels of self-efficacy. *Musculoskeletal Care* 16:233–237. <https://doi.org/10.1002/msc.1194>
6. Jack K, McLean SM, Moffett JK, Gardiner E (2010) Barriers to treatment adherence in physiotherapy outpatient clinics: a systematic review. *Man Ther* 15:220–228. <https://doi.org/10.1016/j.math.2009.12.004>
7. Brown JR, Trojian TH (2004) Anterior and posterior cruciate ligament injuries. *Prim Care* 31:925–956. <https://doi.org/10.1016/j.pop.2004.07.004>
8. Kaeding CC, Léger-St-Jean B, Magnussen RA (2017) Epidemiology and diagnosis of anterior cruciate ligament injuries. *Clin Sports Med* 36:1–8. <https://doi.org/10.1016/j.csm.2016.08.001>
9. Raines BT, Naclerio E, Sherman SL (2017) Management of anterior cruciate ligament injury: what's in and what's out? *Indian J Orthop* 51:563–575. https://doi.org/10.4103/ortho.IJOrtho_245_17
10. LaBella CR, Hennrikus W, Hewett TE, Council on Sports Medicine and Fitness, and Section on Orthopaedics (2014) Anterior cruciate ligament injuries: diagnosis, treatment, and prevention. *Pediatrics* 133:e1437–e1450. <https://doi.org/10.1542/peds.2014-0623>
11. Micheo W, Hernández L, Seda C (2010) Evaluation, management, rehabilitation, and prevention of anterior cruciate ligament injury: current concepts. *PM R* 2:935–944. <https://doi.org/10.1016/j.pmrj.2010.06.014>
12. BruceBlaus (2015) Cruciate ligaments. Wikimedia Commons
13. Ireland ML (2002) The female ACL: why is it more prone to injury? *Orthop Clin North Am* 33:637–651
14. Chan DK, Lonsdale C, Ho PY, Yung PS, Chan KM (2009) Patient motivation and adherence to postsurgery rehabilitation exercise recommendations: the influence of physiotherapists' autonomy-supportive behaviors. *Arch Phys Med Rehabil* 90:1977–1982. <https://doi.org/10.1016/j.apmr.2009.05.024>
15. Kolt GS, McEvoy JF (2003) Adherence to rehabilitation in patients with low back pain. *Man Ther* 8:110–116
16. Bassett SF (2003) The assessment of patient adherence to physiotherapy rehabilitation. *N Z J Physiother* 31:60–66
17. Bandura A (1982) Self-efficacy mechanism in human agency. *Am Psychol* 37:122–147. <https://doi.org/10.1037/0003-066X.37.2.122>
18. Bandura A (1997) Self-efficacy: the exercise of control. W H Freeman/Times Books/ Henry Holt & Co, New York
19. Kim J, Campbell AS, de Ávila BE-F, Wang J (2019) Wearable biosensors for healthcare monitoring. *Nat Biotechnol* 37:389–406. <https://doi.org/10.1038/s41587-019-0045-y>
20. Di Rienzo M, Rizzo F, Parati G et al (2005) MagIC system: a new textile-based wearable device for biological signal monitoring. Applicability in daily life and clinical setting. *Conf Proc Annu Int Conf IEEE Eng Med Biol Soc* 7:7167–7169. <https://doi.org/10.1109/IEMBS.2005.1616161>
21. Boulemtafes A, Badache N (2020) Sensing platforms for prototyping and experimenting wearable continuous health monitoring systems: a quick starter point guide. *Inc Internet Things Healthc Appl Wearable Devices*:212–223. <https://doi.org/10.4018/978-1-7998-1090-2.ch013>
22. Guk K, Han G, Lim J et al (2019) Evolution of wearable devices with real-time disease monitoring for personalized healthcare. *Nanomaterials* 9:813. <https://doi.org/10.3390/nano9060813>
23. Dias D, Paulo Silva Cunha J (2018) Wearable health devices-vital sign monitoring. *Syst Technol Sens* 18. <https://doi.org/10.3390/s18082144>
24. Heintzman ND (2015) A digital ecosystem of diabetes data and technology: services, systems, and tools enabled by Wearables, sensors, and apps. *J Diabetes Sci Technol* 10:35–41. <https://doi.org/10.1177/1932296815622453>
25. Patel S, Park H, Bonato P et al (2012) A review of wearable sensors and systems with application in rehabilitation. *J NeuroEngineering Rehabil* 9:21. <https://doi.org/10.1186/1743-0003-9-21>
26. Mukhopadhyay SC (2015) Wearable sensors for human activity monitoring: a review. *IEEE Sensors J* 15: 1321–1330. <https://doi.org/10.1109/JSEN.2014.2370945>
27. Darwish A, Hassanien AE (2011) Wearable and implantable wireless sensor network solutions for healthcare monitoring. *Sensors* 11:5561–5595. <https://doi.org/10.3390/s110605561>
28. Li J, Ma Q, Chan AHS, Man SS (2019) Health monitoring through wearable technologies for older adults: smart wearables acceptance model. *Appl Ergon* 75:162–169. <https://doi.org/10.1016/j.apergo.2018.10.006>
29. Manas M, Sinha A, Sharma S, Mahboob MR (2019) A novel approach for IoT based wearable health monitoring and messaging system. *J Ambient Intell Humaniz Comput* 10:2817–2828. <https://doi.org/10.1007/s12652-018-1101-z>
30. Behar JA, Oster J, Vos MD, Clifford GD (2019) Wearables and mHealth in mental health and neurological disorders. *Physiol Meas* 40:070401. <https://doi.org/10.1088/1361-6579/ab2057>

31. Ahn JW, Ku Y, Kim HC (2019) A novel wearable EEG and ECG recording system for stress assessment. *Sensors* 19:1991. <https://doi.org/10.3390/s19091991>
32. Malasinghe LP, Ramzan N, Dahal K (2019) Remote patient monitoring: a comprehensive study. *J Ambient Intell Humaniz Comput* 10:57–76. <https://doi.org/10.1007/s12652-017-0598-x>
33. Munro BJ, Campbell TE, Wallace GG, Steele JR (2008) The intelligent knee sleeve: a wearable biofeedback device. *Sens Actuators B Chem* 131:541–547. <https://doi.org/10.1016/j.snb.2007.12.041>
34. Noyes FR, Moar PA, Matthews DS, Butler DL (1983) The symptomatic anterior cruciate-deficient knee. Part I: the long-term functional disability in athletically active individuals *J Bone Joint Surg Am* 65:154–162
35. Ananthanarayan S, Sheh M, Chien A et al (2013) Pt Viz: towards a wearable device for visualizing knee rehabilitation exercises. In: *Proceedings of the SIGCHI conference on human factors in computing systems*. ACM, New York, pp 1247–1250
36. Haladjian J, Hodaie Z, Xu H et al (2015) KneeHapp: a bandage for rehabilitation of knee injuries. In: *Adjunct proceedings of the 2015 ACM international joint conference on pervasive and ubiquitous computing and proceedings of the 2015 ACM international symposium on wearable computers*. ACM, New York, pp 181–184
37. England N, Islam S, Licht H et al (2018) Sensor embedded knee sleeve for post-operative ACL patients. In: *2018 systems and information engineering design symposium (SIEDS)*, pp. 165–170
38. Qiu Y, Li KM, Neoh EC, et al (2017) Fun-knee™: a novel smart knee sleeve for total-knee-replacement rehabilitation with gamification. In: *2017 IEEE 5th international conference on serious games and applications for health (SeGAH)*, pp. 1–8
39. Goodwin K (2009) *Designing for the digital age: how to create human-centered products and services*. Wiley Publishing
40. Reimann R, Cooper A, Cronin D, Noessel C (2014) *About face: the essentials of interaction design*, 4th edn. Wiley, Indianapolis
41. Bachmann C, Oesch P, Bachmann S (2017) Recommendations for improving adherence to home-based exercise: a systematic review. *Phys Med Rehabil Kurortmed*. <https://doi.org/10.1055/s-0043-120527>
42. Essery R, Geraghty AWA, Kirby S, Yardley L (2017) Predictors of adherence to home-based physical therapies: a systematic review. *Disabil Rehabil* 39:519–534. <https://doi.org/10.3109/09638288.2016.1153160>
43. Gemperle F, Kasabach C, Stivoric J et al (1998) Design for wearability. In: *Proceedings of the 2nd IEEE international symposium on wearable computers*, pp 116–122
44. Motti VG, Caine K (2014) Human factors considerations in the Design of Wearable Devices. *Proc Hum Factors Ergon Soc Annu Meet* 58:1820–1824. <https://doi.org/10.1177/1541931214581381>
45. Partheniadis K, Stavrakis M (2018) Design and evaluation of a digital wearable ring and a smartphone application to help monitor and manage the effects of Raynaud's phenomenon. *Multimed Tools Appl* 78: 3365–3394. <https://doi.org/10.1007/s11042-018-6514-3>
46. Kordatos G, Stavrakis M (2018) Preliminary design of a wearable system to increase adherence to rehabilitation programmes in acute Cruciate Ligament (CL) rupture. *EAI, ACM, Bologna*
47. Boulemtafes A, Badache N (2016) Wearable health monitoring systems: an overview of design research areas. In: *Lazakidou AA, Zimeras S, Iliopoulou D, Koutsouris D-D (eds) mHealth ecosystems and social networks in healthcare*. Springer International Publishing, Cham, pp 17–27
48. Fensli R, Boisen E (2008) Human factors affecting the patient's acceptance of wireless biomedical sensors. In: *Biomedical engineering systems and technologies*. Springer, Berlin, Heidelberg, pp 402–412
49. Parette P, Scherer M (2004) Assistive technology use and stigma. *Educ Train Dev Disabil* 39:217–226. <https://doi.org/10.2307/23880164>
50. Design. In: *Mater. Des*. <https://material.io/design/>. Accessed 10 Apr 2019
51. Redl A (2019) Sprinting in Vienna, on Unsplash, <https://unsplash.com/photos/d3bYmnZ0aank>
52. Gao Y, Li H, Luo Y (2015) An empirical study of wearable technology acceptance in healthcare. *Ind Manag Data Syst* 115:1704–1723. <https://doi.org/10.1108/IMDS-03-2015-0087>

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.



George Kordatos is a designer and UI/US engineer from Greece. He recently received his postgraduate degree in Product and System Design Engineering from the University of Aegean, Greece. He currently works as a freelancer who designs and develops interactive systems and products with state-of-the-art technologies and materials for the human wellbeing.



Modestos Stavrakis is a Lecturer in the Department of Products and Systems Design Engineering at the University of the Aegean. He holds a PhD in Design from the same university, an MSc in Computer Aided Graphical Technology Applications and a BA (first class hon) in C. Visualisation from the University of Teesside (UK). His current research interests include interaction design and user experience, design theory and design methodologies, wearable systems, multimedia design, collaborative systems, assistive technologies, digital media design and digital arts.