Requirement Specification for a Remote Monitoring System to Support the Management of Vascular Diseases

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Abstract. The development of smart wearable systems for healthcare monitoring has driven extensive efforts from academia and industry in recent years. The present work sought to identify requirements which are essential for designing a smart wearable remote monitoring system to support the management of selected vascular diseases. To this aim, we reviewed the current research and developments on smart wearable systems for monitoring patients with intermittent claudication (IC), venous ulcers and diabetic foot ulcers (DFU), and a set of functional and technical requirements were extracted and described with the help of clinicians, after studying related projects, clinical scenarios, and healthcare needs. Regarding IC, the requirements focused on measuring the walking capacity and determining the moment at which ambulation cannot continue due to pain. For venous ulcers, sensors will be used to monitor the time spent in a given body position and the pressure applied by compression products. Plantar pressure distribution while standing and temperature will be the main monitored variables for DFU, measured with force and temperature sensors embedded in in-shoe insoles. Coaching services will inform patients and clinicians about the patients' health status, behaviors to adopt and other insights for decision-making support. These users will interact and receive feedback from the system through mobile and web applications. The main innovation aspect of the proposed system consists in a set of intelligent services that allow the smart coaching of patients and healthcare professionals, promoting healthy behaviors and increasing the involvement in treatments, addressing current gaps and needs.

Keywords: mHealth, Personalized Healthcare, Vascular Diseases, Remote Monitoring, Literature Review

1. Introduction

Technological advances have opened several opportunities towards a personalized healthcare, based upon the patient's clinical information and health status [1]. As an example of this trend, there have been increasing efforts from academia and industry regarding the research and development of smart wearable systems for the remote monitoring of patients' health condition, in response to the current health challenges posed by populations ageing, namely the greater levels of disability and chronic diseases' prevalence. The role of such systems is to combine the routine or living environment with the physical and cognitive limitations of those suffering from disabilities or other diseases, improving their health status and quality of life and minimizing the risk of further undesirable outcomes. In general, smart wearable systems have been developed to support independent living for the elderly, postoperative rehabilitation, as well as for the assessment or improvement of individual health, technical or sportive abilities [2].

A smart wearable system should include a variety of implantable or wearable devices, including sensors, smart fabrics, actuators, power supplies, wireless communication networks, processing units, multimedia devices, software, intuitive user interfaces, algorithms for collecting and processing the data, and decision support functionalities [4]. These systems should also enable the measurement of vital signs and physiological parameters (e.g., body and skin temperature, heart rate, respiration rate, blood pressure, blood oxygen saturation (SpO2), electrocardiograms (ECG) or electroencephalograms (EEG)) and forward these measurements via a wireless sensor network, either to a central node or directly to a healthcare setting [4], allowing the medical staff to manage the patients according to the transmitted data. Real-time data collection and processing and personalized feedback to healthcare professionals and patients are thereby key benefits from integrating smart wearable systems into the clinical and daily routine. Patients can typically wear the devices during regular daily life whereas healthcare professionals monitor their condition in real-time for longer periods than it is possible in healthcare facilities.

Amongst the most burdensome conditions that can be addressed by smart wearable systems, vascular diseases such as intermittent claudication (IC), venous ulcers, and diabetic foot ulcers (DFU) are clinically relevant in the sense that they can lead to considerable mobility and quality of life loss, often requiring frequent follow-up and hospitalizations due to their severity [5,6]. Traditional treatment plans for the aforementioned diseases are usually defined according to the patient's clinical condition and comprise pharmacological and physical activity interventions aimed at controlling the disease progression and improving the overall health status. Nevertheless, such follow-ups are done sporadically due to the constraints to monitor the patient's condition outside of healthcare facilities. As the continuous monitoring of these patients has proven to lead to an improvement of their overall health status [5,7,8], technological solutions addressing the current difficulties in remotely monitoring these patients can positively impact the treatment effectiveness and consequently the quality of life and health status for these patients.

In this paper, we present the requirements for a system focusing on non-invasive remote monitoring of patients suffering from IC, venous ulcers and DFU by providing a set of intelligent services to evaluate the patient's adhesion and response to therapeutic interventions, and provide smart coaching of patients and health professionals. We identified the requirements which are relevant for designing a smart wearable remote monitoring system to support the management of the targeted vascular diseases with the help of clinicians, also providing a review of existing or ongoing related projects. The paper is organized as follows: section 2 describes materials and methods; section 3.1 describes the current status of research and developments of smart wearable systems in the context of the selected vascular diseases; section 3.2 describes the technical and functional requirements for the proposed solution; section 4 presents a discussion of the requirements in comparison to the current state-of-the-art and needs, highlighting the clinical benefits of the proposed system; and section 5 draws the main conclusions.

1. Methods

The present work was based on a descriptive and development design. First, a review of the current research and developments of smart wearable systems targeting the selected diseases was performed. The SCOPUS database was used to identify publications on projects related to DFU, IC and venous ulcers. Documents were screened based on whether they present or apply a smart wearable system applicable to these diseases. Works either focusing on systems' development, real application or under clinical validation were considered. Second, the necessary requirements and capabilities for designing a wearable smart system for the selected vascular diseases were defined with the help of clinicians to satisfy the most relevant healthcare needs and current gaps, considering the specific clinical scenarios. Clinicians' feedbacks were obtained from virtual periodic meetings with four physicians working in the Angiology and Vascular Surgery department of a Portuguese public hospital. Furthermore, one in-situ visit to a Portuguese private hospital was scheduled and guided by a physician to follow the compression therapy routine for venous ulcers patients. The in-situ visit for venous ulcers was needed to define how sensors should be developed in order to be integrated to the compressive apparatus that is typically applied in patients suffering from this condition.

2. Results

3.1. State of the Art

A total of 37 studies were retained during the literature review process. Most of the studies focused on DFU (n=18), followed by IC (n=9) and leg venous ulcers (n=5). A total of 5 studies targeted both, DFU and venous ulcers. According to the literature, there are a several projects that have sought to propose and develop smart wearable systems for delivering personalized healthcare to patients suffering from vascular diseases [9,10,11]. In the case of IC, several works were carried out with an activity monitor, working as a sensor to determine the number of steps per day/month, peak walking time (PWT), which is defined as the walking time at which ambulation cannot continue due to maximal pain, and claudication onset time (COT), defined as the walking time at which the subjects first experienced pain. The main objective of these works was to improve the walking capacity of the individuals, and consequently, their quality of life [12-17]. For venous ulcers, the main variable considered was the pressure, measured with force sensors, mostly aimed at developing a device that could monitor the pressure applied by compression products, or even help to improve this pressure by the possibility of the patient adjusting it [18,19]. The main variables evaluated in the DFU case were pressure and temperature, carried out with force and temperature sensors mainly embedded in socks or insoles. The objective was to inform the patient and clinician about the real status of the ulcer, or even prevent the occurrence of these, giving alerts, when necessary, through mobile phone applications [20-25]. Overall, current projects focused mostly on the remote monitoring of clinical information and on the presentation of personalized recommendations regarding physical exercises the patients can perform. Coaching level functionalities concerning the disease management and recommendations on which treatments or interventions to follow are still scarce, as well as the use of user interfaces aimed to support healthcare professionals in the clinical decision-making process. Furthermore, there is a lack of clinical validation on the impact of the systems to assess the improvement on health outcomes or quality of life.

2.2. Requirement Specification

Defining an appropriate scenario is required for the early phase of requirement specification. For this purpose, the clinical scenarios for the three selected vascular diseases were studied and the most relevant healthcare needs and desired capabilities of the smart system were defined with the help of clinicians. The system requirements were divided into functional and technical requirements. The functional requirements specify the services to be provided by the smart system, including user interfaces, user interaction with the system, parameters to be measured, feedback and response to specific inputs. Technical requirements correspond to the technical issues that should be addressed and implemented to successfully achieve the completion of the project and fulfill the functional requirements, including the sensors to be developed (Table 1). Further information regarding the architecture can be found in [26]. The list of functional requirements was defined as follows:

1. To enable the creation of personalized coaching plans and goals: The system should allow physicians to create personalized treatment plans (e.g., definition of intermediate and final goals).

2. To compute metrics for treatment plan progression and goals assessment: The system should compute and enable historical data comparison throughout the treatment of patients to support treatment plan and goals assessment.

3. To display personalized feedback for health care professionals: The system should display feedback/clinical insights to aid health care professionals during the clinical decision making.

4. To display personalized feedback and smart coaching for patients: The system should provide real-time information to the patients on their current health status and provide smart coaching to help them to adopt adequate healthy behaviors and treatment plan compliance.

5. To ensure privacy and security of patient data: The system should comply with current data privacy and security regulations for collection, transmission, and storage of clinical and other sensitive patient data.

6. To enable the measurement of key clinical parameters related to intermittent claudication: The system should enable the measurement in daily routine of parameters related to IC, namely movement variables such as walking distance in meters, speed, slope, frequency and duration of pauses to rest, heart rate and blood oxygen saturation levels (SpO2).

7. To enable physical measurements of the slope of the walking surface: The system should enable measurements of the slope of the walking surface for patients with IC, as well as the percentage of walking distance performed with and without slope.

8. To enable the report of pain episodes duration: The system should enable patients with IC and venous ulcers to report the moment when the pain episodes start and finish.

9. To enable the report of movement interruption due to pain: The system should enable patients with IC to report when their movement is interrupted due to pain.

10. To enable the report of pain site: The system should enable patients with IC to report the pain site.

11. To present alerts to the patients based upon clinical guidelines/ treatment plans: The system should present alert messages whenever the compliance with the treatment plan is at risk.

12. To enable the measurement of key parameters related to the venous ulcers: The system should enable the measurement in daily routine of key parameters related to venous ulcers, namely walking distance in meters, orthostatic blood pressure, blood pressure after lying (decubitus) and sitting, and slope.

13. To enable the measurement of key parameters related to diabetic foot ulcers: The system should enable the measurement in daily routine of the plantar pressure and temperature at several points of the foot, either when the patient is at rest (idle), sitting, laying (decubitus) and in movement, as well as mobility-related parameters, such as walking distance and slope.

14. To allow the measurement and monitoring of the Absolute Claudication Distance (ACD) or maximum walking distance: The system should enable the measurement and monitoring of the ACD, or maximum walking distance to verify clinical goal achievements

15. To allow the measurement and monitoring of the venous ulcer healing time: The system should enable the measurement and monitoring of the venous ulcer healing time to verify clinical goal achievements.

16. To allow the measurement and monitoring of the Diabetic foot ulcer (DFU) healing time: The system should enable the measurement and monitoring of the DFU healing time to verify clinical goal achievements.

Table 1. Technical requirements for a smart wearable system for monitoring vascular diseases.

Technical requirement	**Requirement description**	**Origin (Functional requirements)**
User interface usability	The system should allow end-users to visualize health information, interact and receive feedback by means of intuitive user interfaces.	(1),(3),(4),(8),(9),(10),(11)
Minimum of two languages should be supported.	At least English and Portuguese languages should be supported for increased accessibility.	(1),(3),(4),(8),(9),(10),(11)
Data encryption for transmission and storage	Data should be encrypted during transmission and storage using standard security protocols (e.g., TLS - Transport Layer Security, FHIR - Fast Healthcare Interoperability Resources standard)	(5)
Activity monitor system for IC	The ecosystem should include an activity monitor system for measuring IC parameters by means of sensors embedded in ankle bands, designed to be easy-to-use and comfortable.	(6),(7),(14)
Wireless wearable pressure sensing system	The ecosystem should include a wireless wearable pressure sensing system for measuring parameters related venous ulcers. The sensors should be integrated into a comfortable smart pillow that will measure pressure and patients' mobility parameters. The smart pillow should be suitable to be part of the compression system that is typically applied between the knee and ankle of venous ulcers patients, being placed between the dressing and a layer composed of zinc oxide.	(12),(15)
In-shoe insole sensing system	The ecosystem should include an in-shoe insole sensing system for measuring parameters related to DFU. The sensors should be integrated into a comfortable and thin insole to be placed in the shoes.	(13),(16)
Patient Mobile Application	Patients should interact with the system through a mobile application. This application will also be used to obtain the clinical data collected through the monitoring sensors, to collect feedback from patients and to present personalized recommendations about activities to perform and behaviours to adopt.	(4),(8),(9),(10),(11)

Health Professional Web Application	Health professionals should interact with the system through a Web Application that allow the visualization of the patient's health condition and to receive feedback for clinical decision making.	(1),(3),(14),(15),(16)
User interface for real-time health status monitoring	User interface for visualizing the patients' health status in real time through the health professional web application and the patient mobile application.	(3),(14),(15),(16)
User interface for reporting clinical events	User interface for reporting relevant clinical events in the patient mobile application.	(8),(9),(10)
User interface for defining personalized coaching plans	User interface for defining personalized coaching plans in the health professional web application.	(1)
User interface for treatment plan progression and goals assessment	User interface for treatment plan progression and goals assessment in the health professional web application and the patient mobile application.	(1),(2)
User interface for personalized feedback and smart coaching	User interface for personalized feedback and coaching in the patient mobile application.	(3),(4)
User interface for personalized alerts	User interface for personalized alerts regarding treatment plan compliance risks in the patient mobile application.	(11)
Data Storage	Data Storage complying with basic privacy and security norms should keep the information concerning the patient, such as the clinical data obtained through the monitoring sensors and interactions with the system. It will also contain all the knowledge used in the data processing, such as guidelines used in the generation of personalized recommendations and knowledge inserted by health professionals.	(2), (5)
Coaching Framework service	The Coaching Framework should provide a set of intelligent services for the smart coaching of patients. To do so, the framework will have a Rule-Based System. The rules available in the framework will be based on clinical guidelines defined by the health professionals and will specify the conditions associated to the clinical data that will be used to identify possible recommendations to present to the user.	(3), (4)

User Monitoring and Data Processing	All patient-related data collected through the monitoring sensors should be gathered and a set of artificial intelligence (AI) techniques should be used to process the data and generate meaningful insights.	(3),(4),(6),(12),(13), (14),(15),(16)

3. Discussion

The research and development of innovative solutions for the remote monitoring and self-management of vascular diseases results in an important aid to address the current health challenges. Overall, the proposed smart wearable system will focus on key parameters related to three relevant vascular diseases, namely: walking distance to symptom-forced stop for patients with IC; body position and respective time periods spent in the position and pressure under compressive apparatus throughout the day for patients with venous ulcer; and plantar pressure distribution while standing for patients with diabetic foot.

The definition of the technical and functional requirements was performed with the help of clinicians, in which all clinical scenarios and healthcare needs related to the three vascular conditions were studied. Regarding IC, the system requirements for the proposed system focused on the capability of assessing walking capacity of the individuals, in which the sensors should measure distance in meters walked by the patient, as well as to identify the moment at which ambulation cannot continue due to pain and the amount of time the patients ceased their movement due to pain. Although the standard treatment for IC patients relies in supervised exercise programs aimed at improving walking distances and quality of life [27], patient compliance can be as low as 34% [14], resulting in loss of treatment effectiveness, as the benefit in walking distance for IC patients highly depends on the frequency and maintenance of the exercises programs. Therefore, the main benefit of the proposed system is to facilitate the incorporation of the exercises into the daily routine and to promote behavior change towards improved treatment adhesion and thereby better outcomes in terms of walking distances.

The progression of venous ulcers may require extensive treatment and need for hospitalization [28]. The proposed system will target venous leg ulcers, which is the last stage of the chronic venous disease according to the standard CEAP classification (Clinical-Etiological-Anatomical-Pathophysiological). Patients with this condition are submitted to periodic hospital appointments to receive compressive apparatus therapy in the areas affected by the ulcers. The proposed system will focus on monitoring the pressure under the compression system by introducing a novel smart pillow made of thin and comfortable material. DFU are among the most common and costly lower extremity complications of diabetes, affecting around a quarter of diabetic patients, apart from being the leading cause of hospitalizations related to diabetes [29]. Technology can be used to alert patients about periods of high-risk plantar pressure during daily activities, providing a practical tool to guide the patient into actively correct plantar pressure. For this reason, the proposed system targeted the continuous monitoring of plantar pressure in patients with diabetes presenting susceptibility of developing DFU by using sensors integrated into a comfortable and thin insole to be placed in the shoes.

Overall, the most common and relevant variables according to the literature and to address healthcare needs defined by the physicians will be targeted in the proposed system. Also, the proposed system proposes fills a gap in current developments by proposing a coaching framework service for personalized recommendations (e.g., health status, healthy behaviors to adopt and activities to perform according to the treatment plans set by physicians), which are still scarce for vascular diseases. Furthermore, healthcare professionals will be able to set personalized treatment plans and receive meaningful insights during the processing of the patient data, such as the evaluation of the patients' current health status, reactions to medical interventions, treatment compliance levels, activities performed, among others. Finally, data obtained with the system will allow the quantification, description, and further analysis of the impact of several clinical variables on key outcomes, allowing a better understanding of the clinical evolution of the selected diseases and the discover of possible risk factors.

4. Conclusions

In this paper, we presented a set of technical and functional requirements that are essential for a smart wearable system aimed at remotely monitoring patients with selected vascular diseases. For this purpose, a review of the literature on related projects and the study of clinical scenarios and current needs were performed. The main innovation aspect of the proposed system consists in a set of intelligent services that allow the remote monitoring and smart coaching for patients and healthcare professionals, filling an existing gap for vascular diseases. The proposed intelligent system is expected to promote healthy behaviors and increased involvement in treatments, guiding patients and healthcare professionals by means of a personalized care solution.

Acknowledgements: This research work was developed under the project Inno4Health (ITEA-2019-19008-Inno4Health), funded by the European Regional Development Fund (ERDF) through the Operational Programme for Competitiveness and Internationalization (POCI) (ref. POCI-01-0247-FEDER-069523), and by National Funds through FCT (Fundação para a Ciência e a Tecnologia) under the project UI/DB/00760/2020. Ana Vieira was funded by FCT under PhD grant number UI/BD/151115/2021. Luis Conceição was funded under the PhD grant number SFRH/BD/137150/2018.

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