

Development and Evaluation of a Sensor-Based System for Remote Monitoring and Treatment of Chronic Diseases

the Continuous Care & Coaching Platform

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Abstract: The steep increase in the number of people with chronic diseases in the Western world is a long recognised problem which forces us to look for less labour intensive and more cost effective methods to deliver healthcare. Wider use of telemedicine services seems to be a solution that can contribute substantially to reduction of costs and maintenance of health service quality at a high level, but its implementation in regular healthcare practice often fails. This is no surprise since designing, building and implementing a successful telemedicine application is no trivial task. The reasons for failure are many, and include technical problems and low usability, however there are also organisational factors such as the often disruptive effect the introduction of new technologies can have on existing healthcare processes. This paper presents the experience gathered when building our system: the Continuous Care & Coaching Platform (C3PO). This platform was designed to monitor patients with chronic diseases during daily life and provide them with the support they need to develop and maintain an active lifestyle in order to improve quality of life and offset deterioration of health condition. In this paper we share the lessons learned and present results of evaluation studies using earlier versions of the platform. Innovations in the field of wireless sensor technology as well as changing demands from the users led us to redesign and develop a new version of the platform. This process is described, starting with the gathering of requirements using a user-centred design approach and derivation of specifications. The components of the platform are described as well as results of recent evaluation studies. Our evaluations and experience with working with patients and healthcare professionals indicate that there is currently a great need to add intelligence to the platform. The augmentation of the platform with of a smart autonomous health- and lifestyle coach is the current focus of our research which, we believe, will be a crucial next step towards the future of intelligent telemedicine applications.

1 INTRODUCTION

The world's population is rapidly ageing, as a result of both longer life expectancy and declining fertility rates. Worldwide, the proportion of people aged over 60 is growing faster than any other age group, and by 2050 there will be some 2 billion elderly persons. A person's health typically deteriorates with increasing age and chronic diseases emerge, inducing greater demand for long-term care. According to the United Nations report "World Population Ageing 150-2050" (United Nations, Department of Eco-

nomic and Social Affairs, Population Division, 2002), the mortality, morbidity and disability attributed to the major chronic diseases — heart disease, stroke, cancer, chronic respiratory diseases and diabetes — is expected to rise to 73% of all deaths and 60% of the global burden of disease by 2020. Finding innovative approaches to making our healthcare system affordable and sustainable is needed.

Regular physical activity is beneficial for healthy aging as it substantially delays the deterioration of health status and helps prevent the development of secondary chronic diseases. A focus on (self-) man-

agement of physical condition will become increasingly important in future chronic care and in the support of the healthy elderly population. Information and Communication Technologies play a crucial role in supporting greater independence and self-management of lifestyle and disorders. We need to identify patient management approaches that will ensure appropriate monitoring and treatment remotely. To deal with this problem, Hermens and Vollenbroek-Hutten (Hermens and Vollenbroek-Hutten, 2008) propose to develop remote monitoring and treatment systems. These should integrate ambulant sensing to measure relevant bio signals and context information with secure data handling and appropriate clinical decision support functionality to assist in both technical and clinical decision making. In addition, the system should also provide feedback to both patients and care providers. In other words, such systems should provide continuous monitoring of health status, with the promise of coaching, or continuous motivational aid aimed at achieving behavioural change, whenever required, and efficient and effective individually tailored treatment anywhere anytime.

These systems do promise to make healthcare more quantitative, more efficient and effective and less costly, which is desirable for patients, healthcare professionals and health insurance companies alike. Although the number of available systems is rapidly increasing, still around 75% of the telemedicine initiatives fail during the operational phase after a pilot (Berg, 1999) and, despite numerous trials, very few are transferred successfully into routine health care. Inadequate technical performance as well as low usability of these systems is considered to be among the major barriers for successful implementation (Broens et al., 2007).

Our aim was to develop a remote monitoring and treatment platform for elderly and patients with chronic disorders, to support them in developing and maintaining an active lifestyle and improving their physical condition, either independently or supervised remotely by their healthcare professionals. The platform, focussed on continuous monitoring and feedback to the users is called the **Continuous Care & Coaching Platform** or C3PO. In this paper, we describe the development of the platform and its components: sensors, Smartphone, server and web portal. Section 2 starts with a short overview of the current state of the art of telemedicine platforms and research. We then describe the process of our user-centred design approach, starting with the lessons learned from previously developed remote monitoring systems, the development of functional and technical requirements, the platform design, and system's

evaluation. Finally, we discuss the ongoing work in improving the platform and discuss the future of remote monitoring and treatment systems.

2 BACKGROUND

The field of telemedicine research is large, and rapidly expanding. A systematic review of reviews by Ekeland et al. (Ekeland et al., 2010) found 1593 reviews of telemedicine systems published since 1998. Having included 80 reviews in their analysis, the authors found only 21 reviews that concluded telemedicine to be effective, and 18 that concluded that evidence is "promising but incomplete". Similar results can be found when looking into telemedicine applications targeting physical activity interventions (an important focus of C3PO). A systematic review by LaPlante and Peng (Laplanche and Peng, 2011) analyzed 31 e-Health intervention publications targetting physical activity between 2006 and 2010. Four of the 7 studies that used pure control groups showed support for e-Health, while the others showed no significant differences. The authors conclude that although it is difficult to argue for the benefits of e-Health compared to classic interventions, none of the evaluated platforms fared worse than its control setting. Thus it seems that more research in the area of telemedicine, as well as more standardized and thorough evaluations of its effects are necessary. This conclusion is also found in a review conducted by Polisen et al. who studied home telehealth systems for Chronic Obstructive Pulmonary Disease (COPD), one of the important target groups for the platform. The authors reviewed 9 studies, and concluded that although emergency department visits and hospitalization rates declined, other outcome parameters varied between studies (Polisen et al., 2010).

Telemedicine platforms come in many shapes and forms, some focussing more on vital sign monitoring for e.g. elderly (Czabke et al., 2011) or cardiac patients (Kumar et al., 2008; Jones et al., 2009); others focus more on the human-computer interaction through television (Burkow et al., 2008), smartphones (op den Akker et al., 2010; Wieringa et al., 2011; Ståhl et al., 2008; Chen et al., 2009), web-based communities (Lewis et al., 2008) or web portals (Hermens and Vollenbroek-Hutten, 2008). A full review of all the related aspects of telemedicine platforms would be out of the scope of this paper. It is however important to recognize their complexity in both technical and societal sense, and we strongly believe that careful attention to all aspects, as well as broad user involvement throughout all the stages of devel-

opment can contribute to the potential success of any telemedicine application.

3 FIRST LESSONS LEARNED

In 2006, development started on an ambulant activity monitoring system. In this first version of the platform, a 3D motion sensor (XSens MT9) was used together with a data logger. The sensor contained three separate uni-axial piezoelectric accelerometers with a range of 2g, and was connected over a wire to the data logger. Both devices were worn on a belt on the waist. In one of our first studies on daily physical activity, we used the MT9 to measure the activity levels of chronic low back pain (CLBP) patients in their everyday lives and compared the results of the experimental group with those of healthy controls (Van Weering et al., 2009). Participants wore the devices for 7 consecutive days from 7:00 am until midnight for a maximum of 17 hours per day. After the measurement week, the memory card from the data logger was read out and the data was analyzed. These first studies gave us valuable insights in the activity patterns of CLBP patients, showing for example their tendency to be much more active in the mornings and much less active in the evenings compared to healthy controls. But it had an obvious disadvantage in terms of its size and was not comfortable to wear for long periods of time. Therefore, we started the development of a new version in 2008.

The second iteration of the platform consisted of a wireless 3D accelerometer (XSens MTx-w) and an HTC Smartphone. The sensor connects wirelessly via Bluetooth to the Smartphone, which can be worn on a belt clip or in a pocket. The use of a wireless connection between the sensor and the Smartphone meant the system was easier to operate and more flexible in terms of its placement on the patient's waist. The use of a Smartphone also provided us with the option of designing real-time feedback on the streaming input data and consequently allowed us to design fully ambulatory interventions. The Smartphone could be used to show the patient a real-time graph of his daily activity compared to reference values and based on this provide timely feedback messages designed to encourage the patient to change his physical activity behaviour. The platform was used in a number of studies for monitoring everyday activity patterns in patients with different conditions including chronic low back pain, chronic fatigue syndrome (CFS) and chronic obstructive pulmonary disease (COPD); it was also trialed on cancer survivors and obese subjects. In each of these groups, the pa-

tient's physical activity plays a role in the progression of his condition and general quality of life. In COPD, for example, patients are symptomatic even when performing normal daily life activities. This causes the patient to avoid activity, leading to a decrease in physical fitness which causes a rise in the incidence of COPD exacerbations. In this case, improving the physical activity behaviour can offset this downward spiral that is so commonly seen in COPD. The Smartphone application also prompts patients to answer questions presented at fixed time intervals during the day on self-perceived activity performance, rate their level of pain (in case of CLBP), dyspnoea (in case of COPD), fatigue (in case of CFS, COPD) or to provide information on food intake (in case of obesity) by means of visual analogue scales (VAS). The feedback intervention studies showed that use of the system for a period of several weeks resulted in decreased symptoms and increased activity levels.

Although the second version of the platform was an obvious improvement in terms of usability and flexibility, new issues emerged during the use of this system in the various studies. The wireless Bluetooth connection between the sensor and Smartphone was a drain on the batteries of both devices. For the Smartphone we had to use extended battery packs, making the devices more bulky than they needed to be, and for the sensor, the drain on the batteries meant the device would often run out of power after 12 hours of operation. Another issue was data loss. Because the sensor sends out its raw sampled values continuously, each time the Bluetooth connection is dropped, data is lost. These limitations as well as further advancements in the field of wireless sensor technology and mobile devices led to a further cycle of design and development and a new version of the platform, described in the next section of this article.

4 REQUIREMENTS AND DESIGN

In the following two sections we will explain the process of requirements elicitation for the new platform, called the Continuous Care & Coaching Platform (C3PO) as well as the design of each of its individual components.

4.1 Requirements

Early versions of the platform were mainly designed for research purposes, but the experimental studies indicated that the system had potential utility as a behavioral intervention tool. However, it also became clear that the system needed to be redesigned to bet-

ter meet the user’s needs in terms of being more user friendly and being able to be integrated into the daily work practices of the health care professionals. The early involvement of patients and professionals in the requirements analysis and the design process is crucial for this. Therefore, for developing the requirements of C3PO, we chose to apply an iterative, user-centred design approach, as shown in Figure 1. In this approach the designers take the users as the starting point for design and involve them in the evaluation of design choices.

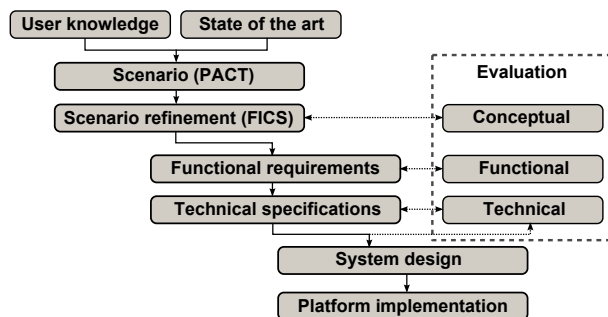


Figure 1: General iterative design process of the platform.

Exactly how to usefully involve users in the development process is far from obvious because of the knowledge gap between the users and developers and their differences in language use which seriously complicates effective communication (Huis in’t Veld et al., 2010). Scenarios are considered an effective technique to bridge these gaps (Carroll, 2000). A scenario is a detailed storyline that describes the users daily activity in the setting of the envisioned application of the system to be designed, from which requirements can be elicited.

A scenario was developed following the People-Activity-Context-Technology (PACT) framework. Using this approach forces to think about all the relevant stakeholders that will be using the new system, the actions that they perform and the (medical) context in which they perform them, as well as the technological innovations that are necessary for successful implementation. Incorporating the principles of evidence-based medicine into PACT scenario development provides a starting point for more effective and efficient design of telemedicine applications (Huis in’t Veld et al., 2010). On the one hand, we performed a state of the art literature research, and on the other hand we assessed the users medical knowledge and needs by means of questionnaires, PACT tables and interviews. From this approach the possibility to have more insight into the health status of the patient for both patient and professional became apparent and the clear need to

involve the healthcare professional in the treatment emerged. Besides the user-centred perspective of PACT, the “designer-centric” components related to system use were added to the scenario: Function and events, Interactions and usability issues, Content and structure, Style and aesthetics (FICS) (Benyon and Macaulay, 2002). The FICS approach is more system descriptive and provides insights for technicians to consider the technical specifications. It became apparent that the platform needed a clear distinction between sensors, the Smartphone, server applications and web portals, as these are the high level building blocks for each of our telemedicine applications. Besides the clear separation of these building blocks, each of the platform components should have a modular set up as well, so they can be easily extended or changed to serve different user groups. Finally, from the requirements and analysis of the gathered data, there were strong indicators that the way we provide feedback to the patients was rather sub-optimal in terms of its coaching ability. The scenario was updated, containing PACT elements combined with FICS elements. From the developed scenario, requirements were elicited by group discussions in a participatory design setting, for example conducted during plenary project meetings where both users and developers were present. For this purpose, tables, textual descriptions, and mock-ups were used. The requirements were prioritized following the MoSCoW method (must have, should have, could have, wouldnt have). A must have for the platform included for example: “*The system must continuously monitor the amount of activity, the activity pattern, and activity intensity*”. The addition of an emergency alarm function on the other hand was an example of a could have. Following this iterative design approach¹, the platform was designed, implemented and evaluated. The evaluation covered conceptual (lessons learned), functional (e.g. usability) and technical (e.g. battery time) aspects, and the scenario and requirements were updated accordingly. More details regarding the evaluation are given in Section 5.

4.2 The Platform

From applying the iterative approach described above, it emerged that the activity monitoring system had to be highly flexible and configurable to accommodate the various requirements coming from different research projects and research goals. Each study

¹Multiple groups of end-users (totalling around 50), covering a variety of patient populations where involved throughout a number of different projects.

employs its own experiment protocol and the different protocols included different procedures such as use of a web portal, or showing a graph to the patient, or providing regular feedback messages, or prompting the user to answer various types of questions. We also want to offer support for easy integration of different sensor types and the possibility to use multiple sensors simultaneously. Figure 2 gives a high level view of the architecture.

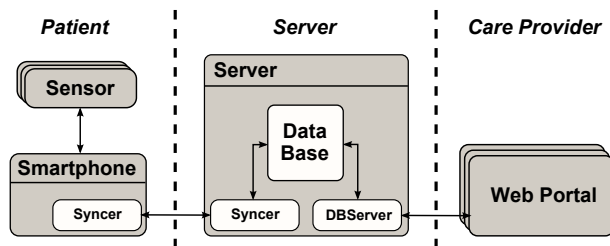


Figure 2: High level architecture overview of the platform.

The individual components are explained in more detail below.

Sensors The ProMove-3D wireless sensor was designed to provide a trade-off among performance, computational and storage resources, wireless capabilities, low-power operation and wearable form factor. The sensor node can capture, process and communicate wireless full 3D motion and orientation information. The main building blocks of the sensor node are the following:

- The sensor modules, including accelerometer, gyroscope and magnetic compass. All chips are single-chip, three-axial, fully digital sensors. The possibility exists to include additional sensors.
- The master microcontroller, which implements all sensor sampling and handling, synchronization mechanisms and the application logic.
- The wireless modules. ProMove-3D implements IEEE 802.15.4 compatible wireless communication in the 2.4 GHz license-free band as well as Bluetooth communication through an optional module.

Through this design, the ProMove-3D becomes a versatile sensor node supporting a large range of activity sensing applications. It can operate as a long-term activity monitoring device, with low power consumption, long sleep cycles and intermittent wireless communication for periodic data transfers. At the other end of the spectrum, it can support high data rate, full 3D motion and orientation data capturing and streaming wireless within accurate synchronization bounds for accurate motion analysis. Figure 3

shows the sensor node from top, side and bottom. The side cap is detachable and gives access for charging the battery. When the cap is attached, the node is automatically switched on. The node can be worn by means of a multi-functional clip holder, which allows various attachments. Two modalities are depicted in Figure 3: a belt clip, which is meant to be used for wearing the node around the waist, and an elastic band clip, which is meant to be used for wrapping the node with an elastic band, for example around limb segments.



Figure 3: ProMove-3D node top view with clip holder (left), side view with belt clip (middle) and bottom view with elastic band clip (right).

Smartphone In order to ensure flexibility — an important system requirement — we designed a Smartphone software framework in which applications can be defined by linking together various modules. Each module performs a typically small, clearly defined task and delivers its output to a central communication module, called the *Hub*. Other modules can subscribe to this information and are notified when new output becomes available. For example: a *BluetoothModule* is tasked with opening, maintaining and closing Bluetooth connections within the device. As output it delivers a stream of data coming from the sensor, as well as updates regarding the status of the connection. A *UserInterfaceModule* can subscribe to the status messages and provide the user with a warning if a Bluetooth connection is lost. Software developers are free to develop their modules without specific limitations and, as long as they adhere to the simple communication protocol with the central Hub, they can share their output with other modules. In order to provide the connection between the Smartphone and server side services, such as web portals that provide information to healthcare professionals, the *AndroidSync* module takes care of synchronizing data between Smartphone and server.

Server On the server side of the platform, the core component is R2D2 (the **R**oessingh **R**esearch and



Figure 4: The old (left) and new (right) versions of the Smartphones and graphical user interface.

Development Database). R2D2 is designed to handle a wide variety of data types such as streaming bio signal data, questionnaire results, context information and subject information. R2D2 offers a fixed structure for storing data uniformly from multiple research projects and applications. This uniform way of storing data makes it possible to do simple comparison studies on data gathered by different researchers in different projects. The design of the data structure is based on two core principles: (1) the subject is at the top of the data structure, and (2) all measured data is linked to a timeline. A subject is an anonymous participant in a research project and all data that is measured is subsequently linked to a subject. Furthermore, for all data that is stored, the time at which the data was gathered is the important factor in linking various layers of data to each other. The subject's activity data, for example, is stored in a signal layer as a constant stream of <time, value>-pairs that indicate their performed activity intensity during the day. Another layer is used for storing the time at which the subject received feedback from the system and which exact message was displayed to the user; these are events that are stored in an event layer. Similar layers exist for storing interval data (in which a period of time can be labelled as e.g. walking or lying), questionnaire data (in which questionnaire results can be stored) and video data (if a camera is used for e.g. gait analysis). Figure 5 shows a screenshot of a data viewer application, the RRDToolkit, showing various layers of measured data on a timeline. A server application handles secure synchronous access to the database. Password protected user accounts provide access to the various sets of data that are stored in the database, and locking mechanisms are in place to pre-

vent simultaneous write operations, that could result in data corruption.

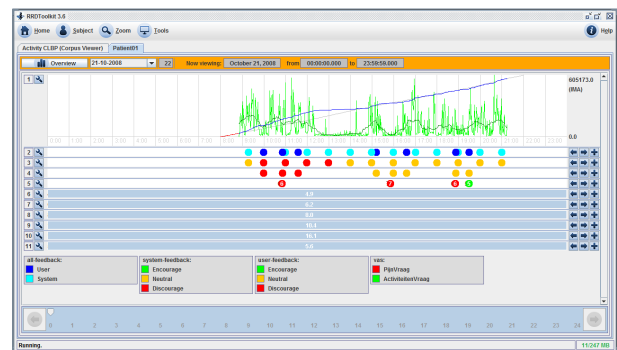


Figure 5: A screenshot of the RRDToolkit, a data viewer for researchers, showing an activity graph (signal layer), feedback events (event layers) and weather data (interval layers) for a day of measurement of a Chronic Low Back Pain patient.

Web portal To provide a useful view on the data for biomedical researchers, patients and healthcare professionals, we designed a modular framework for developing web portals, in much the same way as the Smartphone application. Different remote monitoring and treatment applications focus on different types of measurements and different types of feedback, but a general component in many applications is a portal that allows patients and healthcare professionals to track disease progression or health status. The primary goal of the web portal is to display measurement data to the patient or the healthcare professional in an easy to understand way. Figure 6 shows a screenshot of the web portal developed within the Dutch "ConditionCoach" project, showing the view for COPD patients who are able to track their own levels of physical activity, and progression over the week, month or year. But the portal can also be used for gathering new data. For example, an electronic triage application was developed for COPD patients where patients receive a set of questions on their health status (Effing et al., 2009) on a daily basis via the portal and can give their responses via the portal. In a trial with COPD patients, subjects were asked daily if their symptoms were more severe than normal. If the patient answered "yes", they were asked to report on all their symptoms irrespective of whether the level of each was normal, slightly increased, or greatly increased. A rule-based system (an action plan) implemented on the web portal decides when the patient needs to start taking medication. This diary form was successfully used in clinical care as part of a regime of self-treatment of exacerbations in COPD patients.

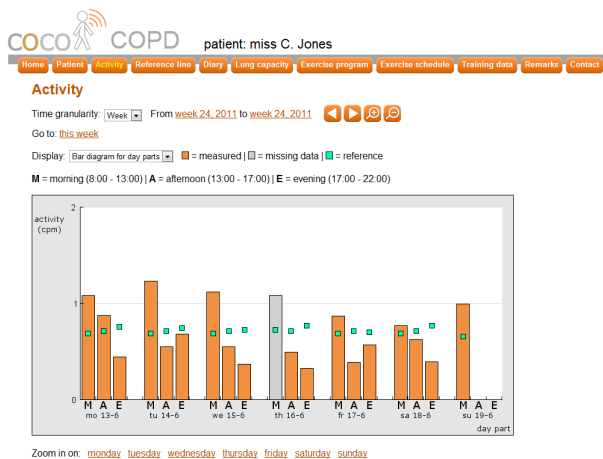


Figure 6: Screenshot of the Dutch CoCo (ConditionCoach) project web portal, showing a weekly overview of activity data (center) and links to all the separate available modules (top) for a patient.

5 EVALUATION

Earlier versions of the platform, and especially the second platform iteration was extensively evaluated in trials with different patient groups and their healthcare professionals by means of questionnaires and in-depth semi-structured interviews. An important outcome was the perceived acceptability of the system, especially by physical therapists.

For C3PO, a small-scale evaluation study was performed to optimize the usability, and to assess intention of use of the patients. In the Netherlands, six patients with a clinical diagnosis of stable COPD were included. COPD is a patient group of mainly elderly people, who are in many cases not as familiar with modern technology as younger generations. The experiment was designed to simulate daily use of the system and daily life activities in a laboratory setting. Each patient wore the system while performing a number of daily life tasks in the laboratory setting while the system measured activity levels and gave feedback. Usability scores were assessed by the System Usability Scale (SUS). For the activity monitoring and feedback a mean SUS score of 67.1 was found (range: 47.5 - 90.0), which corresponds to the average scores found in the literature, but also indicated that usability should be improved. A questionnaire, specifically designed for the platform, was filled in by the patients to assess the usability of specific parts of the system. The questionnaire consisted of 27 statements about the system with a 7-point Likert scale ranging from 'strongly disagree' to 'strongly agree'. Example statements include: *"The meaning of the*

graph is not clear to me" or *"I find it easy to unlock the Smartphone"*. The questionnaire results provided us with detailed information about every aspect of the Smartphone application and highlighted further points for improvement. These improvements were implemented before clinical trials started and we expect that the usability score will improve following the modifications to the application.

The web portal was evaluated in a separate trial. An evaluation study was carried out into the experiences of end-users during a four week testing period with the C3PO portal. Data was collected through in-depth semi-structured interviews with five COPD patients, two physical therapists, one nurse practitioner and two lung specialists, and through participative observations. Five aspects of acceptability of innovations were addressed (relative advantage, compatibility, ease of use, image, and voluntariness). Quantitative data was used as a secondary source of data providing supportive information.

There was a perceived high potential acceptability, especially to physical therapists. The electronic diary was considered easy to use and possibly of high value to both patients and professionals. The use of a web based portal was accepted by patients but professionals experienced it as time consuming and hence professionals' acceptance was lower than patients' acceptance. Quantitative data showed that patients used the portal at variable hours throughout the day, for 3 to 4 minutes per session. In addition, several points for enhancing the portal emerged. These improvements were implemented and, to increase acceptance by the professionals, the portal was improved in close collaboration with the healthcare professionals. Taking into account the feedback from patients and healthcare professionals allowed us to build a remote monitoring and treatment platform with a high usability and acceptability for its different classes of end-users.

6 DISCUSSION AND WORK IN PROGRESS

Over the years many small and larger trials with a wide variety of patients have been performed, and following each trial the feedback from the various users was taken into account. The re-design and re-implementation of the C3PO platform resulted in a system that is stable and flexible in operation, as well as simple to use for patients and healthcare professionals alike. However, one of the major issues that arose from the requirements and analysis of older versions of the platform has not yet been fully addressed. This concerns automated coaching, the means to pro-

vide real time feedback to the patients on their daily physical activity in order to encourage behavioural change. In the current platform, feedback is still simplistic: feedback messages are presented at fixed time intervals, related to the amount of activity performed compared to a reference value. Because effective coaching is a crucial element in affecting behavioural change, current research is focussing on developing an intelligent coach that runs on the Smartphone and acts as a personal companion that helps patients achieve their activity goals. It is based on the principles that feedback should be tailored to individual users in terms of its timing, content and style of presentation to the patient. The next evolution of the system will be able to learn to predict the optimum timing for providing feedback by analyzing previously given feedback messages and learning when a patient is likely to respond well to a given message by relating relevant context factors to patient compliance (op den Akker et al., 2010). In related work by Wieringa et al. (Wieringa et al., 2011) the Smartphone application also learns to adapt the feedback message content to the patient. Feedback messages are stored in a structured manner based on message content and style. During operation, the system stores the reaction of the patient to each feedback instance in order to make informed decisions on which type of messages are most likely to elicit a positive response the next time feedback is needed. As for the mode and style of presentation of feedback to the patient, this remains a significant challenge in Human Computer Interaction research. Ongoing and planned research will evaluate the effects of the smart feedback coach on patient's physical activity patterns and their perception of the system in terms of usability and treatment compliance. Currently, trials are running in which COPD patients will use the smart feedback coach for a period of three months. In the meantime, large scale evaluations of the remote monitoring and treatment platform are running in which the platform is used in a daily clinical care setting. These larger scale evaluations will show us how the system performs under stress and will enable us to receive valuable feedback on the latest version of the platform which can help us to keep improving the system.

Based on the results of the research described in this paper, we are confident that C3PO has the potential to contribute to delivering more cost effective and qualitative healthcare. We believe our approach will be part of the solution by providing more cost effective rehabilitation and secondary prevention since it supports self management of patients; thereby shifting the focus of control towards the patient. Using C3PO the patient can determine where, when and how

intensively he follows his treatment regimen. It also enables the health care professional to treat more patients at the same time, decreasing the per-patient cost of highly trained personnel. Last but not least, automatic data collection is facilitated by the use of this technology and the data aggregated will result in large corpora of clinical data which has the potential to support evidence based medicine. On the one hand it enables an efficient comparison of efficacy of different interventions, and on the other, data mining can generate new clinical knowledge of general relevance as well as determining optimal treatments for a specific patient.

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