Monitoring Patients in Ambulatory Palliative Care: a Design for an Observational Study

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Abstract

We present the setup of an observational study that aims to examine the application of wearables in ambulatory palliative care to monitor the patients' health status – especially during the transition phase from hospital to home since this phase is critical and often patients are re-hospitalised. Following an user-centred design approach, we performed interviews with patients recruited at the Clinic of Radiation Oncology of the University Hospital Zurich, Switzerland. The patient group was perceived as vulnerable and varied largely in physiological burden and mental aspects. Special needs concern primarily obtrusiveness of the system and sensitivity in the work with this patient group. With the deployment of the system, we gathered first experiences: the first patient was tracked over 12 weeks resulting in 84 tracked days, 181 digital questionnaire answers, 40908 collected GPS points, 861 hours of heart rate measurements and positive feedback of the patient.

1. Introduction

Palliative care (PC) is a set of practices aiming to preserve quality of life in patients with a life-threatening disease by means of efficient symptom controll (e.g., pain, fatigue, breathlessness, sleeplessness) enclosing psychosocial and spiritual needs [1].

The remote monitoring of PC patients after discharge from hospital care might be a promising tool to support patients during the adaption process and in case of crisis. Medical professionals with constant access to trasfered data could start early interventions in case of deterioration.

PC patients, oftenly suffering from different physical and psychological disorders, are more vulnerable than many other patients groups. Conventional monitoring systems may not be adequate.

We present a patient-centric design of a new monitoring system tailored to PC patients, where the patients are fully involved in the design of the part of the system which affects them the most, i.e., the patient interface. The design process is carried out through guided interviews. The patient interface consists of questionnaires and feedback mechanisms, while the monitoring system also logs various sensor data relevant for predicting changes in patient conditions. Sensor data are collected both through a smartphone and an armband equipped with sensors. Since the system is to be used in an observational study, we involve patients for the system design with the same inclusion criteria as the clinical trial, thereby maximising the representativeness of the outcome.

In this paper we present the patient-centric design procedure, the lessons learned and the final monitoring system, along with the protocol for the observational study as well as data of one patient as a proof of concept.

2. Related Work

Mobile health, without the use of wearable sensors, has been explored in many diseases and patient groups, e.g., in cardiovascular diseases [2], mental disorders

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[3, 4], stroke rehabilitation [5] and stressed persons [6]. Estimating a general health status from smart-phone sensor data was investigated in [7]. The collection of patient subjective reported outcome using mobile health is already established in oncology and has been proven feasible in younger palliative care patients [8].

Monitoring systems including also wearable sensors have been developed for specific patient groups, e.g. patients who suffered from a heart failure [9], and to measure stress, activities or health status in less specific groups [10]. The application of monitoring systems has been proven beneficial for patients with schizophrenia [11] and heart failure [12], resulting in reduced hospitalisations and mortality.

For the specific case of PC patients, until now monitoring systems are limited to the digital collection of questionnaires or self reports through a smart-phone [13]. While the usability of smart-phone-based questionnaires was investigated [14], to our knowledge no study was conducted with a system including other wearable sensors, like an armband. Furthermore, it was not yet investigated which type of feedback (if any at all) would be desirable for PC patients.

We aim to fill this gap with an unobtrusive monitoring system designed specifically for and with the help of PC patients, using a patient-centric design approach. We advance the state of the art with an observational study to examine a real-world deployment of our system with this vulnerable patient group, which will lead to a future clinical study.

3. Procedure for the Observational Study

In this section we present the goals of the observational study with the resulting requirements for the monitoring system. Furthermore, we outline the procedure envisioned for the study.

The observational study aims to evaluate feasibility and acceptance of monitoring by means of wearable devices within the vulnerable palliative care patient group. The system should provide data whose analysis will allow to find correlations between subjective patient ratings concerning distress, quality of life and pain and objective measurements from the wearables in order to detect deterioration of symptoms.

Similarly to related work [3, 15], we choose a sample size of 30 participants. Patients are recruited at the Radiation-Oncology ward of the University Hospital Zurich, Switzerland, under the condition that they are aged > 18 years, have an estimated life expectancy < 12 months (physician's estimation) and > 8 weeks, are able to de-ambulate and to perform all self-care. Patients may be unable to carry out any work activities for up to at least 50% of the time they are awake [16].

Study participants receive a smart-phone Samsung Galaxy S5 (if not already using an appropriate device)

and a Biovotion Everion armband, (i.e., non-obtrusive devices in contrast to e.g., chest belts or adhesive electrodes) to log their physical and social activity as well as vital parameters. For that purpose, the participants shall wear the devices with them all day long. They shall charge the smart-phone over night and the armband once a day. If tolerable for the participants, they shall wear the armband also during night. Once a day, the smart-phone will ask patients to rate their current level of distress according to the NCCN[1] distress thermometer ([17]) and their level of pain on visual scales from $0 - 10$. Distress and pain mainly influence the quality of life of palliative patients and are also regularly assessed by physicians [18, 19]. The design of the interface between the smart-phone app and the patient (patient interface) is investigated thoroughly in Section 5, leading to a patient-centric design approach.

In case of consent, patients receive the devices and will be introduced to them while still hospitalized. Three days after hospital discharge, a member of the scientific staff visits the patient at home to clarify questions of the patient and to ensure accurate data recording. We call patients weekly for questionnaire-based interviews, e.g., EORTC QLQ-C30[2] and to verify device usage. Patients will be tracked over 12 weeks ending with a final interview about the device usage and their experiences.

4. System overview

Figure 1 sketches the technical system deployed in the study.

4.1. Smart-phone and App

According to our study protocol, the main requirements towards the smart-phone app are the following:

- **Power consumption** The smart-phone will be charged during night. Therefore, the data logging is designed to consume only as much power as a normal phone usage with one charging per day is ensured.

- **Ease of use** The app user interface shall follow an intuitive, simple design as elaborated in Section 5.

- **Reliability** Once started, the app shall run continuously in the background and restart automatically after a reboot of the smart-phone.

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[1] US National Comprehensive Cancer Network
[2] EORTC: European Organization for Research and Treatment of Cancer, QLQ-C30: standardised questionnaire to measure quality of life of cancer patients
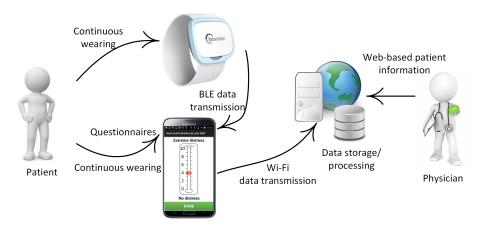
Figure 1. System Overview: body–worn, non–obtrusive sensors, regular encrypted data upload to a secured server, secured web interface for data analysis.

- **Data Storage** The recorded data shall be stored so that they are not visible in the file explorer of the phone in order to not

The smart-phone provides data as shown in Table 1.

4.2. Armband

With respect to ethical considerations, the requirements towards an armband are the following:

- **Data privacy** The armsensor shall be connected with our app via bluetooth low energy and must not send the data to any other device or app. This ensures that the data access is controlled by the study team.

- **Easy to use** The armsensor shall not require additional interaction from the patient, except wearing and charging, i.e., no additional button like power on etc.

- **Runtime** The device shall measure continously (e.g. with a sampling rate of 1 Hz) at least 20 hours per day without recharging.

Note that, at least at the design time in 2016, according to our research, the first requirement already exluded all common fitness trackers like Fitbit Charge HR. At that time, smartwatches could not provide the required runtime. According to our research, only two devices fulfilled the requirements: the Empatica E4 and the Biovotion Everion. After comparison of the specifications, we decided to use the Biovotion Everion for the study. The armband provides vital parameters and activity data with a sampling rate of $1Hz$ (except heart rate variability) as listed in Table 2

5. Interviews with Palliative Patients and Resulting User Interface

Given the requirements outlined in Section 4, we now proceed with the patient-centric design of the patient interface and we define possible feedback channels.

Since usability and convenience of the devices are crucial factors influencing the study, we involved potential users in our iterative system development. After receiving the ethical vote, we conducted qualitative interviews [27] in form of guided conversations. Furthermore, we showed patients different smart-phones of the Samsung Galaxy series and commercial armbands (Fitbit Charge HR and Angel Sensor, since Biovotion Everion was not available at that time) and let the patients choose between different design variants and control concepts. Finally, we asked them to use a prototype app on a Samsung Galaxy S5.

We present the observations in topical subsections together with our conclusions.

5.1. Characterization of Patients

We conducted interviews with 12 cancer patients between 49 and 80 years old (median: 63.5, standard deviation: 10.07). Table 3 shows descriptions of the patients. We encountered a broad spectrum of patients differing in many facets. Concerning the physiological aspects, the spectrum ranged from symptoms not observable by a non-expert to physiological burdens like tracheotomy. Concerning mental aspects, we encountered patients fully aware of their situations and patients blocking out that they are terminally ill. Also the mood of the patients varied strongly, from unhappy or depressed to happy and even euphoric.

5.2. Usability of the Smart–Phone App

- After a short introduction, all patients but one were able to use the smart-phone and to

Table 1. Recorded smart-phone data, grouped by the measurement goals self-reporting, physical activity, location and social activity

Modality	Sampling Rate	Description
Self-Reporting	1/day	digital questionnaires concerning pain and distress by means of visual analogue scales (VAS) from 0 (no pain/distress) – 10 (extreme pain/distress)
Physical Activity		The sampling rate is controlled by Android and varies depending on phone usage. Resampling of the recorded data is done offline (server-side). The gyroscope is not recorded in order to reduce battery consumption.
Accelerometer	40 Hz	
Barometer	2 Hz	
Magnetometer	10 Hz	
Location		Location provides several features, e.g., visited places (time and duration), duration of stay at home, number of transitions, etc. These features indicate behavioural changes such as social interactions [20], which are also known to be a health indicator [21].
GPS	every 3 min	Trade-off between collected data amount and battery consumption.
WiFi	every 20 sec	can be used for indoor and outdoor localization
Social Activity		in addition to the location, app usage and phone call statistics will be examined
app statistics	every 2 min	list of currently running apps
phone call statistics	1/day	time, duration, direction and encrypted id of phone calls
Emotions		in addition to the wristband sensor data, emotions can be inferred from voice [22]
encrypted phone calls	n/a	voice analysis based on features, e.g., energy of the signal, Mel Frequency Cepstral Coefficients, etc.

Table 2. Recorded armband data, grouped by sensor type

Modality	Unit	Description
Photoplethysmography (PPG)		
Heart rate	bpm	The heart rate is correlated with stress, physical activity and health, e.g., elevated resting heart rate, has been shown to correlate with increased risks of all-cause and cardiovascular mortality. [23]
Blood oxygenation (SpO2)	%	Levels below 90 are considered as hypoxemia, levels below 80 percent can compromise organ function. Therefore, it is an important health indicator.
Perfusion Index	%	Serves as indicator for peripheral perfusion index which has been shown to be related to the central-to-toe temperature difference. [22] Unsufficient perfusion decreases the PPG measurement quality.
Blood pulse wave	digits	Indicator for arterial stiffness.
Energy Expenditure (EE)	cal/s	Can serve as an indicator for activity.
Respiration Rate (RR)	bpm	An abnormal RR can be an indicator for several diseases.
Heart rate variability (inter pulse interval)	ms	Several statistical features have been shown to be health & stress indicators, e.g. balancing between sympathetic and parasympathetic nervous system [24]
Galvanic skin response (GSR)		
Impedance	kOhm	The GSR is used to detect stress [25].
Accelerometer		
Activity	digits (0..255)	Activity level calculated out of the three axis of the accelerometer
Steps	steps/s	The amount of steps is also a measure of physical activity (PA). PA has been shown to correlate with different diseases, e.g., chronical fatigue [26]
Barometer		
pressure	hPa	used for altitude calculation
Temperature		
skin temperature	100°C	health indicator; note that skin temperature is different to body core temperature
device temperature	100°C	used for altitude calculation

Table 3. List of Interviewed Patients; f=female, m=male

ID	Gender	Age	Interviewer's Assessment
1	f	51	autonomous and independent person; background in programming
2	f	71	euphoric mood due to recovery from acute symptoms and aware about illness; technical background
3	f	80	patient told off-topic stories, interview aborted after few questions about attitude toward smart-phones
4	m	68	self-reported suffering from pain not noticeable during interview
5	m	72	patient suffered from acute symptoms, interview aborted before talking about wristbands due to difficulties to speak
6	m	52	very positive, optimistic despite progressive disease. Maybe blocking preoccupation with limited lifetime
7	m	50	optimistic to recover; helpful despite critical towards research projects
8	m	68	impressive entrepreneur with good profiling skills; handles his situation with humour in the outer world
9	m	63	not that experienced with technology, but adventurous; hoping to have at least some years left despite divergent physician's guess
10	f	61	values good quality and aesthetics – therefore critical; main symptoms: fatigue due to progressive disease, treatment and pain
11	m	49	hopes for some years; very positive vibes despite of high symptom burden (weight loss of 25 kg, swollen belly, jaundice); interested to contribute to research
12	m	64	fatigue due to disease and treatment

answer the questionnaire as shown in Figure 2 autonomously – including patients who never used a smart-phone before (25 % of the sample).

- Special needs came from co-morbidities or age (e.g., limited visual skills).

- Confirmatory gesture: All patients but one chose to have an extra confirmatory tap to save the questionnaire values. The confirmation dialogue was evaluated positively as providing reassurance and not as annoyance.

- Design: Patients of all ages preferred big numbers (24 sp). The topic of smiley usage evoke emotional statements, e.g., *"I hate smileys."* (no. 8), *"I think smileys are sweet."* (no. 11). In our sample, all the patients who preferred smileys also preferred a colourful design of the distress thermometer and pain scale.

Conclusion: *Palliative care patients that fulfill the above mentioned inclusion criteria are willing and capable to use smart-phones. Concerning the app design, we could not find any requirements constituted in the palliative situation. Based on the interviews, we finalized the design as illustrated in Figure 2.*

5.3. Usability of a Wristband or Armband

Since the Everion was not available during the interviews, we showed the patients two commercial wristbands and explained the usage of it

- All patients understood how to deal with a wristband.

- Most patients showed a big interest and curiosity in the wristband.

Conclusion: *Palliative care patients are capable to use a fitness tracker and they are willing to wear it for the study period.*

5.4. Feedback through the Smart-Phone App

We explained the patients that an app can show them informations about their behaviour, e.g., the steps they have made during a day or the current heart rate.

- Eight out of 10 patients understood what is meant with feedback through the app.

- Three out of those 8 (no. 8, 11, 12) would be interested in feedback concerning their physical activity – but not more often than once a day. Those three patients already had experiences with fitness tracking apps.
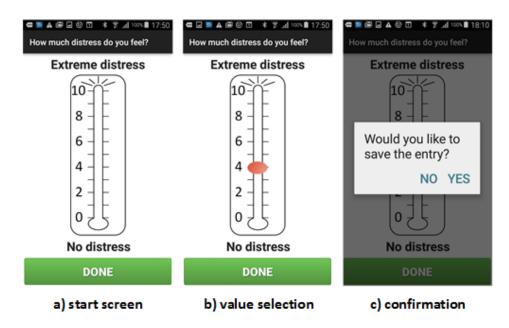
Figure 2. Digital Version of the NCCN Distress Thermometer: a) graphical design is based on validated paper version of the NCCN Distress Thermometer [17], b) value selection by tapping and sliding, c) confirmation dialogue

- Depending on the patient, the feedback serves more for information and support and encouragement (no. 11, 12) or has an entertaining character (no. 8).

Conclusion: Most of the patients of our sample were not interested in direct feedback through the app – at least as long as it was not experienced before. However, feedback serves an informational, encouraging or entertaining purpose for some patients. Feedback could destabilize easily palliative patients since they carry already a high mental burden. Therefore, the app as used for the study provides for the user a simple daily step counter as well as the current heart rate. Displaying this information can be enabled by the study staff.

5.5. Motivation to Use a Monitoring System

- Nine out of 12 patients gave positive comments on the presented monitoring system, e.g., patient no. 2 said: *"I take the smart-phone always with me when I am leaving home. It gives me a more secure feeling, e.g., when driving alone. Such a system is useful, it makes me feel more safe."*

- Patients no. 7 and 10 were concerned about data security and privacy.

- Patients no. 10 and 12, suffering from fatigue (they are chronically exhausted) commented the task to take the phone with them the whole day long:*"I imagine it really cumbersome."*

Conclusion: In the sample, a positive attitude towards a monitoring system was dominant. Sceptical statements
concerned mainly privacy issues. Comprehensibly, fatigue reduces the willingness to use the presented monitoring system. Important requirements towards the armband are easy to handle closing and charging mechanism and no user interaction in terms of buttons required.*

5.6. Vulnerability and Sensitivity of Palliative Care Patients

- Not all patients are conscious about their health situation, e.g., patient no. 7 stated: *"I already survived cancer once and I am confident to recover again."* Thus, the monitoring system is not named as a system for palliative care, but as a system *for patients like you*, when you leave hospital.

- Interviewer and interviewees met for the first time. The exceptional situation of the patients and the chosen interview technique (guided conversation) yielded to a momentum in the relationship that required mindfulness, an open attitude and willingness to get involved in those relationships.

- Nevertheless, all patients with a severe cancer illness are in extreme and very demanding situations. Patient no. 10 stated: *"I would like to enjoy the time I have left and such stuff should not limit myself."*

- Some patients appreciated the opportunity to talk. When planning interviews with vulnerable user groups the aspect of "time to merely talk"

should be taken into account (median of gross duration 62.5 min vs. 48 min net duration).

Conclusion: *To equip palliative patients with tracking devices requires empathy and mindfulness. The goal of palliative care is to provide the best quality of life possible, not only with respect to medical, but also to psychosocial and spiritual needs. A monitoring system should not interfere with these profound human wants.*

6. Case Study: Application during Study

In the following, we present the data of one patient (61 years, male) as proof of concept. The patient was included with ECOG[3] level 2, i.e. he could de-ambulate with full capabilities of self-care and able to be up more than 50% of working hours, but unable to carry out working activities. He was diagnosed a tonsil carcinoma. He received the devices during his stay in the university hospital. Since he had already a smart-phone that was incompatible with the Everion, he received a smart-phone that was newer than his own (Samsung Galaxy S7).
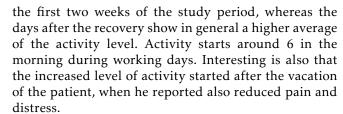
The data could be collected over the whole study period of 12 weeks. The study was paused while the patient was in vacation. In total, 84 days were recorded. The patient delivered 181 digital questionnaire answers and an amount of 861 hours of valid vital data was collected during 66 days. From the smart-phone, 40908 GPS points were collected.

The subjective self-rating of the patient via the digital questionnaires gives a first insight into the course of the recovery of the patient: Figure 3 shows an improvement directly after dismission from hospital. The patient recovered during vacation and rating of pain and distres declined. After turning back to every-day life the burden of symptoms, e.g.pain when opening the mouth, rose again.

In this patient, the weekly phone interviews were replaced by electronical transmission of the paper-based questionnaires by means of scans or photos, since this fitted better to the work situation of the patient.

Exemplatory for signals from the armsensor, Figure 4 shows the activity level and number of steps of the patient as measured by the Everion. The activity level delivered by the Everion can take a value from 0 to 255 and is based on the euclidean norm of the three signals of a 3-axis accelerometer. Average values were calculated on windows of 15 minutes. For the representation, the logarithm was applied. One day is represented by one row from left to right, starting from the top with day 1. On the right hand side, we report the amount of steps per day, normalized over the number of samples per day. Figure 4 illustrates less activity during

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[3] http://ecog-acrin.org/resources/ecog-performance-status

the first two weeks of the study period, whereas the days after the recovery show in general a higher average of the activity level. Activity starts around 6 in the morning during working days. Interesting is also that the increased level of activity started after the vacation of the patient, when he reported also reduced pain and distress.

In general, data collection has to deal with the daily life of the patient, e.g., work and vacation by adopting to the individual situation of the patient. In the final interview, the patient stated that carrying the devices with him and wearing the armsensor was no problem for him and he would have continued wearing the devices if asked.

7. Conclusion and Outlook

In this work, we presented a monitoring system that was developed with early participation of vulnerable patients and that will be fully evaluated by means of an observational study. The interviews demonstrated the huge variety of the patient group. We presented data of the first patient that was collected over 12 weeks. The continous monitoring of the patient's daily life required a certain flexibility to adapt to the personal situation of each patient. The amount of collected data lies in the range of our expectations.

The next steps consist of more detailed data analysis and continued patient recruitment and data collection. Patients' experiences will be used to improve the monitoring system.

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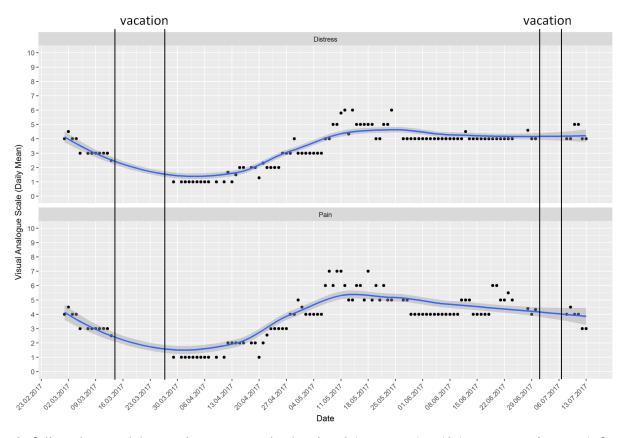
Figure 3. Self-rated pain and distress of one patient with values from 0 (no symptom) to 10 (max. severity of symptom). Symptoms were reduced after vacation and increased during daily life.

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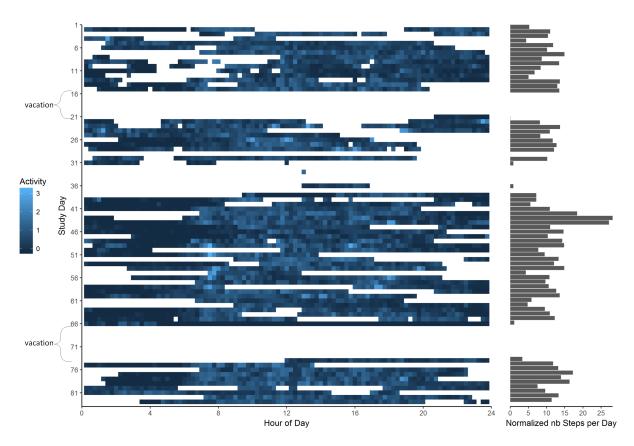
Figure 4. Activity levels ($\log(mean($activity over 15 minutes$)))$ over the study period: rows represent days from 0:00 to 24:00. The right hand side presents the number of stes normalized to the number of measurement samples per day.

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