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DOI: https://doi.org/10.1159/000501433

Oncology and Informatics – Research Article

Oncology

Oncology
DOI: 10.1159/000501433

Received: March 3, 2019
Accepted after revision: June 7, 2019
Published online: July 23, 2019

Feasibility and Usability Aspects of Continuous Remote Monitoring of Health Status in Palliative Cancer Patients Using Wearables

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Keywords
Mobile health · Wearables · Health status monitoring · Cancer patients · Digital health · Oncology · Palliative care

Abstract
Background: Mobile health is a promising strategy aiming to anticipate and prevent the deterioration of health status in palliative cancer patients. A prerequisite for successful implementation of this technology into clinical routine is a high level of usability and acceptance of devices. ***Objectives:*** We aimed to evaluate feasibility as well as patients' acceptance of remote monitoring using wearables in palliative cancer patients. ***Methods:*** In this prospective single-center observational feasibility study, 30 cancer patients treated with palliative intent in an inpatient setting with an estimated life expectancy of >8 weeks and <12 months were provided with a smartphone including a pre-installed "Activity Monitoring" app and a sensor-equipped bracelet and monitored over a period of 12 weeks starting at discharge from hospital. We report detailed feasibility and usability aspects and comment on patients' acceptance of the wearables. ***Results:*** Between February 2017 and May 2018 a total of 30 patients were included in the study. From these, 25 participants (83%) completed the whole study period. On average, the bracelet was worn on 53% and smartphone used on 85% of the study days. The completion rate of daily digital questionnaires for subjective ratings (pain and distress scale) was 73%, and 28 patients were able to handle the wearables and to operate the app without major problems. Use of the bracelet was low during the night hours, with a wearing time of 1.7% of all night hours (8 p.m. to 8 a.m.). ***Conclusions:*** Remote monitoring of health care status in palliative cancer patients with a limited life expectancy is feasible and patients are able to handle the smartphone and the sensor-equipped bracelet. Feedback towards use of this monitoring system was mostly positive.

Introduction

Cancer patients in palliative care are a high-burdened patient population who experience several health problems and symptoms. Deterioration of health status is common. In consequence, emergency visits and the need for inpatient care to stabilize symptoms such as pain, dyspnea, nausea, or fatigue are frequent [1–3]. Up to 50% of

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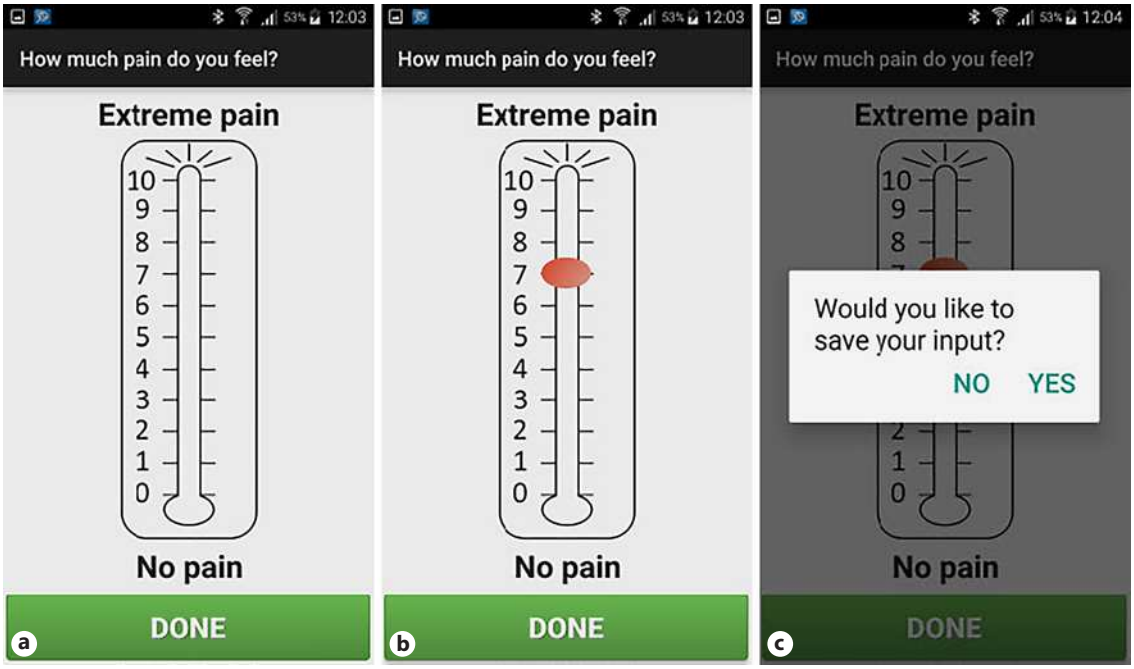

Fig. 1. Illustration of the app interface for the rating of pain VAS: start screen (**a**), value selection (**b**), and confirmation (**c**).

emergency visits and readmissions in this patient group are deemed avoidable [4, 5]. Therefore, strategies to anticipate and prevent the deterioration of health status are needed. However, continuous monitoring of patients in an outpatient setting is often not feasible due to lack of human resources, calling for novel and innovative approaches. Recent developments in wearables technology make them suitable for healthcare purposes. Mobile health technology has been explored in different diseases and patient groups [6–9] and the use of wearables including smartphones and sensor-equipped devices in medical research is growing constantly. There is research activity in cancer patients using activity monitors, consisting mostly of a pedometer or accelerometer [10]. However, the use of wearables in healthcare is still in its early phase, and despite evolving evidence in the field of mobile health technology in different patient groups, there is scarce knowledge about the use of wearables in palliative cancer patients. Prospective trials are needed to assess the effectivity of wearables and their impact on clinical outcome. A prerequisite for successful implementation of this technology into clinical routine is a high level of usability of devices to sustain their usage. There is increasing evidence that usage of wearables and mobile applications to report symptoms in cancer patients in general is feasible [10, 11]. Palliative cancer patients experience more and worse symptoms than cancer patients treated in a curative setting and are therefore often considered too burdened to deal with a new technology [12]. Accordingly, evidence on mobile health technology in palliative cancer patients including knowledge on usability aspects is lacking. Only 3 out of 41 trials in a review on wearable activity monitors in oncology included patients with metastatic cancer [10].

In this prospective observational study, we aimed to evaluate the feasibility as well as patients' acceptance of remote monitoring in an outpatient setting using wearables in palliative cancer patients. The hypothesis was that health monitoring by a smartphone and sensor-equipped arm bracelet is feasible in this severely ill patient group and enables the prediction of a decline in health status. The results on mobile health features as predictive biomarkers will be reported elsewhere [unpubl. data]. Here, we report detailed usability aspects and patients' acceptance of wearables.

Materials and Methods

Patient Cohort

This prospective observational study was conducted at the University Hospital Zurich. A more detailed research protocol has been described before [13]. Eligibility criteria were age >18 years, pres-

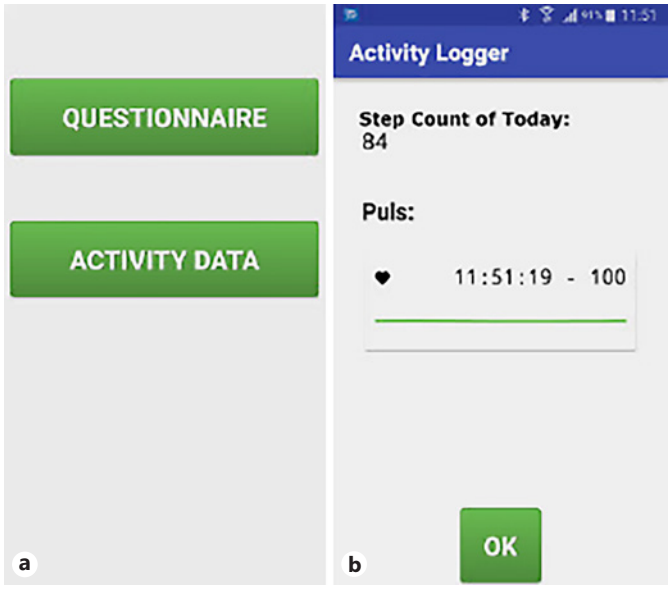

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Fig. 2. Illustration of the start screen (**a**) and display of heart rate and daily step count (**b**).

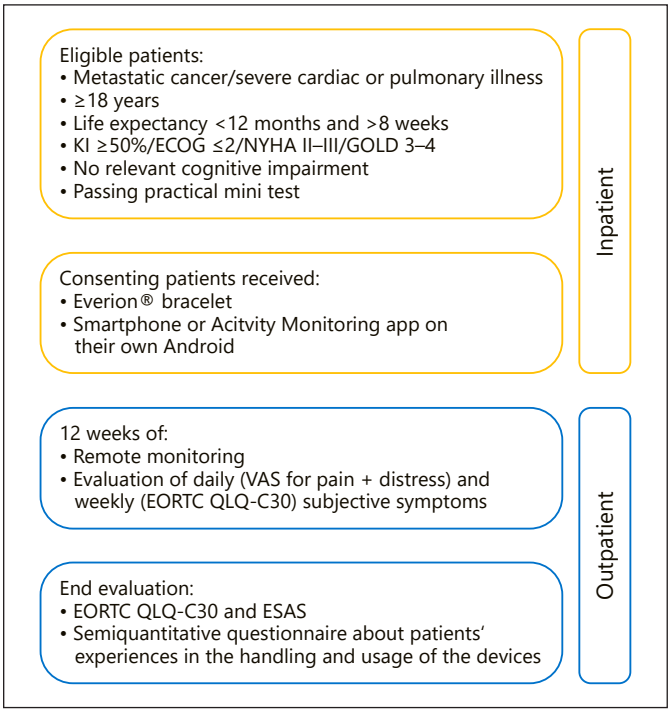

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Fig. 3. Overview of the study procedures.

ence of a severe medical condition (incurable cancer with an estimated life expectancy of >8 weeks to <12 months judged by a physician of the project team, severe cardiac disease with NYHA III–IV symptoms or severe pulmonary disease having a COPD GOLD III–IV), performance status of ECOG ≤2 and/or KPS ≥50%, no relevant cognitive impairment and good knowledge of the German language. In addition, patients had to be able to handle a smartphone, which was briefly tested. After instructions on how to use and handle the smartphone as well as the bracelet, patients had to pass a mini practical test, ensuring that they were able to handle the devices. We aimed to include 30 patients being discharged from inpatient care at the radiation oncology or specialized palliative care ward. The study was proposed to all eligible patients. All were asked to complete a questionnaire about their previous experience with electronic devices. Patients who refused participation in the study were asked about their reasons for declining.

Electronic Devices and the Active Monitoring App

Participating patients were provided with devices consisting of a smartphone Galaxy S5 mini, equipped with a prepaid SIM card, and the bracelet Everion® by Biovotion (Biovotion, Zurich, Switzerland). Patients also had the possibility to use their own smartphone (Android smartphone). In this case, the "Activity Monitoring" app was installed on the patients' smartphone. We chose the Biovotion bracelet because of its official approval as a medical device in the USA (ISD 890.5360) and in Europe (CE 0123), the broad range of parameters measured by the device and the possibility for storage of data outside of the companies' cloud service. The bracelet was worn on the upper arm, fixed by an elastic belt. The size of the belt was fitted to the patients' arm. A smartphone belt was optional.

The "Activity Monitoring" app has been designed and adapted specifically for the needs of palliative care patients. To evaluate and finalize the app's user interface, an interview study including 12 cancer patients was previously conducted and the results were implemented [14, 15]. Variations in the font size and color of the interface elements as well as different control elements (a button or a slider) were proposed. According to patients' preferences, the app was designed with large numbers and a rather simple design to ensure easier handling (Fig. 1). The app consists of two parts: a patient interface providing digital questionnaires to rate the subjective pain and distress on a visual analog scale (VAS) and a sensor logging module for recording and transmitting signals from smartphone sensors. Additionally, the app includes an interface to the bracelet – for management of Bluetooth connection and to request, receive, and record sensor signals of the bracelet and transmit these signals encrypted to a secured server at the Swiss Federal Institute of Technology (ETH Zurich). Sensitive data, such as GPS, were anonymized. The app additionally provided and displayed information about the current heart rate and daily step count that was measured by the smartphone sensor (Fig. 2). Patients without internet connection at home were provided with a mobile Wi-Fi hotspot.

Study Procedures and Evaluation of Usability Aspects

The study phase of 12 weeks started at discharge from hospital. Patients were asked to wear the devices as often and long as possible – ideally all day long including during night hours – except for the time needed to charge the battery. During the first week at home, a study member visited the patient to ensure the correct deployment of the device, mainly configuration of Wi-Fi for data transmission. Patients staying first in a rehabilitation unit after discharge from hospital were visited when returning home. Patients going on vacation during the study period paused tracking during their holiday and resumed after returning home. Subjective ratings of symptoms were

Table 1. Patient characteristics

	Participants (n = 31)	Non-participants (n = 28)	p value (SD)
Age, years	64 (53.00–71.00)	69 (63.00–73.75)	0.136 (0.329)
Sex			
Male	22 (71.0)	17 (60.7)	0.425 (0.217)
Female	9 (29.0)	11 (39.3)	
ICD code			
C34 (lung cancer)	9 (29.0)	11 (39.3)	
C71 (brain tumor)	6 (19.4)	3 (10.7)	0.562 (1.339)
C50 (breast cancer)	3 (9.7)	2 (7.1)	
Other	13 (42)	11 (43)	
Age-adjusted CCI			
	5 (4–7)	6 (4–8)	0.323 (0.276)
ECOG			
0–1	18 (58.1)	13 (48.1)	0.534 (0.317)
2	13 (41.9)	14 (51.9)	
KPS			
80–100	13 (52.0)	7 (31.7)	0.300 (0.736)
50–70	12 (48.0)	15 (68.2)	

Values are the median (range) or n (%). CCI, Charlson Comorbidity Index; ECOG, Eastern Co-Operative Oncology Group; KPS, Karnofsky Performance Status.

evaluated 1 day prior to discharge using the EORTC-QLQ-C30. This was repeated weekly during a phone call. The Edmonton Symptom Assessment System (ESAS) was filled out 1 day before discharge and at the end of the study period. VAS for pain and distress were rated daily in the app. A vibration alarm reminded the patients to fill out the VAS. At the time of vibration, the questionnaire showed up automatically on the screen. In case it was not answered immediately, the alarm was repeated up to five times every 5 min. The time window the questionnaire showed up was randomized between 8 a.m. and 8 p.m., but it was also possible to adapt the time window to patients' wishes (for example between 10 a.m. and 12 a.m.). Patients could also start the VAS on their own if they felt like and were free to answer it multiple times a day. If a score of ≥5 for distress was reached within a week, the second part of the distress questionnaire, evaluating reasons for this distress, was filled out during the weekly phone call. During the weekly interviews patients reported any problems with charging or operating the wearables. Additionally, they were asked if they had difficulties with the "Activity Monitoring" app. A more detailed semi-structured interview on usability aspects containing nine open-ended questions was performed at the study end (see Appendix Fig. A1 and A2 for details of the questions asked). An overview of study procedures is shown in Figure 3.

Data Analysis

Results obtained in this prospective trial concerning feasibility and usability aspects are of a qualitative nature and accordingly evaluated and presented [16]. Qualitative questionnaire responses of the weekly and final interview were analyzed manually and the most prevalent and significant comments and experiences summarized as the main findings. Quotes are provided to concretize the interview results.

Results

Demographics

Between February 2017 and February 2018, a total of 68 patients fulfilled all the eligibility criteria. Of these, 31 patients consented to participate and were included. One patient died only a few days after discharge before any usage of wearables, thus no data are available for this patient. Nine of the 30 patients included in the analysis were female and 21 were male. The median age was 64 years (range 39–85). Table 1 provides more details about demographic data on participants and eligible patients not willing to participate. None of the patient characteristics differed significantly between study participants and eligible non-participants. Information on previous experience with electronic devices as well as reasons for rejection of study participation are reported in a not yet published paper, together with the results on the predictive ability of remote monitoring.

Completeness of Data Collection

Twenty-five out of 30 patients (83%) completed the full study period of 12 weeks. Two out of 5 dropouts were due to technical problems with Bluetooth connection; in 1 of these cases the Bluetooth module in the smartphone was defect. The other dropouts were health related: all 3 patients had to quit the study because of severe deteriora-

tion of health status with consecutive death shortly thereafter. The smartphone was worn on average for 85% (SD 19.4) and the bracelet for 53% (SD 28.0) of all study days. Eighteen patients (60%) wore the bracelet for more than 50% of the study days. Concerning the smartphone usage rate, the number of patients wearing it for more than 50% of the days was higher (28 patients; 93.3%). Twenty-three of the 30 patients (76.7%) carried the smartphone with them for more than 80% of all study days. On those days, when the wearables were put on, the bracelet was worn for 63% (SD 16.8) and the smartphone for 50% (SD 24.2) of the day time (considered as between 8 a.m. and 8 p.m.). Patients were also told to wear the bracelet during night hours if they were motivated to do so. Seven patients (23.3%) never put the bracelet on during the night and, overall, patients wore the bracelet for 1.7% of all night hours (considered as between 8 p.m. and 8 a.m.). The digital questionnaires (pain VAS and distress thermometer) were answered on 73% (SD 22.8) of the days. It is noteworthy that some patients answered the digital questionnaires more than the requested once per day. In total, 13 out of 30 patients answered the questionnaire on average >1.5 times per day. The maximal answering rate was 5.7 times per day in 1 patient – in the final interview the patient explained that he wanted to report every change in subjective symptoms. The proportion of patients carrying the wearables, usage time, and rate of patients answering the digital questionnaires did not drop during the study period. Weekly interviews on device handling were answered in 83% of all weeks (all patients in total considered). One patient was excluded from this analysis because he experienced severe hoarseness and could therefore hardly speak on the phone. He was one of the patients who quit the study due to health deterioration. Final interviews were completed by 26 out of 30 participants (86.7%).

Feedback Concerning the Handling of Wearables and the "Activity Monitoring" App

Nine out of the 30 patients (30%) did not report any problems during the whole study period. Twenty-one patients (70%) reported difficulty at least once with either one of the wearables or the app. However, in most cases, problems related not to the handling of the device or app itself, but rather to technical problems occurring occasionally during the operation of the electronic devices, like a crash of the app or the touchscreen not responding, with both events demanding a restart. A secondary issue was mainly that the step count or the heart rate were not displayed correctly (according to the judgement of participants), or not at all. Furthermore, the sensor occasionally lost connection to the smartphone and had to be reconnected "manually."

Only 2 study participants (6.7%) had problems handling the wearables from the outset of the study. Both participants had no previous experience with smartphones or activity tracking watches. One of the 2 patients who struggled with the smartphone and bracelet was aged 85 years, the oldest participant in the study. Both patients had problems operating the devices and app, such as forgetting how to make a phone call or write a message. The 85-year-old patient filled out the digital questionnaires on only 11.8% of all study days, and wore the bracelet on 10.5% and carried the smartphone on 51.3% of the days. She explained that she is forgetful in addition to having problems operating the app. The other patient who experienced difficulties handling the wearables and the app was a 67-year-old participant without any memory issues. On several occasions she requested support from the study team, who instructed her on how to use the wearables and the app, after which she was able to learn the procedures. In contrast to the other patients she had high completion rates, filling out the questionnaires, wearing the bracelet, and carrying the smartphone on 86.2, 92.6, and 95.7% of all study days, respectively.

Concerning usage of the "Activity Monitoring" app, 21 patients (70%) stated during the whole period that handling was easy. Only 9 of the 30 patients (30%) stated in at least one of the weekly interviews that usage of the app needed some customization or was even cumbersome. However, 7 of these 9 patients rated in only one of all of their interviews that they need to familiarize themselves with handling of the app, mainly during one of the first weeks of the study, and in the remaining interviews reported handling to be easy. Therefore, overall, the majority of the participants (28 out of 30 patients) were able to operate the app easily.

Feedback on the Comfort of the Bracelet

As reported above, usage of the bracelet during night hours was sparse. The main reason for not wearing the bracelet was using night hours to charge the bracelet, as reported by 21 patients. Only 6 participants specified in any of the weekly interviews that it felt uncomfortable to wear the bracelet while sleeping. Another 3 patients reported that it was uncomfortable to wear the bracelet when the weather was too hot – the elastic belt led to annoying sweating. All these patients participated during the summer, commencing in June 2017. Six patients reported the elastic belt becoming loose within a few weeks. One of

the patients then tried to wear it on their leg and rated this as very convenient. Another patient continued to have problems with an uncomfortable elastic belt even after exchanging to another one – he had a slightly larger upper arm and experienced that the band rolled up. Two patients would have favored wearing the bracelet on their wrist.

General Perception of the Study and Comments on Devices, Pitfalls, and Suggestions for Improvements

In general, 20 patients stated a positive overall rating concerning the study. Only 1 patient reported to be happy that the study was over. Others did not state if they rated the study rather positively or negatively, but gave direct answers to the questions: "What is your general impression on the study?" and "What went well and what was difficult?" Here are some examples: "The devices are quite eye-catching," "The biggest problem was that the battery of the smartphone switched to energy-saving mode due to fast consumption despite normal usage," and "It is cumbersome to operate even more devices." The last quote was from a patient who had to walk on crutches and reported difficulties in putting the bracelet on and wearing the smartphone on their body. Feedback from others in contact with the subjects was either positive or people expressed curiosity, but no negative comments were given. One participant discussed the issue of data security with friends and relatives. Three patients declared spontaneously that they would like to see all their data collected by the wearables. Nine participants in total stated that they had to recharge the battery of the wearables (either smartphone or bracelet or both) very often. Four patients stated that having no display of the battery load of the bracelet was cumbersome and would therefore like to see the percentage of battery charge.

Concerning recommendations for future applications and developments, comments were mainly related to aspects perceived as cumbersome and already stated in the first part of the interview (prolong battery life of wearables, display of battery life of the bracelet, and 2 patients commented that they would suggest a bracelet for the wrist). Three patients suggested that the data captured during the study should be discussed with the patients: "Feedback should be given to the patient if there is a worrisome trend in vital signs."

Discussion

The overall aim of remote monitoring using mobile health technology is to advance the care of palliative cancer patients. Wearables could lead to a reduction of re-admissions or emergency visits by anticipating a health status deterioration. For successful implementation of electronic devices into the clinical routine, it is of utmost importance that patients are able to cope with these devices. We could show that continuous health monitoring using mobile technology in palliative cancer patients is feasible and accepted by the majority of patients. Patients were able to use and handle the smartphone as well as the bracelet over a long period of 12 weeks. Out of 30 patients included, 28 reported no major issues with handling and were able to handle the devices and the app during the whole study period. Feedback on remote monitoring using the wearables was mostly positive.

This finding is of importance as so far there are limited data available on the feasibility of use of mobile technology in palliative oncological patients. However, this is a premise for successful implementation of such a system. Most data are on the usage of remote communication systems or electronic symptom-reporting systems, which are feasible in palliative care patients [17–19]. McCall et al. [20] have proven that oncological patients receiving palliative care in their homes are able to report their symptoms electronically daily over a period of 30 days. However, activity and vital signs monitors are so far not widely investigated in this patient group, and existing data are mostly on accelerometers and pedometers [21, 22]. Therefore, evidence that handling of two devices – a smartphone with the pre-installed app as well as a sensor-equipped bracelet measuring a lot of different features – is feasible, provides important information.

Our results are in line with the limited data already existing on this topic. Low et al. [23] investigated a monitoring system consisting of an android with the AWARE framework (an application for capturing data) installed on it, as well as a Fitbit. Fourteen patients undergoing chemotherapy for gastrointestinal cancer participated for a mean duration of 21.07 days. The authors concluded the use of such a monitoring system being feasible in these patients. However, no details on usability aspects and acceptance were given. Wright et al. [24] evaluated an accelerometer-based monitoring system over a period of 30 days in 10 gynecological patients undergoing palliative chemotherapy focusing on feasibility, acceptability, and perceived effectiveness. These patients used a smartphone with the Beiwe research platform (also a tool for the collection of data) on it and two accelerometers. Adherence rates of 70% to smartphone surveys and 90% to wearable accelerometers were re-

ported. It is notable that adherence was fulfilled if surveys or accelerometers were operated a minimum of 4 days per week, which is different to our study where we counted each day and provided the number of days patients wore the wearables in relation to the total study duration. Nine out of the 10 patients did not regret having participated in the study and would recommend the application to a friend.

To our knowledge there is no other trial reporting the feasibility of mobile health technology consisting of two wearables over such a long period and in such a distinct patient cohort with initially defined concise inclusion criteria concerning life expectancy and health status. Patients were able to participate for the full study period of 12 weeks in most cases (25 out of 30 patients). The proportion of days on which wearables were worn at all was much higher for the smartphone compared to the bracelet, at 85% (SD 19.4) and 53% (SD 28.0) of all study days, respectively. Conversely, the wearing time per day was higher for the bracelet compared to the smartphone, at 63% (SD 16.8) and 50% (SD 24.2), respectively. This finding is not surprising: patients did take the smartphone with them often; however, when at home they did not wear it on their body but generally left it in a certain place, for example on the table while they were in the living room. Once the bracelet had been put on, the patients left it on until they needed to remove it. The usage rate and time during night hours was limited. Adherence was stable over the length of the study, indicating that participants who tolerate monitoring from the start will continue to do so in the future.

Our feasibility study has some limitations. First of all, the small number of patients precluded a thorough analysis of the patient factors predictive of compliance and the successful use of wearables. Furthermore, we did not evaluate reasons for the acceptance of wearables or patients' expectations on the impact of such devices. El Shafie et al. [25] performed a survey evaluating the acceptance and expectations of use of a mobile app in breast and prostate cancer patients undergoing radiation therapy. A large proportion (>70% of patients) showed strong interest in using a mobile app during radiotherapy and clinical follow-up. Most commonly, appointment scheduling was reported as a possible useful mobile tool. However, the surveyed patient cohort was distinct from the patient population in our study. Only 15.5% of them received a palliative treatment, whereas the vast majority underwent treatment in a curative setting. Not only acceptance by patients, but also by health care providers, is a requirement for the broad implementation of electronic devices for remote monitoring into a clinical routine. We did not analyze the opinion of medical staff on the use of the wearables. Kessel et al. [26] performed a survey investigating the attitude of health care professionals, working in the field of oncology, towards mobile health. Overall, of 108 professionals 88.9% considered telemedicine to be a useful tool. The patient group was not further specified within the survey and thus results applied for oncological patients in general. Cox et al. [12] interviewed physicians working with lung cancer patients in a palliative care setting and analyzed their perceptions of e-technology for symptom assessment. They regarded cancer patients treated in a palliative setting as generally too old and too burdened to deal with a new technology. This is in contrast to the results of our feasibility study.

In conclusion, here we provide evidence that remote monitoring of health status in palliative cancer patients with a limited life expectancy is feasible and patients are able to handle the smartphone and the sensor-equipped bracelet as long as their condition is not worsening in a very rapid way. Monitoring during night hours was not achieved. Given the possibilities of remote monitoring and hope for improvement of patient care by preventing re-admissions, further research in this area is warranted. In doing so, the mobile health community should not only focus on the development of mobile health apps and devices and research on algorithms for outcome prediction, but should also put effort into exploring and defining legal aspects (data security and privacy) and prove the cost-effectiveness of digital health tools [27]. Our results support the effort put into mobile health technology in palliative cancer patients and provide impetus to maintaining the research focus not only on patient-reported outcomes, which were proven to have a clinical significance, but also investigate the impact of activity and vital signs monitoring in palliative cancer patients [28, 29].

Acknowledgements

We acknowledge Deborah Mittner and Sonja Schwenne for their contributions to the project (acquisition of data).

Statement of Ethics

This prospective observational study was approved by the local ethics committee (PB_2016-00895) and all patients provided written informed consent.

Disclosure Statement

The authors have no conflicts of interest to declare.

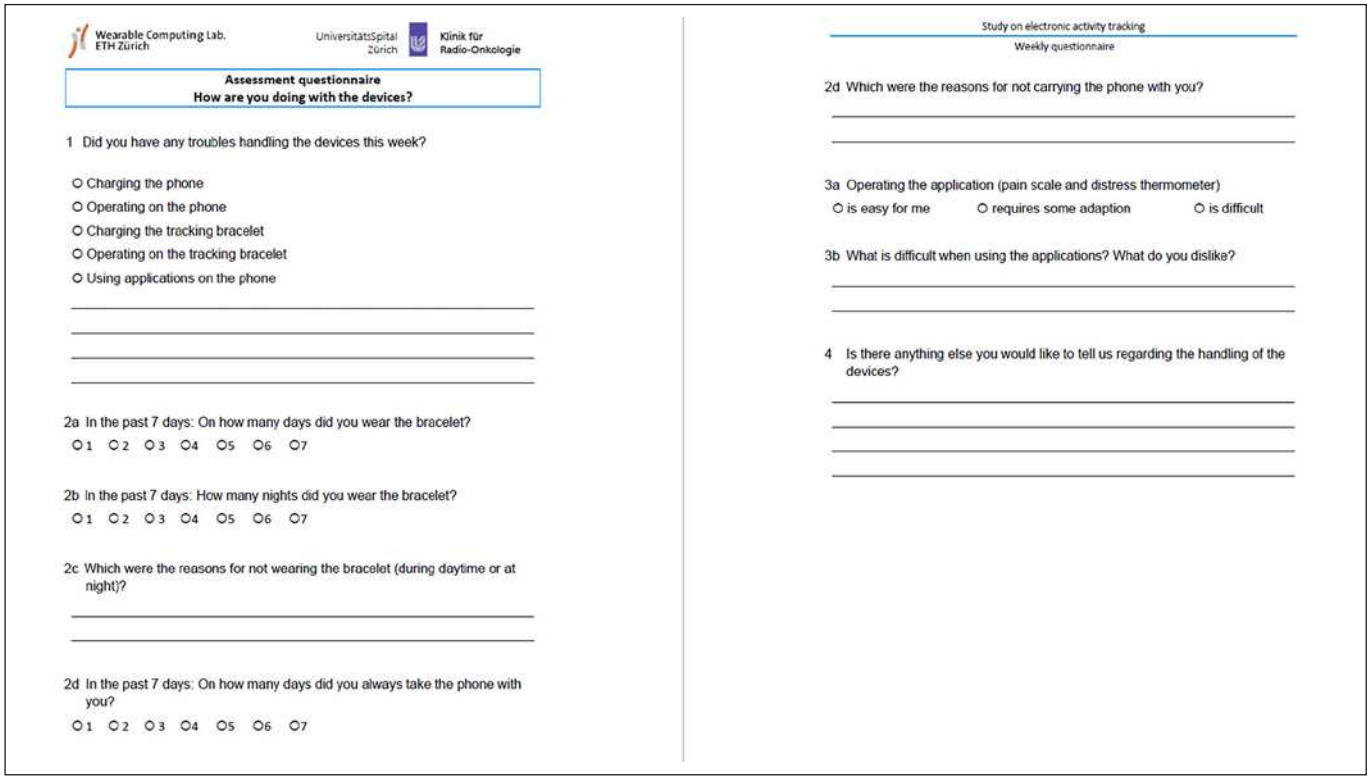
Funding Sources

The study was funded by the foundation program "Research in Palliative Care" of the Swiss Academy of Medical Sciences (SAMW) and the "Gottfried and Julia Bangerter-Rhyner Foundation" and "Stanley Thomas Johnson Foundation." The funders had no influence on project development, study realization, or manuscript writing.

Author Contributions

Matea Pavic: acquisition, analysis, and interpretation of data; writing – original draft; writing – review and editing; project administration; study supervision and final approval. Vanessa Klaas: conceptualization; acquisition, analysis and interpretation of data; writing – review and editing; project administration; study supervision and final approval. Gudrun Theile: conceptualization; drafting of study protocol; writing – review and editing; project administration; study supervision and final approval. Johannes Kraft: acquisition of data; writing – review and editing; final approval. Gerhard Tröster: conceptualization; writing – review and editing; final approval. Matthias Guckenberger: conceptualization; writing – review and editing; project administration, study supervision and final approval.

Appendix


Wearable Computing Lab. ETH Zürich
UniversitätsSpital Zürich
Klinik für Radio-Onkologie

Assessment questionnaire
How are you doing with the devices?

1 Did you have any troubles handling the devices this week?

- O Charging the phone
- O Operating on the phone
- O Charging the tracking bracelet
- O Operating on the tracking bracelet
- O Using applications on the phone

2a In the past 7 days: On how many days did you wear the bracelet?
O1 O2 O3 O4 O5 O6 O7

2b In the past 7 days: How many nights did you wear the bracelet?
O1 O2 O3 O4 O5 O6 O7

2c Which were the reasons for not wearing the bracelet (during daytime or at night)?

2d In the past 7 days: On how many days did you always take the phone with you?
O1 O2 O3 O4 O5 O6 O7

Study on electronic activity tracking
Weekly questionnaire

2d Which were the reasons for not carrying the phone with you?

3a Operating the application (pain scale and distress thermometer)
O is easy for me O requires some adaption O is difficult

3b What is difficult when using the applications? What do you dislike?

4 Is there anything else you would like to tell us regarding the handling of the devices?

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Fig. A1. Weekly assessment questionnaire.

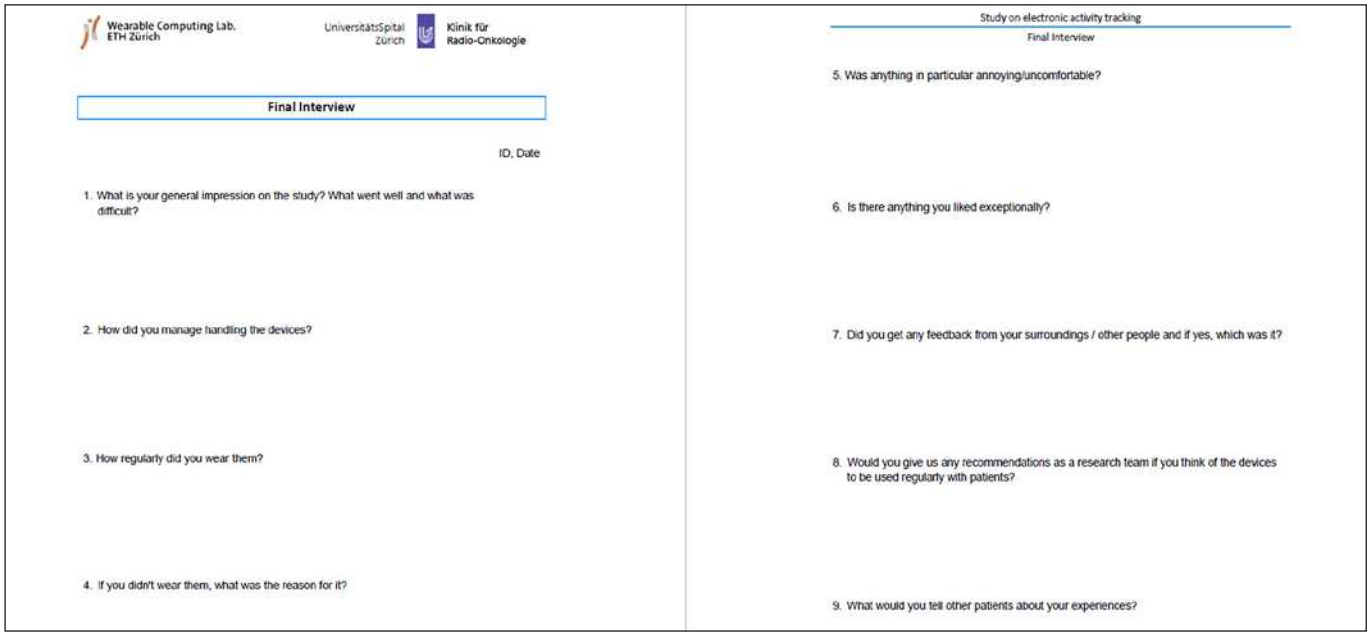

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Fig. A2. Final interview.

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