Troiani *et al*. *J Smart Environ Green Comput* 2021;1:189-201
DOI: 10.20517/jsegc.2021.10

Journal of Smart Environments and Green Computing

Original Article

Open Access

Enabling smart environment for monitoring cancer patients therapy through OncoSmart

Teresa Troiani[1], Stefania Napolitano[1], Marinella Terminiello[1], Pietro Paolo Vitiello[1], Fortunato Ciardiello[1], Erika Martinelli[1], Giuseppe Fenza[2,3], Francesco J. Orciuoli[3], Luca Romanelli[3]

[1]Dipartimento di Medicina di Precisione, Oncologia Medica, University of Campania Luigi Vanvitelli, Naples 80138, Italy.
[2]Department of Management & Innovation Systems, University of Salerno, Fisciano 84084, Italy.
[3]RiAtlas Srl, c/o Università degli Studi di Salerno, Fisciano 84084, Italy.

Correspondence to: Prof.Giuseppe Fenza, Department of Management & Innovation Systems, University of Salerno, Salerno, Italy. E-mail:gfenza@unisa.it; Dr.Teresa Troiani, Dipartimento di Medicina di Precisione, Oncologia Medica, University of Campania Luigi Vanvitelli, Naples, Italy. E-mail:teresa.troiani@unicampania.it

How to cite this article: Troiani T, Napolitano S, Terminiello M, Vitiello PP, Ciardiello F, Martinelli E, Fenza G, Orciuoli FJ, Romanelli L. Enabling smart environment for monitoring cancer patients therapy through OncoSmart. *J Smart Environ Green Comput* 2021;2:xx. http://dx.doi.org/10.20517/jsegc.2021.10

Received: 15 Jun 2021 **First Decision:** 11 Oct 2021 **Revised:** 15 Nov 2021 **Accepted:** 29 Nov 2021 **Published:** 25 Dec 2021

Academic Editor: Shun-Feng Su **Copy Editor:** Yue-Yue Zhang **Production Editor:** Yue-Yue Zhang

Abstract

Aim: Treatment-related health symptoms strongly compromise the success of therapy and the quality of life of cancer patients. Patient smart monitoring through wearable devices and the management of electronic patient-reported outcomes (ePROs) prevent missing symptomatic toxicities. This study describes a preliminary clinical trial adopting OncoSmart Software as a Medical Device in the Health Continuum Cancer Care Pathways, realized by Riatlas srl.

Methods: The preliminary study enrolled eight mCRC (metastatic colorectal cancer) patients under active medical treatment between June 2019 and January 2020. OncoSmart provides a mobile app integrated with a smartwatch. The mobile app alerts patients to fill ePROs and integrates the smartwatch to collect vital parameters (blood pressure, heart rate, oxygen saturation, respiratory rate, pedometer, sleeping, *etc*.). On the physician side, OncoSmart provides an interactive dashboard for monitoring the patient's therapy and treatment-related health symptoms.

Results: Despite the low number of enrolled patients, the trial revealed interesting results about OncoSmart's adoption, measured in compliance and concordance. Compliance is the participation of patients in self-reports, which was about 77%. Overall concordance between ePRO and symptoms detected by physicians at clinical visits was 80%. The

remaining 20% included 15% of cases where ePROs included symptoms missed during the visit and 5% of cases where physicians reported toxicities not recorded by patients. Regarding the symptoms that led to treatment modifications and/or suspension, the concordance between PROs and the physician's evaluation during the visit was 100%.

Conclusion: New medical treatments aim at improving patients' survival and quality of life; using solutions such as OncoSmart increases patient empowerment and engagement. The preliminary results of OncoSmart suggest pursuing further assessment of the impact of a PRO solution in routine clinical practice.

Keywords: Patient-reported outcomes, quality of life, digital therapy, digital health smart monitoring

INTRODUCTION

Based on an estimation of the International Agency for Research on Cancer in 2018, there were were 18.1 million new cancer cases, with more than 9 million deaths[1]. Despite studies that highlight a trend toward increased survival[2], new cases are relevant, and therapies are generally costly. Thus, new treatments should focus not only on improving overall survival but also on the quality of life (QoL). Furthermore, the advent of self-administered therapies enhances the need for specific adverse events (AEs) monitoring without direct medical supervision.

Treatment-related health symptoms may induce side effects and long-term consequences, compromising patients' QoL, which is sometimes underestimated by physicians[3]. These side effects are among the most popular factors motivating therapy changes and are highly correlated with the complexity, intensity, and toxicity of the treatment. In this context, it is crucial to promptly recognize the adverse events of cancer therapies for early alerting and requesting medical interventions.

The systematic collection of patient-reported outcomes (PROs) has been demonstrated to be a valid, reliable, feasible, and precise approach to tabulating symptomatic toxicities and detecting symptoms missed by clinicians[4]. Technologies that facilitate communication between cancer treatment teams and patients may be helpful and will probably be integrated into typical hospital communication systems in the near future (https://www.oeci.eu/Attachments/OECI_Yearbook2018-2019.pdf).

Patient monitoring heavily relies on the availability of smart devices able to gather useful data. Devices devoted to collect vital signs (i.e., wearable devices) or, in general, patients' information (drug administration, patient's movements, *etc.*), become essential in the new generation of health management. In this sense, the advent of the Internet of Things (IoT), in which everyday life objects are connected to the Internet, enables the smart environments and, in particular, the spreading of e-health. In 2013, Peeters *et al.*[5] studied and confirmed the positive contribution of technology in the quality of care and, more in detail, for self-monitoring activities. More recently, Cajamarca *et al.*[6] made a systematic literature review on the diffusion of mobile health technologies specifically for older adults. From more than 600 screened articles, it emerges that smartphones and tablets are relevant technologies for self-monitoring.

Following the creation of a "User's Guide to Implementing PRO Assessment in Clinical Practice" by the International Society for Quality of Life Research (ISOQOL), volunteers from ISOQOL sought to create a companion guide to assist healthcare providers with the scientific and practical considerations involved in implementing and using PRO measures in clinical care by using information from real-world case studies. A US randomized controlled trial with 766 metastatic cancer patients shows that digital symptoms monitoring during chemotherapy (i.e., diarrhea, pain, fatigue, and emotional distress) helps patients live longer (5.2 months longer median overall survival), improves the quality of life (31% of patients), and reduces hospitalization (4%) and visits

(7%)[7]. Although PRO represents a tool established over the past three decades or more, the spreading of web-enabled devices (smartphones, tablets, *etc.*), by facilitating real-time self-reporting in at home, has only recently increased its adoption[8].

This study presents and assesses the suitability of the OncoSmart solution as a software medical device for collecting PROs and monitoring treatment-related health symptoms for early alerting physicians about adverse effects and inducing therapy changes eventually. OncoSmart also provides an alerting service that is tunable by physicians about vital parameters collected with wearable devices. It helps in organizing a cost-effective clinical assessment/follow-up process for colorectal cancer patients. OncoSmart is realized by Riatlas, which filed a patent (Nr.102019000007139)[1]: "Computer implemented method for classifying a patient based on classes of at least one predetermined patient classification".) concerning an AI-based tool that classifies patient health status using the International Classification of Functioning, Disability and Health (ICF), a taxonomy defined by the WHO. The tool, at each clinical assessment of the patient, identifies and suggests to the physician (who simply validates it) the "appropriate" ICF codes (as digital biomarkers) in terms of functioning, activity, and participation. The tool simplifies the physician's tasks by reducing the time to insert data and mitigates the risk of subjective interpretations of patient classification and performance status evaluation. It supports the right treatment/therapy and favors the introduction of "pay-for-outcome" models.

Eight adult patients diagnosed with metastatic colorectal cancer (mCRC) and eligible for pharmaceutical treatments participated in the assessment study. The suitability and efficacy of OncoSmart were evaluated through two measures: (1) the compliance, which is strictly related to the level of acceptance and patient engagement; and (2) the concordance between electronic patient-reported outcome (ePRO) and symptoms detected by physicians. Compliance was 77% and overall concordance was 80%. These preliminary results are promising, even if we recommend further assessing.

The remainder of this paper is organized as follows. Section Related Works analyzes the state of the art in the areas of patient monitoring and smart environments for e-health. The overall user journey implemented by the OncoSmart solution and details about its implementation are in Section OncoSmart: Software As Medical Device. This section also introduces the main components of OncoSmart (see, Section Mobile app and wearable) and the patient data flow (see, Section Patients Data Collection and Analysis Workflow). Section Clinical Trial Dataset introduces patients' recruitment and the collected dataset during the clinical trial. Section Experimental Results summarizes the experimental results by detailing the participating patients, defining the adopted evaluation measures, and discussing the evaluation results of the clinical trial. Finally, Section Conclusions closes the work.

RELATED WORKS

In the literature, there are many systems assisting cancer patients through self-reporting[9,10], demonstrating the effectiveness of this type of communication in symptom awareness[11] and speeding up of interventions[12]. OncoKompas[13] is a web-based self-management tool particularly focused on patient engagement; it allows outcome reporting, generates tailored feedbacks, and selects optimal supportive care services. ASyMS[14] is a mobile-phone-based remote monitoring and alert system focusing on chemotherapy-related symptoms. BREATH (Breast cancer e-health)[15] offers psychological support to women affected by breast cancer. COMPASS[16] is an e-Health platform that combines PROs with passive monitoring through sensor data. Interaktor[17], through a web interface and an app, provides symptom monitoring (including frequency and distress level), an advising system of relevant websites related to symptoms, and an alerting system for nurses. Kaiku[18] collects adverse effects of patients treated by radiotherapy and evaluates the usability of the offered Internet-based application. Finally, Cancer.net Mobile (https://www.cancer.net/navigating-cancer-care/managing-your-care/cancernet-mobile) is a mobile application from the American Society of Clinical Oncology. It offers

a set of tools to help manage cancer cases (track symptoms, record questions, log medications, appointments, *etc*.).

Beyond cancer patients' monitoring, smart environments are adopted efficiently for many other chronic diseases or, in general, elderly people monitoring. For example, patients with cardio problems are monitored by ECG data from their remote locations[19]. Elderly people living alone are controlled through contextual data (e.g., achievement of daily activities) that give an evaluation of their health status[20].

The literature highlights an important contribution of smart environments in enabling e-health solutions and "patient empowerment" platforms. iManageCancer[21] combines personal health systems, serious games, psychoemotional monitoring, and decision-support tools to improve patient engagement. An IoT application based on remote sensing architecture was proposed by Gharsellaoui *et al.*[22] to assist patients having a pacemaker. Similarly, disease activity monitoring on patient empowerment and treatment in Parkinson's disease is proposed in Karni *et al.*[23].

As expressed in this section, numerous trials have tried to test the patient experience with new applications, even though there are already existing ones. Often, the objective is to demonstrate the compliance of a new solution according to the ePRO method. This is particularly useful for oncological patients who often meet toxic side effects and could benefit from physicians' early alerting.

ONCOSMART: SOFTWARE AS MEDICAL DEVICE

OncoSmart is an all-in-one solution acquiring data from clinical and personal context, supporting clinical decision-making and patient engagement through the care pathway. The scope is to provide personalized health continuum care, incorporating more innovative monitoring and early detection methods for metastatic colorectal cancer patients. OncoSmart enables vital signs and symptoms monitoring and alerting, reporting early detections of clinical risks; health status patient assessment, favoring objective outcome evaluation; personalized treatments, supporting precision medicine; and de-hospitalization support, improving adherence/appropriateness of therapy/treatment.

Mobile app and wearable

The main components of OncoSmart are:

1. The mobile app is used at the patient side for patient-reported outcomes. It is integrated with a smartwatch used to collect vital signs.
2. The health data hub collects data coming from heterogeneous sources (i.e., EHR, self-assessment forms, laboratory data, and vital signs), adopting an HL7-FHIR framework (https://www.hl7.org/fhir/summary.html).
3. The AI-based data analysis application supports patient health status updates, clinical decision-making tasks, and early detection of clinical risks.

OncoSmart platform, at the physician side, allows physicians to manage the patient information, social and clinical data, and update health status at every follow-up. The application supports the physician in assessing the patient's health status adopting the ICF classification proposed by WHO. OncoSmart, at each clinical assessment of the patient, simplifies the physician's work (who simply validates it) by suggesting the "appropriate" ICF codes classifying patient health status. It also supports qualifiers (gravity level) valorization (score) for each ICF code, using recognized taxonomies and assessment scales. A user-friendly visualization (intelligent dashboard) supports pro-active monitoring of ICF codes, observing qualifiers evolution during the care pathway. From the patient's point of view, OncoSmart allows the self-monitoring of symptoms evolution, finding disease information, and keeping track of prescribed therapies through their smartphone. The users' journey

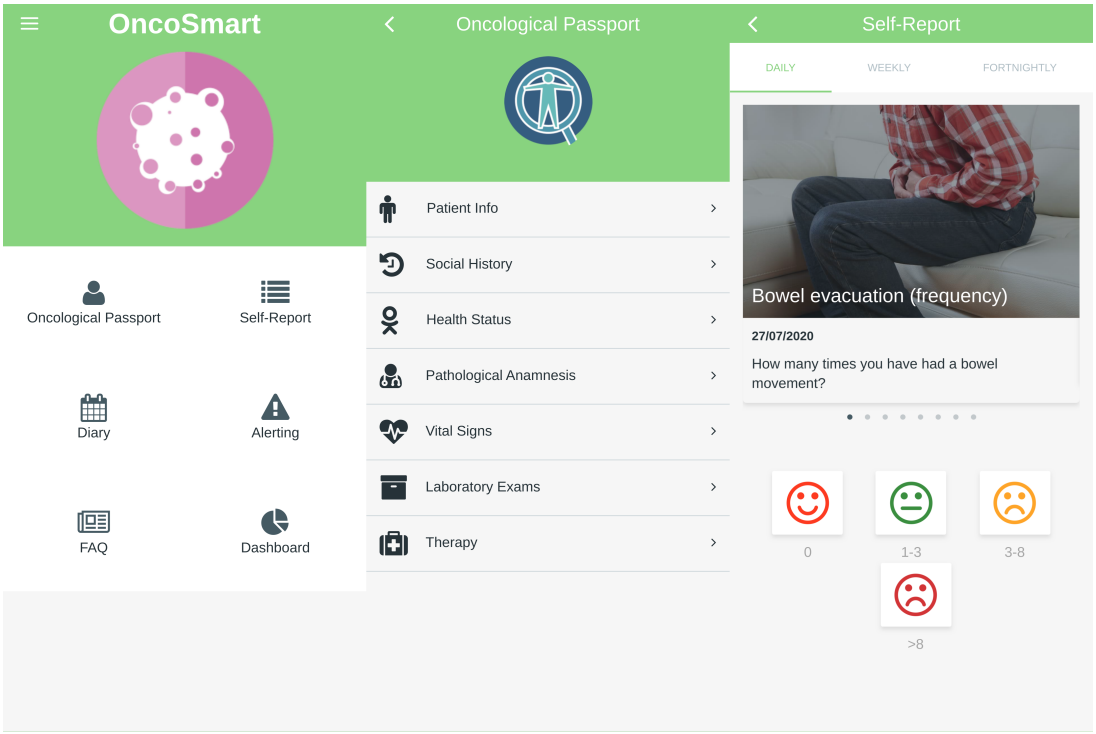

Figure 1. Screenshots of the mobile app

through the OncoSmart solution is summarized as follows:

- *Prescribe*: The physician sets up OncoSmart, enrols the patient, and assigns therapy and treatments, including drugs. The patient gets access to the mobile app and wears the wearable device.
- *Report*: The patient is involved in self-assessment activities (symptoms of pain, fatigue, nausea, *etc.*), filling questionnaires, and providing biomedical data through the wearable device.
- *Monitor*: OncoSmart monitors symptoms severity and notifies physicians about the adherence of the therapy (treatment-related toxicities, side effects, drug reactions, *etc.*) and response to treatments.
- *Evaluate*: Physicians, through a personalized dashboard, observe patients' performance and progresses, supported by an AI-based tool that summarizes health status (digital biomarker) and quantifies disability level, using clinically recognized taxonomies and assessment scales (i.e., EORTC QLQ-C30).

The mobile app [Figure 1] provided to the patient was developed with a multi-platform technology. It is composed of several sections:

- The oncological passport is where the patient can see their data, inserted on the clinical web application.
- The self-report is where the patient can answer periodically given questionnaires.
- The diary is where patient's activities to be done are reported daily, such as a questionnaire or a reminder for taking a medicine assigned as a home therapy.
- The alert is where the patient can report a problem with the app or wearable device.
- The FAQ is where the patient can find much information about diseases and several helpful questions and answers to make him more aware.
- The dashboard is where some charts that resume the patient's participation in the diary activities are reported.

The wearable device, without any operation by the patient, connects to the app and automatically collects and sends all vital sign measures using Bluetooth on the smartphone. The measures provided by the smartwatch are blood pressure, heart rate, breath rate, saturation (only with manual request), number of steps, sleep infor-

Figure 2. Example of the dashboard.

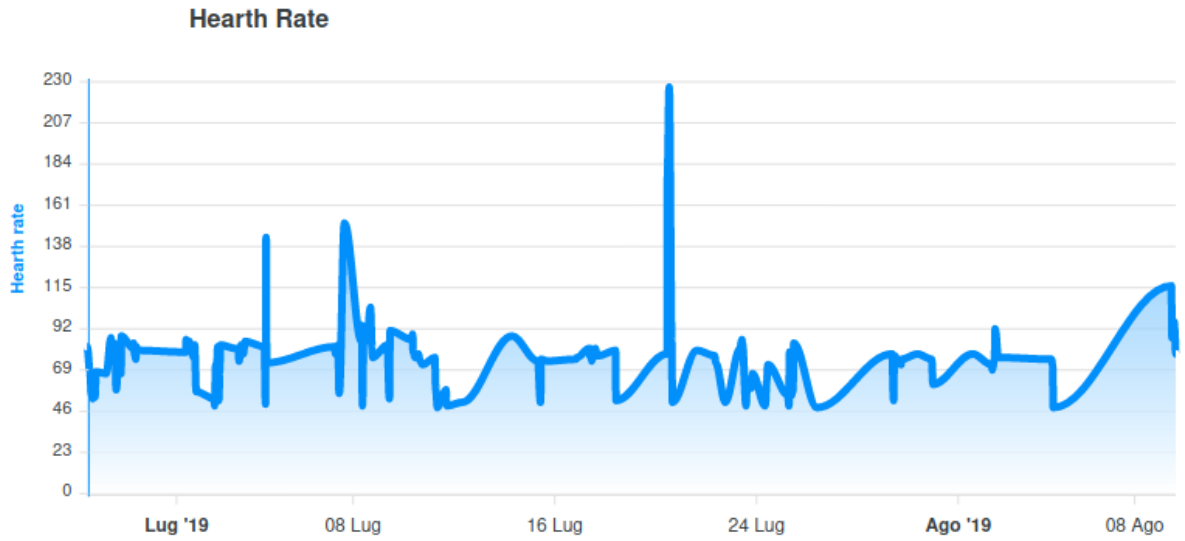

Figure 3. Heart rate chart.

mation (only during the night), mood, and energy.

Healthcare professionals can explore the symptoms and vital signs from the smartwatch through a dashboard that summarizes their trends through graphs, as shown in Figures 2 and 3.

Patients Data Collection and Analysis Workflow

The software solution outlined in Section 3.1 allows collecting patient data and implementing a processing workflow for enabling evaluation of the level of symptoms severity. During the usage, OncoSmart collected patients data from the daily, weekly, and fortnightly self-report questionnaires, while vital signs were collected through the smartwatch and the mobile application provided to the patients. The self-report questionnaires were mainly extracted from the quality of life questionnaire EORTC QLQ-C30. From this questionnaire, it was possible to distinguish two kinds of questions: some related to symptoms/adverse events and others concerning the quality of life.

All the responses related to symptoms/adverse events were interpreted using the Common Terminology Criteria for Adverse Events (CTCAE). For every event extracted from the questionnaire, the severity levels were identified using the same CTCAE dictionary definitions. In this way, it was possible to compare the information extracted from self-reports and the information reported during visits, using the same terminology. Others symptoms were calculated using the guide of the questionnaire EORTC QLQ-C30, which defines how to calculate, for instance, the pain score.

The analysis workflow to extract information from the collected data was performed by means of a semi-

automatic procedure.

First, it was necessary to distinguish between the questions extracted from the EORTC QLQ-C30 questionnaire and those extracted directly from the CTCAE. For the questions extracted from the EORTC QLQ-C30 questionnaire, the score of the answers, using the guide of the questionnaire itself, is a numerical score between 0 and 100. The possible answers to the EORTC QLQ-C30 questionnaire have a corresponding interpretation defined in the CTCAE for certain side effects. In this way, by dividing the numerical score into four bands, it was possible to translate it into severity levels expressed by the CTCAE (from G0 to G4).

As for CTCAE questions, the answers are directly brought out from the interpretation that this scale has given at each severity level for each considered symptom; therefore, the transformation is direct.

The choice to use a question from EORTC QLQ-C30 compared to other CTCAE is because, for some symptoms/side effects, the extraction of the CTCAE led to a freer interpretation of the answers and, therefore, the EORTC QLQ-C30 questionnaire supports in calculating a more rigorous score.

Once the severity levels were extracted, day by day, for each symptom, it was necessary to average these levels over one week period in order to have a general picture of the symptom value as well as a period of time in which to evaluate the actual severity compared to the values of the individual days. The extracted values were then compared with the severity levels entered by the physician during the visit. Fully automating the overall procedure for extracting the severity levels is the next future work.

CLINICAL TRIAL DATASET

A retrospective pilot study was performed on eight mCRC patients treated at the Department of Oncology, Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy. The pilot approval was obtained from the Ethics Committee of the Università degli Studi della Campania "Luigi Vanvitelli" (Prot. 321 del 22/05/2019). Participation in the pilot study was voluntary. All parts of the study were performed in compliance with the principles of the Declaration of Helsinki.

The study was performed from June 2019 to January 2020 and the duration was about five months. Eight patients were asked and agreed to participate in the study during their treatment pathway at different times. Two female (25%) and six male (75%) patients were included; the age was in the range [35, 69], while the median age was 54 years. Among the agreeing patients, one retired from the vital signs monitoring due to an allergic reaction to the wearable device's strap. Patient eligibility was constrained on the use of a compatible smartphone.

During the study, no intervention from the physicians was required. This way was useful to understand what concordance the application can reach without any external interventions and how effectively it can help the physician in early identifying adverse events. After agreeing to participate in the study, the patients were enrolled and registered on the OncoSmart platform.

Patients were invited to answer questionnaires about symptoms/adverse events and their quality of life at different time intervals: daily, weekly, and fortnightly. The daily questionnaire contained questions about symptoms/adverse events, while weekly and fortnightly questionnaires focused on information about the quality of life. Table 1 reports the number of questionnaires completed by each patient. The main symptoms/adverse events found from self-report questionnaires are as follows:

- Pain

Table 1. Patients' questionnaire

Patient ID	#Q Daily	#Q Weekly	#Q Fortnightly	Duration (days)
1	29	4	1	43
2	31	4	2	45
3	132	20	10	165
4	133	19	9	172
5	50	7	4	64
6	30	3	1	43
7	10	1	1	11
8	11	1	0	12

Table 2. The number of times vital signs were hourly collected for each patient during the trial. They differ according to the monitoring period corresponding to each patient

Patient ID	#Vital sign values
1	200
2	500
3	2000
4	2200
5	960
6	480
7	150
8	90

- Asthenia
- Nausea
- Rash
- Paresthesia
- Diarrhea
- Constipation
- Stomatitis

Regarding vital signs collected through wearable devices, Table 2 contains the number of collected data for each patient. The smartwatch automatically started the acquisition of the measures every hour.

EXPERIMENTAL RESULTS

This section describes the clinical trial results conducted at the Department of Oncology, Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy. Clinical trial results aim to assess OncoSmart to digitally monitor the adherence of the therapy, supporting clinical decision-making and patient engagement. In this sense, the results are measured in terms of compliance and concordance, which measure OncoSmart's suitability and reliability.

The following subsections describe the measures adopted for evaluating performance, and the results are illustrated with the corresponding discussion.

Measure

The trial was conducted by evaluating two important measures:

1. The *compliance* measures the patient's participation and was evaluated as the total number of questions answered by the patient over the total number of submitted ones. This measure is a relative value not impacted by the duration of participation, which was not the same for all patients (and is included in a specific column in Table 1).
2. The *concordance* is defined as the agreement between the symptoms/adverse events identified through patients' answers to the self-reports and the clinical results of the visit.

Table 3. Patients' compliance

Patient ID	Compliance
1	67%
2	68%
3	80%
4	77%
5	77%
6	69%
7	88%
8	90%

Table 4. Symptoms concordance

Symptoms	Concordance
Pain	80%
Asthenia	50%
Nausea	90%
Rash	78%
Paresthesia	87%
Diarrhea	81%
Constipation	96%
Stomatitis	93%

Results

In this study, OncoSmart results, measured in terms of compliance and concordance, are related to the following activities:

- Monitoring the trends of vital signs and symptoms of the patients when they were at home, between visits;
- Identifying the adverse events raised from the treatment, supporting healthcare professionals on how to manage the patients when they came/returned to visit/clinical assessment;
- Assessing and summarizing patient health status using the international classification of the WHO called ICF, monitoring ICF codes, and observing the evolution during the care pathway.

The achieved average compliance of all patients was around 77%. Table 3 details the compliance percentage of every patient.

The average concordance regarding these symptoms was around 80%; the remaining 20% was divided into 15% where the patient reported symptoms through the mobile app but not during the visit and 5% where the patient declared symptoms during the visit but not through the mobile app.

In Table 4, the concordance is explicated for each of the most reported symptoms/adverse events. In particular, asthenia is the event that had the lowest concordance value; all others had a significantly higher concordance value.

Additionally, Figure 4 reports average values of the deviations between the measures collected using the smartwatch and values observed during the visits with medical devices. To compare these values, the evaluated deviation considers the trend of measures collected through the smartwatch between two visits. Figure 4 reveals that the trend of measures for vital signs collected by OncoSmart through the smartwatch is reliable, although there was a slight deviation.

The example in Figure 5 shows that vital signs trends agree with the ones revealed by the physician during visits. For instance, if a patient, between visits, has had high blood pressure problems, this can be identified from the smartwatch data trend.

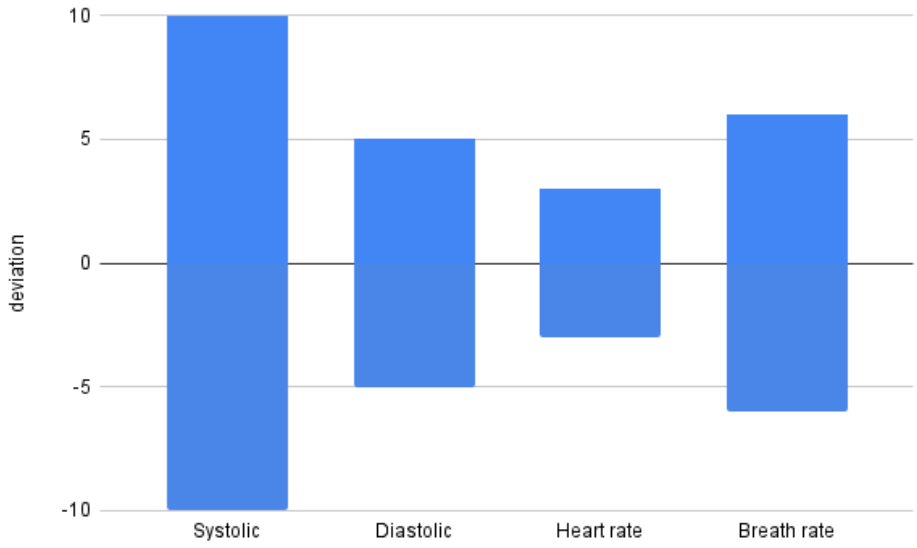

Figure 4. The deviation of the vital signs measures collected by OncoSmart averaged on all patients.

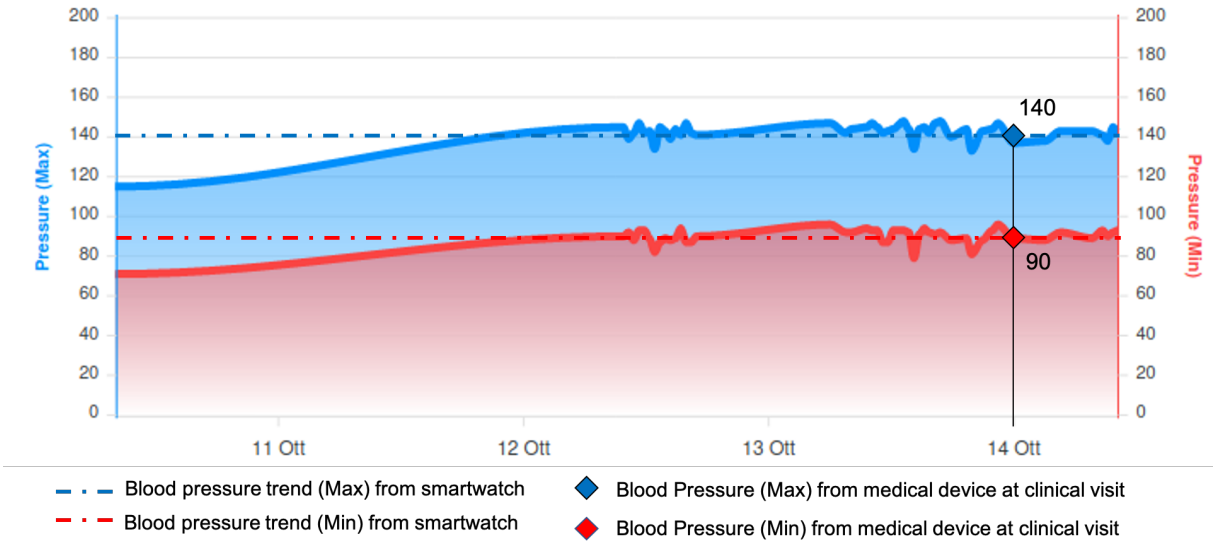

Figure 5. Example of blood pressure measured by the smartwatch and data reported in the visit.

The mobile app and a smartwatch were assigned to each patient. Details about visit outcomes and registered events, reported during the trial, are summarized in Visit 1. During Visit 2, nothing relevant was reported by the physician, but, subsequently, the mobile app identified an episode of pain not reported during the visit (referring to the 15% of symptoms not reported during the visit). At Visit 3, there was a concordance between the physician's report and data collected by the mobile app before the visit (i.e., an episode of severe diarrhea). The event, classified as adverse, led to a change of therapy. This highlights that the collected data (i.e., symptoms from self-reports and vital signs) suggested by the mobile app to the physicians as an adverse event correlated to the patient's therapy can conduct and guide the physician in changing/suspending/postponing the therapy.

During the trial, for three patients, the occurrence of a severe adverse event brought a therapy change. In

Table 5. Events related to a patient during the trial

#Visit	Events derived from the visit	Events derived from OncoSmart	Therapy
Visit 1	Abdominal pain	App assignement	FOLFIRI + AFLIBERCEPT
Visit 2 (after 15 days)	Nothing of relevant	Slight pain (G1)	FOLFIRI + AFLIBERCEPT
Visit 3 (after 1 month)	Diarrhea G2	Diarrhea G2 (identified before the visit)	FOLFIRI + AFLIBERCEPT (80% and without bolo of 5FU)

that case, the OncoSmart system identified, with a concordance of 100%, the symptoms that were classified as severe adverse events, suggesting a revaluation of therapy. An example is reported in Table 5 where a severe episode of diarrhea appears as a side effect of the treatment; the other two cases include another severe episode of diarrhea for a patient and an intense episode of rash for another. In these three cases, the symptoms were already identified when the patients were at home, bringing out the potential of the system of early detection of clinical risks.

Discussion

Although the number of involved patients (i.e., eight) seems to be low, it is not so far from other existing studies. For example, in Peltola *et al.*[18], the trial involved five patients, while, in Bengtsson *et al.*[24], the were 20 patients. Moreover, the results highlight a correspondence of high compliance rates with some existing studies[18,25]. Concordance, adopted for comparing patients *vs*. physicians' opinions (i.e., 80%), results in line with 70% reported by Crespo-Lessmann *et al.*[26], while there is a disagreement with 40% reported by Chandwani *et al.*[27].

Overall, despite the limited number of patients and data, the results of the adoption of OncoSmart from real patients are encouraging. Without any physician's supervision, collected data have a very good level of concordance with reported ones. This shows that more precise data could be collected by involving the physician during the observation, and the physician can have more information (i.e., hidden events) before or during therapy administration. In this way, physicians are able to change the therapy before the symptoms become too severe, even when adverse effects are not correctly reported during visits.

CONCLUSIONS

With the growth of cancer cases overall in the world, new treatments may consider not only improving patients' survival but their quality of life. In this sense, self-administered therapies are spreading, enhancing the need for specific adverse events monitoring without direct medical supervision. The systematic collection of patient-reported outcomes (PROs) has been demonstrated to be a valid, reliable, feasible, and precise approach to tabulating symptomatic toxicities and detecting symptoms missed by clinicians. In this sense, smart environments are key enabling factors to allow physicians to take care of patients in their normal living environment.

This work proposes OncoSmart as a software as a medical device for collecting PROs and monitoring treatment-related health symptoms. The objective is an early alerting of physicians about vital parameters collected with wearable devices and patients' self-reported symptoms.

Experiments conducted with eight mCRC patients showed the suitability and efficacy of the system in terms of

compliance (i.e., level of acceptance and patient engagement) and concordance between PROs and symptoms detected by physicians. These preliminary results are promising, even if we recommend further assessing the impact of a PRO solution in routine clinical practice.

DECLARATIONS

Authors' contributions

Made substantial contributions to conception and design of the study and performed data analysis and interpretation: Troiani T, Napolitano S, Terminiello M, Vitiello PP, Ciardiello F, Martinelli E, Fenza G, Orciuoli FJ, Romanelli L

Availability of data and materials

Not applicable.

Financial support and sponsorship

None.

Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

REFERENCES

1. Ferlay J, Colombet M, Soerjomataram I, et al. Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods. *Int J Cancer* 2019;144:1941-53.
2. Allemani C, Matsuda T, Di Carlo V, et al. Global surveillance of trends in cancer survival 2000–14 (CONCORD-3): analysis of individual records for 37 513 025 patients diagnosed with one of 18 cancers from 322 population-based registries in 71 countries. *Lancet* 2018;391:1023-75.
3. Laugsand EA, Sprangers MA, Bjordal K, Skorpen F, Kaasa S, Klepstad P. Health care providers underestimate symptom intensities of cancer patients: a multicenter European study. *Health Qual Life Outcomes* 2010;8:104.
4. Di Maio M, Basch E, Bryce J, Perrone F. Patient-reported outcomes in the evaluation of toxicity of anticancer treatments. *Nat Rev Clin Oncol* 2016;13:319-25.
5. Peeters JM, Wiegers TA, Friele RD. How technology in care at home affects patient self-care and self-management: a scoping review. *Int J Environ Res Public Health* 2013;10:5541-64.
6. Cajamarca G, Herskovic V, Rossel PO. Enabling older adults' health self-management through self-report and visualization—a systematic literature review. *Sensors* 2020;0:4348.
7. Basch E, Deal AM, Dueck AC, et al. Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *JAMA* 2017;318:197-8.
8. Basch E. Patient-reported outcomes - harnessing patients' voices to improve clinical care. *N Engl J Med* 2017;376:105-8.

9. Absolom K, Holch P, Warrington L, et al; eRAPID systemic treatment work group. Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice (eRAPID): a randomised controlled trial in systemic cancer treatment. *BMC Cancer* 2017;17:318.
10. Basch E, Deal AM, Kris MG, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial. *J Clin Oncol* 2016;34:557-65.
11. Yang LY, Manhas DS, Howard AF, Olson RA. Patient-reported outcome use in oncology: a systematic review of the impact on patient-clinician communication. *Support Care Cancer* 2018;26:41-60.
12. Wong EC, Kaplan CP, Dreher N, Hwang J, Van't Veer L, Melisko ME. Integration of health questionnaire systems to facilitate supportive care services for patients at an academic breast care center. *JCO Clin Cancer Inform* 2018;2:1-13.
13. Matthijs de Wit L, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a web-based self-management application "Oncokompas" in routine cancer care: a national pilot study. *Support Care Cancer* 2019;27:2911-20.
14. Harris J, Armes J, Cheevers K, et al. (2018) eSMART: A European RCT Evaluating Electronic Symptom Management Using the Advanced Symptom Management System (ASyMS) During Adjuvant Chemotherapy. British Psychosocial Oncology Society Annual Conference, Southampton, UK, 8-9 Mar 2018.
15. Ozkan B, Eskiyurt R, Oztas D. Evaluation of the Effectiveness of Web-based Intervention for Patients with Breast Cancer. *Eur J Ther* 2018.
16. Lucas AR, Bass MB, Rothrock NE, et al. Development of an ehealth system to capture and analyze patient sensor and self-report data: mixed-methods assessment of potential applications to improve cancer care delivery. *JMIR Med Inform* 2018;6:e46.
17. Sundberg K, Wengström Y, Blomberg K, Hälleberg-Nyman M, Frank C, Langius-Eklöf A. Early detection and management of symptoms using an interactive smartphone application (Interaktor) during radiotherapy for prostate cancer. *Support Care Cancer* 2017;25:2195-204.
18. Peltola MK, Lehikoinen JS, Sippola LT, Saarilahti K, Mäkitie AA. A novel digital patient-reported outcome platform for head and neck oncology patients-a pilot study. *Clin Med Insights Ear Nose Throat* 2016;9:1-6.
19. Neyja M, Mumtaz S, Huq KMS, et al. An IoT-based e-health monitoring system using ECG signal. GLOBECOM 2017-2017 IEEE Global Communications Conference; 2017 Dec 4-8; Singapore. IEEE; 2017. p. 1-6.
20. Mshali H, Lemlouma T, Magoni D. Adaptive monitoring system for e-health smart homes. *Pervasive Mob Comput* 2018;43:1-19.
21. Kondylakis H, Bucur A, Crico C, et al. Patient empowerment for cancer patients through a novel ICT infrastructure. *J Biomed Inform* 2020;101:103342.
22. Gharsellaoui H, Khemaissia I, Alshahrani A. New approach for cardiac patients based on pacemaker device. *J Ambient Intell Human Comput* 2021;1-9.
23. Karni L, Memedi M, Kolkowska E, Klein GO. EMPARK: Internet of things for empowerment and improved treatment of patients with parkinson's disease. International Congress of Parkinson´s Disease and Movement Disorders; 2018 Oct 5-9; Hong Kong, People's Republic of China. John Wiley & Sons; 2018.
24. Bengtsson U, Kjellgren K, Hallberg I, Lundin M, Mäitalo Å. Patient contributions during primary care consultations for hypertension after self-reporting via a mobile phone self-management support system. *Scand J Prim Health Care* 2018;6:70-9.
25. Laborde CR, Cenko E, Mardini MT, et al. Satisfaction, usability, and compliance with the use of smartwatches for ecological momentary assessment of knee osteoarthritis symptoms in older adults: usability study. *JMIR Aging* 2021;4:e24553.
26. Crespo-Lessmann A, Plaza V, González-Barcala FJ, Fernández-Sánchez T, Sastre J. Concordance of opinions between patients and physicians and their relationship with symptomatic control and future risk in patients with moderate–severe asthma. *BMJ Open Respir Res* 2017;4:e000189.
27. Chandwani KD, Zhao F, Morrow GR, et al. Lack of patient-clinician concordance in cancer patients: its relation with patient variables. *J Pain Symptom Manage* 2017;53:988-98.