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Acceptance of physical activity monitoring in cancer patients during radiotherapy, the GIROfit phase 2 pilot trial

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ABSTRACT

Background: In radiotherapy the timely identification of patients needing intervention and supportive care due to side effects is an important task especially in the outpatient setting. Activity trackers as an increasingly used lifestyle device may enable physicians to monitor patient's physical activity (PA) and to intervene early during the course of radiotherapy.
Objective: The primary aim of this trial was to assess patient acceptance of PA monitoring in an outpatient setting and to correlate changes in PA with toxicity and changes in quality of life.
Methods: Patients undergoing radio(chemo-)therapy with a curative intent were eligible to participate in this prospective pilot phase II trial. Patients were instructed to wear a commercially available activity tracker during the course of radiotherapy and four weeks afterwards. Quality of life (QoL) and fatigue was scored using the Functional assessment of Chronic Illness Therapy questionnaire. A linear regression was performed to determine baseline activity and changes in step counts during radiotherapy.
Results: We included 23 patients in this trial. Two withdrew consent before the start of treatment, two patients were excluded after prophylactic feeding tube placement and prolonged recovery. Compliance in the remaining 19 patients was high, with availability of step-counts on 92% of the days. Baseline step counts were 6274 for breast cancer patients and 3621 for patients with other entities. Decreasing activity during radiotherapy coincided with the development of side effects and declines in quality of life.
Conclusions: Activity trackers as tool to monitor PA during and after radiotherapy were accepted by a majority of the patients included in the current trial. Observed changes in PA correlated with patient reported side effects and QoL in some of the patients.

Introduction

Radiotherapy alone or in combination with systemic therapies is a curative treatment for various tumor sites. Over the last decades technological progress such as image guidance and intensity modulated radiotherapy have led to increasingly precise treatment delivery and thus improved sparing of normal tissue resulting in reduced side effects [1,2]. Still, side effects are inevitable in many cases. It is well known for various tumor sites that treatment interruptions or decreased compliance is associated with poor outcome [3–5]. Therefore, timely identification of patients in need of supportive care is a key component for successful treatment. Activity trackers are increasingly used as a lifestyle product to record personal activity data. At the same time there is growing interest in activity trackers in medicine ranging from weight loss programs to the treatment of depression [6,7]. Also, in medical oncology, activity trackers have been used in various scenarios, yet for radiotherapy data is limited thus far [8]. A key advantage of activity trackers is that they provide an objective measure of patients' level of physical activity (PA) and therefore performance status. This is of clinical relevance since it has been shown previously that routinely used physician scored parameters of functional status such as the "Eastern cooperative group performance status" (ECOG) are highly subjective

Abbreviations: ECOG, Eastern cooperative group performance status; ePROM, electronic patient reported outcome measures; FACIT, Functional Assessment of Chronic Illness Therapy; FACT-G, Functional Assessment of Cancer Therapy General; PA, physical activity; PEG, percutaneous endoscopic gastrostomy; PWB, physical well being; QoL, quality of life.

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and prone to biases [9]. On the other hand, several individual trials and *meta*-analyses have shown that physical activity during oncological treatment can improve quality of life or lessen side effects. For instance, a recent *meta*-analysis by Schumacher et al. was able to show that exercise during radiotherapy for prostate cancer patients not only improved physical functioning but also had positive effect on urinary toxicity [10]. Moreover, for breast cancer patients exercise was shown to significantly reduce fatigue in a pooled analysis of 802 patients [11].

The goal of the present prospective study was to investigate the acceptance of activity trackers in cancer patients during and after radiotherapy. Furthermore, we aimed to study whether daily step counts can be a useful and an easy to measure surrogate for quality of life and treatment related toxicities requiring intervention (QoL).

Methods

The study was approved by the local institutional review board (447/2017B01). Patients were eligible for participation in this prospective phase II trial if they had a histologically confirmed malignancy with an indication for curative pre- or postoperative radio(chemo)therapy or definitive radiochemotherapy. ECOG $\geq$ 3 and comorbidities with impaired mobility such as leg paresis were criteria of exclusion. Patients were recruited at the outpatient clinic of the Department of Radiation Oncology in Tübingen. In this clinic patients with a wide range of oncological diagnoses are seen. After informed consent for the oncological treatment patients were asked by one of the study team members if they would be interested in participating in the present "activity tracker study". The study team member was not necessarily the treating physician. In the case of participation in the study, a commercially available activity tracker (AS95, Beurer GmbH, Ulm, Germany) was handed to the patient. The device is easy to use with only a single button to switch through different functions. Patients were briefly introduced in the usage of the device. They were instructed to wear it continuously. No instructions regarding daily step counts were made. The device can store daily step counts for up to 28 days. Activity trackers were read out weekly using an in-house, android based application via the Bluetooth interface. We had decided to use this in-house solution instead of the manufacturer's app for data extraction in order to avoid data safety issues. Furthermore, we were able to access the raw data recorded and not potentially smoothened or interpolated data. At the end of radiotherapy patients were offered to use the tracker for another 28 days and return it via mail to the study center where a final read out was performed.

Statistical analysis

We quantified "patient acceptance" as the number of days the activity tracker was worn during treatment divided by the total number of treatment days. A simple linear regression with time and step counts as continuous variables was performed to estimate the average daily change in step counts over the course of treatment. "Daily step counts" were used as the dependent variable and "days" as the independent variable. Furthermore, the baseline step count was defined as the value of the regression line on day zero. Group comparisons were carried out using t-tests. A p-value < 0.05 was considered statistically significant. All statistics were performed in Microsoft Excel and SPSS Version 23 (IBM, Armonk, USA).

Assessment of quality of life

Quality of life was scored using the FACIT questionnaire with its Fatigue submodule (FACIT-F). Information about the FACIT questionnaire can be found elsewhere [12]. Quality of life was assessed at baseline, at the end of radiotherapy and 4 weeks after the end of radiotherapy.

The study was registered at clinicaltrials.gov (NCT03610854).

Results

Between April and August 2018, 23 patients provided written informed consent. Four patients were excluded from analysis before the start of radiotherapy. Two patients received a percutaneous endoscopic gastrostomy (PEG) with a prolonged inpatient treatment. The two other patients withdrew consent before the start of treatment, one because the size of the step count was considered too small. In the other case no specific reason was provided. A description of the remaining patients is shown in Table 1. Nine patients were treated with postoperative radiotherapy after breast cancer surgery. Ten patients had tumors of different sites of the gastrointestinal tract (n = 3), head and neck (n = 5) or lung cancer (n = 2). Median patient age at inclusion was 57 years (interquartile range 50 to 67 years).

Patient acceptance in these 19 patients was high and daily step counts were available on an average of 92% of treatment days (range 75–100%). Breast cancer patients showed a trend towards a higher baseline step count as determined by linear regression compared with patients with other tumors (6274 vs. 3621 steps/day, p = 0.077). Daily step counts remained constant in all but one breast cancer patient (Table 2). At the end of radiotherapy 12 of the 19 patients agreed to wear the activity tracker for another 28 days. Fig. 1 shows the average step count over time of all breast cancer patients together with QoL parameters. No significant change in terms of physical-wellbeing, fatigue and overall QoL as reflected by the FACT-G sum score was seen. In this single breast cancer patient physical activity increased during treatment with a slope of 182 steps per day. No correlation between preoperative chemotherapy and activity was seen. Among patients with head and neck tumors daily step counts decreased during treatment in all but one patient. The latter already started with the lowest of all activity levels and remained at that level. In some patients, changes in activity levels correlated with patient scored toxicity or inpatient treatment. Three examples are shown in Fig. 2. Fig. 2a shows the course of a 75-year-old male patient (ECOG 0 at start of treatment) who was treated for oropharyngeal cancer. Treatment took place in an outpatient setting with 70 Gy over seven weeks with addition of weekly cisplatin. This patient also participated in a trial testing an inhouse patient webapp for the scoring of patient reported outcomes [13]. It can clearly

Table 1
Patient and treatment characteristics.

Characteristics	N	(%)
Total patients	19	(100)
Gender		
Male	12	(63,2)
Female	7	(36,8)
Weight (kg)		
Median (IQR)	71,0	(62–82)
BMI		
Median (IQR)	24,0	(22–27)
Age (years)		
Median (IQR)	57	(52–66)
Cancer type		
Breast Cancer	9	(47,4)
Head and Neck cancer	5	(26,3)
Lung Cancer	2	(10,5)
Anal cancer	1	(5,3)
Esophageal Cancer	1	(5,3)
Pancreatic Cancer	1	(5,3)
UICC Stage		
0 (pTis)	2	(10,5)
I	4	(21,1)
II	4	(21,1)
III	5	(26,3)
IV	4	(21,1)
RT Indication		
Preoperative	1	(5,3)
Postoperative	11	(57,9)
Definitive	7	(36,8)

Table 2
Patient data including baseline step count and daily change determined by linear regression.

Patient	Age	BMI	Entitiy	UICC stage	RT-Indication	Systemic treatment	RT-Dose (Gy) *	Sex	Baseline	Change per day	p
1	54	26,5	Breast Cancer	IA	Postoperative	–	2.67/40.05**	Female	9671	32,53	0,62
2	40	22,0	Breast Cancer	IIA	Postoperative	pre-OP Chx	2/66	Female	3912	3,15	0,91
3	50	17,6	Breast Cancer	IA	Postoperative	–	2.67/40.05**	Female	5866	211,40	0,13
4	64	20,8	Breast Cancer	IA	Postoperative	–	2.67/40.05	Female	13,390	−29,41	0,86
5	56	23,2	Breast Cancer	IA	Postoperative	–	2.67/40.05**	Female	8076	30,20	0,81
6	58	22,0	Breast Cancer	0	Postoperative	–	2/50	Female	4234	−21,92	0,12
7	57	21,9	Breast Cancer	IIA	Postoperative	pre-OP Chx	2/66	Female	4112	−19,54	0,33
8	50	26,1	Breast Cancer	0	Postoperative	–	2/50	Female	4365	−9,71	0,79
9	55	27,2	Breast Cancer	IIIB	Postoperative	pre-OP Chx	2/50	Female	2839	181,75	**<0,05**
10	50	19,4	Esophageal Cancer	IIIB	Definitive	Conc. Chx	2/60	Female	3183	−25,50	0,20
11	75	22,4	Head and Neck cancer	II	Definitive	Conc. Chx	2/70	Male	4671	−83,62	**<0,05**
12	71	24,0	Head and Neck cancer	IVA	Postoperative	–	2/64	Male	2624	−25,69	0,08
13	62	29,2	Head and Neck cancer	II	Definitive	Conc. Cetuximab	2/70	Male	2626	−39,90	**<0,05**
14	69	23,5	Head and Neck cancer	IVB	Definitive	Conc. Cetuximab	2/70	Male	1401	−17,89	**<0,05**
15	68	27,7	Head and Neck cancer	IVA	Definitive	–	2/70	Male	878	−0,93	0,89
16	62	30,2	Anal cancer	IIIB	Definitive	Conc. Chx	2/60	Male	5248	−38,04	**<0,05**
17	47	32,8	Pancreatic Cancer	III	Postoperative	Conc. Chx	2/54	Female	4903	14,37	0,66
18	57	24,8	Lung Cancer	IIIA	Preoperative	Conc. Chx	1.5***/45	Male	9728	249,96	0,15
19	67	25,6	Lung Cancer	IV	Definitive	Conc. Chx	2/60	Female	950	−0,40	0,96

UICC - Union International contre le cancer, TNM 8th edition 2018. pre-OP-preoperative. Chx-Chemotherapy. Conc.-Concommitant. RT-Radiotherapy. BMI-body mass index.

* Dose per fraction / Total dose.

** followed by 5x2Gy tumor bed boost.

*** twice a day.

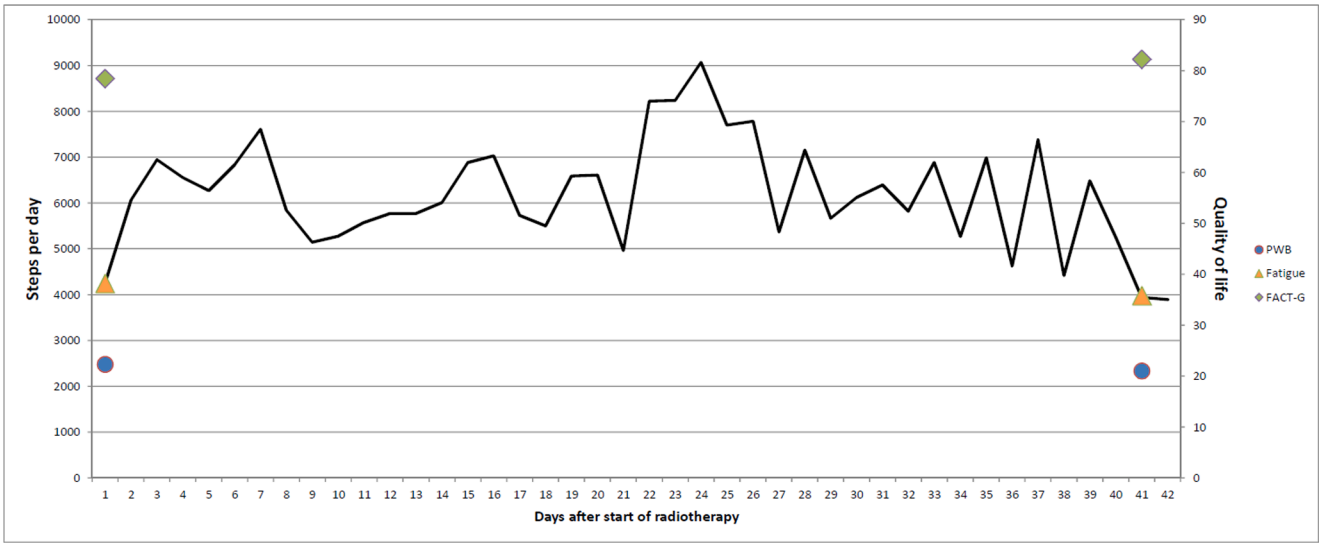

Fig. 1. Mean daily step counts during postoperative radiotherapy of the nine patients with breast cancer and corresponding quality of life data. PWB-Physical well-being. FACT-G indicates a summed score of overall quality of life.

be seen that with increasing toxicity, the daily step count continuously decreased. However, within four weeks after treatment, both physical activity and toxicities recovered to the baseline level. A very similar pattern is seen in Fig. 2b showing another head and neck patient with a continuous decline in activity and recovery thereafter. In this patient, outcomes for QoL were measured paper and pencil based using the FACIT questionnaire. The weekly "dips" in the activity level correlate with the weekly applications of cetuximab in the day unit. In contrast to this, Fig. 2c shows the case of 59-year-old patients who received pre-operative radiochemotherapy (Total 45 Gy with single doses of 1.5 Gy twice-daily) for lung cancer. While this treatment is frequently associated with relevant toxicities, this patient was among those with the highest step counts during treatment. At the same time he reported no more than PRO-CTCAE grade I odynophagia and PRO-CTCAE grade 0 fatigue over the entire course. Supplemental Fig. 1 shows the course of a patient with anal cancer treated with radiochemotherapy. Systemic treatment was given in an inpatient setting as continuous venous infusion with apparent abrupt decreases of the activity level in these periods. Between the two inpatient treatments a more linear decrease during ambulatory treatment is seen. QoL decreased during treatment and recovered thereafter.

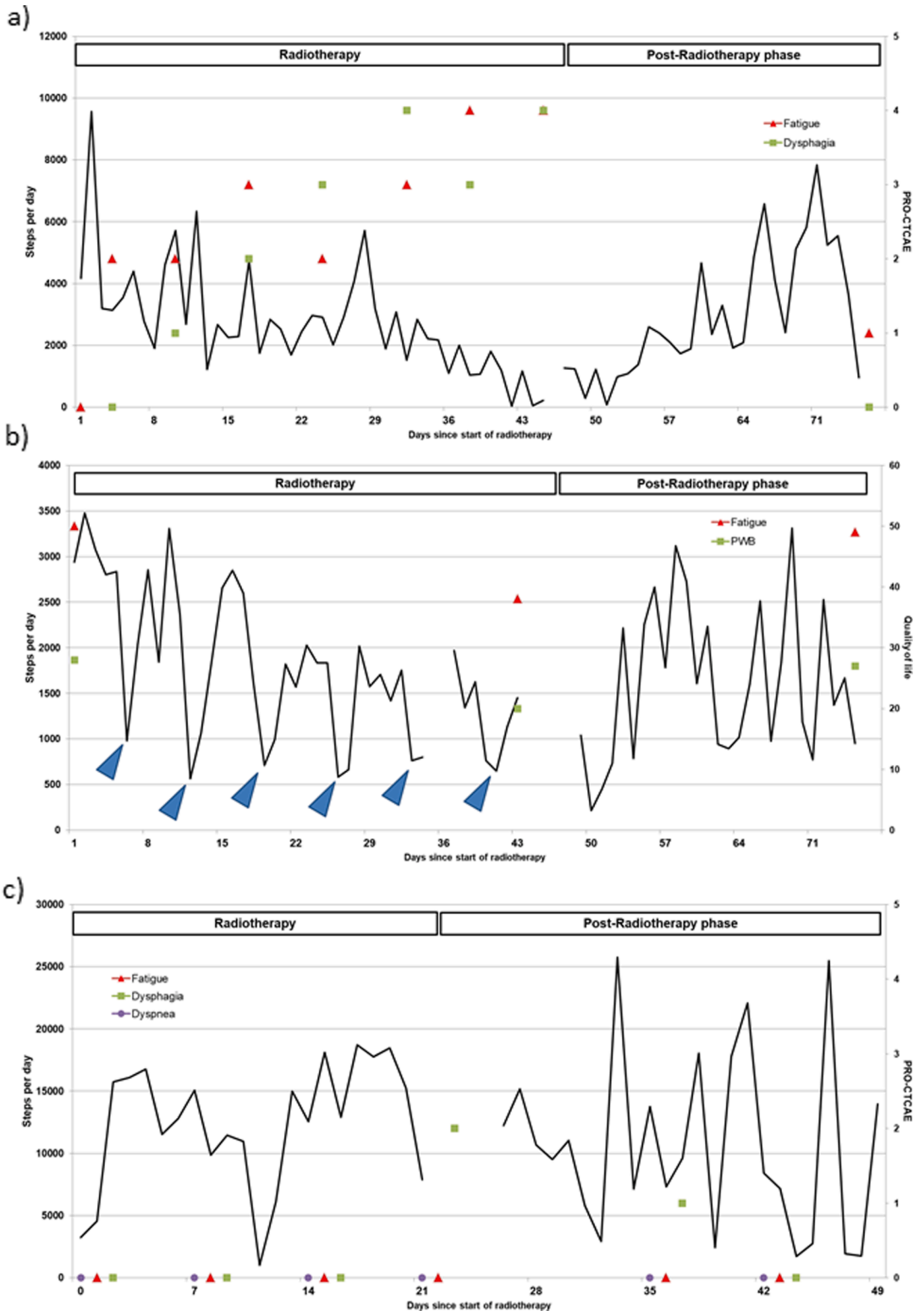

Fig. 2. a) 75 year old patient (ID number 11 in Table 2) with oropharyngeal cancer treated with concurrent chemoradiotherapy in curative intent. The patient used a patient web-app "PROMetheus" for regular scoring of toxicity data. b) 62 year old patient (ID number 13 in Table 2) with a tumor at the base of the tongue. Treatment consistent combined radioimmunotherapy with cetuximab. Weekly decreases in step counts (blue arrowheads) correspond to treatments in our day unit. Quality of life was assessed using the FACIT-F questionnaire. c) 57 year old patient (ID number 18 in Table 2) with non-small cell lung cancer treated with pre-operative radiochemotherapy. Patient went hiking regularly during treatment and also used "PROMetheus" for scoring of patient reported toxicity. Note that the three toxicity items were scored weekly and the same day but for easier visibility are shown next to each other. Note in all cases that missing data between "radiotherapy phase" and "post-radiotherapy" phase is due storage limitations that occurred between the patient returning the activity tracker via mail and the read out in clinic. PRO-CTCAE – Patient reported outcome version of common toxicity criteria of adverse events. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Discussion

The primary goal of the present study was to assess the acceptance of activity trackers to monitor PA among patients being treated curatively with radiotherapy. Another goal was to correlate changes seen on activity levels with clinical data such as inpatient treatments or treatment related toxicities and the timepoint during treatment. Regarding the primary aspect we observed a high degree of acceptance. Besides the two patients who discontinued due to a prolonged recovery after feeding tube placement, only two patients stopped usage at a very early time point. In the remaining patients, activity data was available on more than 90% of treatment days. Among them, in patients with breast cancer physical activity remained stable during treatment, which is in line with another recent study by Champ and colleagues who made a similar observation in their study on activity tracker usage in breast cancer patients [14]. While cancer-related fatigue is a very common observation in patients receiving radiotherapy no significant changes in fatigue during treatment was observed in our patients with breast cancer. Even though no instructions were made regarding daily goals for physical activity it is possible that patients have set goals themselves for remaining above beyond thresholds which might have had a positive effect on QoL. A very different pattern was observed in the patients with other tumor entities, often treated as combined modality treatment and frequently associated with high grade toxicities. In our study particular patients treated for head and neck tumors showed a considerable decline in their step counts with a clear correlation with patient reported QoL and increasing toxicities during the course of radiotherapy. Similarly, Ohri et. al. noted that a severe decline of daily step counts in patients with concomitant radiochemotherapy was a strong risk factor for hospitalization due to treatment related side effects [15]. In a study of advanced cancer patients (not limited to radiotherapy patients), Greshem and colleagues were able to show data from wearable activity devices such as daily step counts strongly correlate not only with performance status but also overall survival [16]. There are various reasons why activity trackers appear as very promising to improve patient care in radiotherapy: Most patients are treated in an outpatient setting. The downside of ambulatory treatment is that the caregiver during weekly visits might underestimate the patients' need for intensified supportive care or even inpatient treatment, as shown in a variety of trials [17,18]. Both our study and the previously mentioned study by Ohri et al. show that activity data might give very valuable information regarding the patients' constitution during treatment [15]. In particular, the combined usage of ePROMs with activity data would provide a comprehensive overview. From our point of view, the highest clinical relevance of this study is the opportunity to not only monitor the decline in physical activity but also the recovery thereafter. Finally, while activity trackers in the present study were solely used for monitoring purposes, their usage can also be extended to an interventional tool. There are a few reports of exercise programs in the literature that have incorporated activity trackers. For instance, Jahaveri and colleagues report a feasibility trial of 21 patients with breast cancer or head and neck tumors who received weekly goals for step counts [19]. In this study a high compliance with over 90% of the target goals met was shown. We have recently launched two prospective randomized trials that will test the efficacy of an activity tracker-based exercise program during radiotherapy. The OnkoFit I trial is tailored specifically for breast cancer patients and has the goal to reduce cancer related fatigue (NCT04506476), while OnkoFit II will include patients with various tumors treated curatively. In the latter the goal is to improve overall quality of life and preserve fitness specifically in patients who are scheduled for surgery after radiotherapy (NCT04517019). In both trials the intervention consists of weekly individually adapted goals for step counts based on the previous weeks step counts [20].

Our study has some limitations. First, the number of patients is small and we cannot rule out selection bias, since particularly younger patients with an interest in technology and already high baseline physical activity might have been more likely to participate in our trial. This is reflected by the median participant age of 57 years. Furthermore, a lack of recorded steps does not necessarily prove that the patient was not active on a given day. A patient diary where days of non-usage are reported could solve this problem or the usage of devices that also continuously count vital parameters such as pulse rate. The devices used in our study were also able to measure pulse rates but this function had to be re-activated manually several times a day by the patient to ensure continuous measurement, so this information has not been recorded in most cases. And finally, we acknowledge that step counts assessed by an activity tracker can only be considered as a surrogate for aerobic exercise and not for other forms of physical activity such as resistance training. These aspects clearly have to be considered when interventional clinical trials are designed.

Conclusions

Though limited by the small number of patients, the prospectively collected data suggests the feasibility of monitoring physical activity measured by a high acceptance of activity trackers in a mixed cohort of cancer patients undergoing curatively intended radiotherapy. Changes in activity levels appear to be associated with side effects and quality of life impairments and may therefore represent a valuable tool to remotely identify patients with a need for supportive care. This promising approach warrants further investigation which is currently ongoing in our department.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The Department of Radiation Oncology Tübingen receives within the frame of research agreements financial and technical support as well as sponsoring for travels and scientific symposia from Elekta AB (Stockholm, Sweden), Kaiku Health (Helsinki, Finland) TheraPanacea (Paris, France), Philips GmbH (Best, The Netherlands); Dr. Sennewald Medizintechnik GmbH (München, Germany), PTW Freiburg (Germany).

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tipsro.2022.03.004.

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