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Big Data From Small Devices: The Future of Smartphones in Oncology

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Abstract

Technological advancements in the capabilities of modern smartphones offer tremendous potential to generate big data from small devices that could influence oncologists' decision-making. Here we describe the value of patient-generated health data (PGHD) that can be captured using mobile devices. We comment on the current use of smartphones in oncology clinical research and describe how smartphones will bring big data into the oncology clinic by enabling continuous patient monitoring, information sharing, and personalized clinical decision making in cancer care. Lastly, we describe practical considerations about how we can access and store PGHD in the future, describing how to harness the clinical value of PGHD and comment on the emerging applications for digital biomarkers captured by smartphones.

Introduction

The number of global smartphone users worldwide in 2019 is expected to exceed 2.5 billion.

¹ Modern smartphones are sensor-rich and computationally powerful companions that capture information about daily activities, movement patterns, and social behaviors. Smartphone-sensing systems run consumer-generated applications ('apps') that allow for collection, storage, and streaming of large volume data from patients. Over 165,000 mobile device health apps—many of which are focused on fitness, stress, or diet/nutrition—are available via the Apple App Store and Google Play.

Digital biomarkers include consumer-generated physiologic and behavioral measures collected through digital tools, such as calories, steps taken, sleep efficiency, heart rate

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variability, and body temperature. Large studies have demonstrated the validity of wearable sensors, such as smartwatches, accelerometers, and smartphones, to capture digital biomarkers from diverse patient populations for the purpose of enhancing health outcomes.²⁻⁴ Smartphone-generated data streams could be particularly useful in providing continuous, dynamic, and objective assessments of cancer patients' health status between clinician visits.

The Value of Patient-Generated Health Data in Oncology

Patient-generated health data (PGHD) has been defined as “health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information created, recorded, gathered, or inferred by or from patients or their designees (ie, care partners or those who assist them) to help address a health concern.”⁵ The key features of PGHD are that patients, not providers, collect and record their data.

Traditionally, PGHD have been collected through patient-reported outcomes (PROs), which provide direct information about symptom burden, self-care tasks, and patients' ability to adhere to treatments and lifestyle recommendations. Self-administered instruments can be burdensome to both patients and research staff. Other limitations include poor patient recall, inaccurate reporting, and missing or inconsistent data. These shortcomings can be surmounted by other forms of PGHD that can be collected passively, continuously, and objectively by personal devices.

Measuring Physical Activity in Oncology

Physical activity level, assessed before, during, and after cancer treatment, is known to be a meaningful predictor of long-term clinical outcomes.⁶ Changes in pain, anxiety, fatigue, or sleep patterns may manifest as changes in physical activity (or vice versa),⁷ and all of these parameters may influence quality of life, tolerance to and efficacy of treatment, and subsequent clinical outcomes. Capturing physical activity is facilitated by recent technological advances that can provide a window into patients' experiences between clinic visits.

The value of activity data generated by wearable devices has been explored in numerous cancer care settings. Observational studies have demonstrated that step counts tend to decline during a course of radiotherapy⁸ or following surgery and that increases in daily step counts correspond to decreases in pain,⁹ improved quality of life,^{10,11} and favorable performance status.¹² It has also been demonstrated that declining step counts measured by a pedometer in cancer patients during chem- and radiotherapy is associated with increased risk of hospitalization during treatment.¹³ It is possible that activity data from wearable devices can supplant existing scales of cancer patients' functional capacity.¹⁴

Modern smartphones are equipped with accelerometers that record accelerations in one or more planes. These data elements are processed into more meaningful variables, such as step counts; time spent in sedentary, light, moderate, or vigorous physical activity; and flights of stairs climbed. These data are readily available to smartphone users and could easily be shared with health care providers.

Other Forms of PGHD

Smartphones increasingly include numerous diverse embedded sensors for data capture and can interface with “wearables” and other devices to collect a variety of digital biomarkers. Pattern recognition algorithms can aggregate these and other measures to generate estimates of users’ status such as stress level or mood. Smartphone-based sensors include cameras, accelerometers, gyroscopes,¹⁵ magnetometers, proximity sensors, light or UV sensors,¹⁶ barometers, thermometers, air humidity sensors, and pedometers. Additional biometric data can be captured using multifunctional sensor platforms. These include pulse, heart rate variability, respiratory rate, blood pressure, body temperature, weight, environmental exposures, sleep behavior, communication patterns, and events related to mobility, such as gait changes and falls.

Add-on sensors use external devices, such as smartphone cases to detect environmental exposures¹⁷ or wearable pedometers to measure physical activity. Monitoring vital signs through smartphones has classically relied on standard point-of-care tools (blood pressure cuff, pulse-oximeter, etc) that require manual entry of health data into apps by either patients or health care staff. Small studies in healthy subjects have demonstrated that smart phones can accurately measure respiratory rate¹⁸ and heart rate¹⁹ without the need for peripheral devices. While validation of these findings is needed in cancer patients, peripheral devices can already be linked with smartphones using Near Field Communication Technology to provide real-time data to clinicians.^{20–23}

Smartphones in Cancer Research

Several reports indicate that cancer patients demonstrate a high level of acceptance of smartphone-based trials and interventions.^{24,25} A systematic search of published clinical studies (Fig. 1) in cancer patients that incorporated the use of a smartphone app found 18 such studies where the app was designed for patient use, 14 of which relied upon data entry by patients (summarized in Table 1). In these studies, smartphone apps were largely evaluated as tools to enhance physical function and physical activity^{26–29}; enhance quality of life^{29–31}; reduce treatment related symptoms,³² including pain³³ and treatment complications³⁴; deliver health information³²; and offer clinical follow-up.²⁶

Some studies describing smartphone collection of PROs related to sleep, anxiety, mood and relationship communication,^{35,36} and toxicity monitoring³⁷ have utilized the smartphone app itself as a platform for patient self-reporting, discarding the need for ancillary patient surveys and tools. Though many of these studies are collecting valuable PGHD, the process of acquiring data requires active patient engagement and are limited by the flaws of self-report methods, and more importantly, limited in the ability to generate big data over long periods of time.

Objective parameters of patients’ daily function, such as physical activity, has been shown to correlate with QoL.³⁸ Smartphone metadata may even have the capacity to independently assess certain aspects of patients’ QoL.³⁹ We have only identified 4 published studies leveraging smartphones as stand-alone devices to collect objective PGHD^{40–43} (Table 2). Other studies utilized apps paired with pedometers to measure step counts as part of an

exercise intervention, where physical activity measurements were also captured by patient self-report^{30,44} or with traditional biometric measurements of cardiorespiratory endurance, lower extremity strength, and gait speed.^{27,32}

Passively recorded data will expand the roles smartphones can play in enhancing cancer patients' evaluation and care at the time of diagnosis, during treatment, and in the post-treatment survivorship setting. Push notifications can create a feedback loop between data recorded passively and active patient engagement. Smartphones could therefore play a central role in a class of trials where mobile devices implement an activity intervention, record uptake of the intervention, and measure effects of the intervention on patients' behavior and health.

Evaluating the Cancer Patient

Practice-shaping clinical trials in oncology often limit enrollment to patients with excellent performance status and limited medical comorbidities. In the real world, clinicians consider a large range of factors to try to determine if a patient is likely to tolerate aggressive cancer therapy. PGHD from smartphones could help identify such patients. Incorporating PGHD in clinical trials might even reveal factors that predict benefit from treatment. PGHD could then conceivably serve as a biomarker upon which clinical decisions are based.

A systematic review concluded that in healthy volunteers the accuracy of smartphones in measuring physical activity was rated "average-to-excellent"⁴⁵ and smartphone-measured step counts have demonstrated excellent validity and reliability when tested against a stand-alone accelerometer among patients undergoing active cancer treatment.⁴⁰ Daily step count, which is perhaps the simplest form of activity-related PGHD obtainable using wearable devices, has already been shown to be a powerful predictor of symptom burden,^{9,38} hospital admissions,^{13,46} and death⁴⁶ in several trials.

Monitoring Patients During Cancer Therapy

The potential for enhanced patient monitoring to improve clinical outcomes among cancer patients undergoing chemotherapy has been demonstrated using symptom self-reporting tools.⁴⁷ PROs and other forms of PGHD acquired using mobile devices can provide further gains in understanding our patients' experiences, predicting adverse events, and improving long-term clinical outcomes.

Among cancer patients, a smartphone-based symptom reporting tool used during chemotherapy has been shown to yield high rates of patient engagement and satisfaction⁴⁸ and is being tested in an 1100-patient randomized trial.⁴⁹ In a pilot study of adult patients with active cancer receiving chemotherapy, daily steps were monitored by a smartphone accelerometer. Chemotherapy-related toxicities were reported using the smartphone app on days in which a greater than 15% decline in the number of steps were recorded (30%, n = 6). For 60% of patients, toxicities were managed over the phone and for 27.5% of patients were sent for urgent medical intervention.⁴¹

Other opportunities to monitor patients during cancer therapy using digital biomarkers include recording heart rate variability⁵⁰ and tracking sleep patterns,⁵¹ both with patterns

that have been linked to risk of death. The boundaries of digital PGHD may be expanded to include data that are not directly health-related but may nevertheless influence health outcomes. Examples include location, social, or financial information, all shown to influence treatment adherence in patients treated with definitive radiotherapy.^{52,53}

Post-treatment Survivorship Period

Capturing long-term QoL data in the survivorship setting represents a major challenge in oncology. Longitudinal symptom profiling using digital biomarkers could be ideal for the post-treatment setting, a time where face-to-face clinician encounters become infrequent.^{42,54} Many potential sequelae of cancer therapy that would be difficult to assess during standard encounters, such as sleep aberrations, decreased mobility, and cognitive decline, could longitudinally be tracked using mobile devices.

To date, there is a lack of published studies that used objective smartphone sensing to capture metrics directly related to QoL in the post-treatment survivorship period. In a study of healthy subjects, an app designed for continuous multiparametric acquisition of movement, location, phone calls, conversations, and data use from patient smartphones was employed to monitor the physical, social, psychological, and environmental aspects of patient health.⁵⁵ While feasibility in this population was demonstrated, further studies in cancer patients are needed to accurately correlate QoL items with objective smartphone data. The ability to continuously monitor QoL parameters using PGHD will provide important insight into the long-term morbidity of disease and treatment.

Practical Considerations

Data Collection: Choosing Digital Endpoints

There are several important considerations when using a digital approach to gather PGHD (Fig. 2). Selection of a digital biomarker and an appropriate smartphone sensor platform would ideally be based on high-level clinical data. Physical activity metrics captured using smartphone accelerometers have received the most attention to date. Other digital biomarkers related to toxicity monitoring, such as sleep,⁵⁶ movement,⁵⁷ vital signs, and quality of life, are actively being researched by several groups.

Endpoints of early-phase trials should include feasibility of data collection and management as well as validation of device reliability. Validation studies may be particularly challenging, as 'gold standard' measurements may be unavailable or prohibitively challenging to acquire. It then becomes important to focus on within-subject differences, with the expectation that longitudinal changes throughout the treatment or post-treatment survivorship period may have clinical utility.

It will be important to consider the timeframe for PGHD collection with respect to the window when clinical events of interest are likely to occur. For example, when using smartphones to acquire PGHD to predict serious treatment-emergent adverse events, understanding of the physiology of the adverse events would facilitate identification of plausible prodromal periods within a dataset.

Data Collection: Smartphone App Design and Selection

As opposed to an ideal scenario where patients' mobile devices are standardized and provided for the specific purpose of collecting PGHD, many groups will pursue a practical approach, where participants' own mobile devices will be used to obtain PGHD. Allowing participants to use their own mobile devices,^{37,42} rather than providing patients smartphones,²⁹ yields data with high fidelity and ecological validity, though one must be conscious of "a digital divide" among oncology patients and the resulting possibility for bias.

Disparities, including differences in technological availability, health literacy, digital health literacy, and Wi-Fi access may bias investigators to study patients with high socioeconomic status. Most apps available in the Apple mobile application marketplace are in English only,⁵⁸ written at reading levels that are too advanced for many patients.⁵⁹ Significant differences in digital health use by socioeconomic status for healthcare and health information-seeking items has been reported using data from National Cancer Institute's 2012 Health Information National Trends Survey.⁶⁰ Due to these factors, the introduction of technology-based solutions into routine clinical practice could theoretically exacerbate inequities in cancer outcomes. Alternatively, as the use of mobile technology is becoming widespread in low-income and diverse racial/ethnic populations, some have championed mobile health as a strategy for reducing health disparities.⁶¹

Data Storage

Data collected by an app from a series of sensors is sent to a portal server, where it is stored as part of the back-end component of application software systems. Many apps automatically transport data to their back-end servers when participants gain access to a Wi-Fi or cellular connection. If these data are deemed to represent protected health information, secure storage strategies will be required. Consolidated data should be stored by researchers in password-protected servers and in a deidentified fashion. To allow data to be collected from multiple apps, third-party data integration platforms for secure storage, monitoring, and analysis of PGHD have been developed.

Concluding Thoughts

Smartphones: Big Data, Big Promises

Smartphones are expanding the scope of data gathered in clinical trials and can facilitate the study of novel technology-based interventions for cancer patients. Additionally, mobile devices can provide novel forms of multidimensional data from large patient cohorts. Machine learning techniques, which have already been explored in the field of Radiation Oncology for the development of automated contouring, knowledge-based treatment planning, radiomics-based image analysis, and outcomes modeling, will also play a key role in transforming technical innovations related to mobile devices into clinical gains for our patients. Establishing a scalable infrastructure for collecting, storing, and analyzing information from mobile devices will be critical, as the breadth and depth of available data are expanding rapidly.

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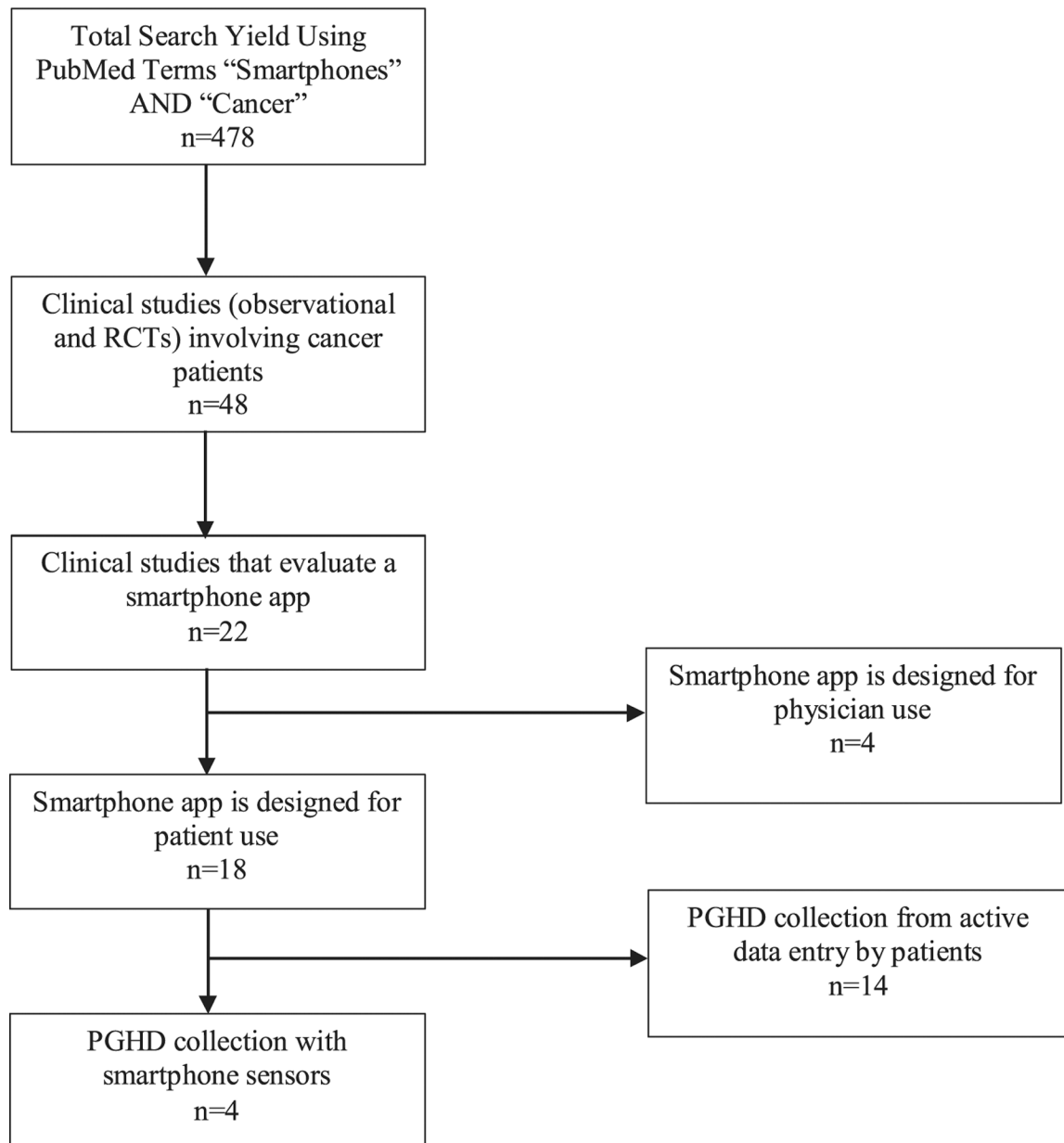


Figure 1. Published clinical studies using smartphones in cancer patients.

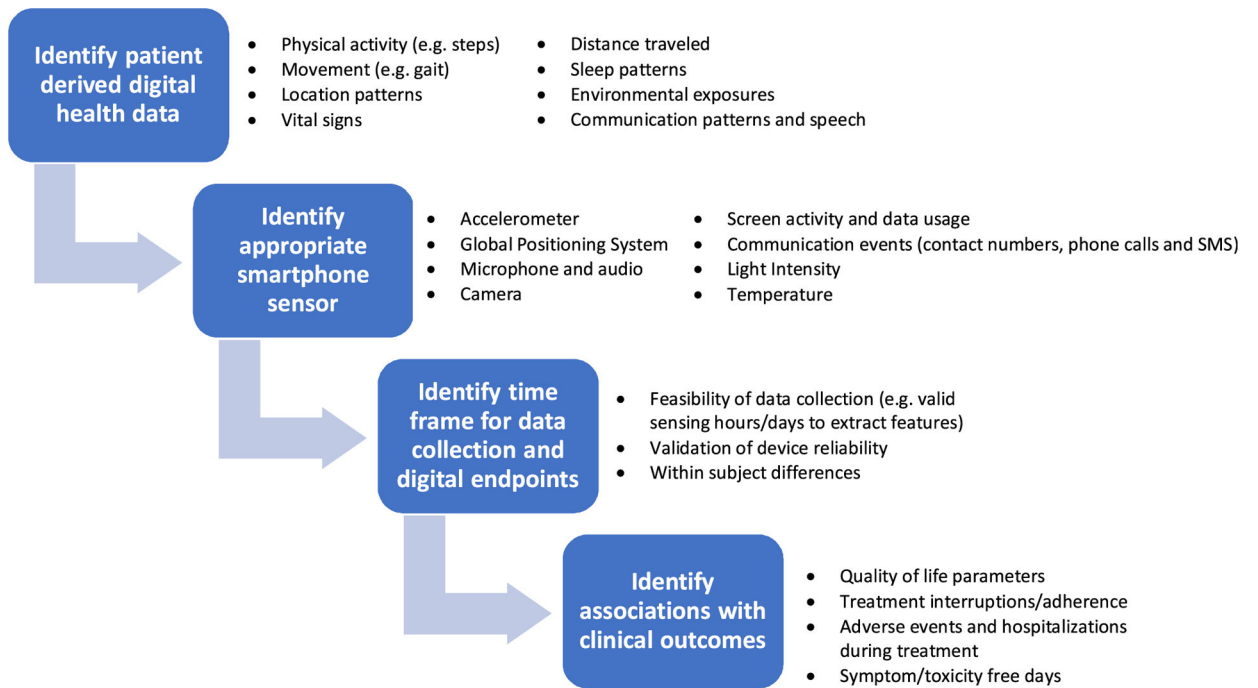


Figure 2. Designing cancer studies using smartphones to collect patient generated health data.

Table 1
Clinical Studies in Cancer Patients Using Smartphone Apps and Patient Self-report Methods to Collect PGHD

Patients	Smartphone Application and Supported Operating System (OS)	Purpose of Smartphone App	Patient Generated Health Data (PGHD)	Source of PGHD	Key Findings
108 patients diagnosed with head and neck cancer randomized to smartphone app vs. standard telephone follow-up ^{2,6}	App: WeChat OS: not specified	Clinical follow-up	• User satisfaction	Self-report on surveys	• Time consumption for each patient (23.36 ± 6.16 min) was significantly shorter compared to telephone follow-up (42.89 ± 7.15 min) ($P < 0.001$) • The overall satisfaction rate with smartphone follow-up was 94.34% compared with 80.43% in telephone follow-up group (95% CI: 0.057–0.067; $P = 0.034$)
132 patients with nasopharyngeal carcinoma who underwent concurrent chemoradiotherapy randomized to smartphone app vs. standard of care ^{3,4}	App: not specified OS: not specified	Reduce treatment complications and improve quality of life in the post-treatment period	• Adverse effects of radio- and chemotherapy • Quality of life	Self-report on surveys	• Incidence of adverse effects was significantly lower than in the control group and QoL was significantly higher than in the control group ($P < 0.05$)
88 breast cancer survivors who carried out a 12-week exercise program via smartphone app with pedometer ⁴	App: Smart After Care OS: not specified	Promote physical activity	• User satisfaction	Self-report on surveys	• Mean score of overall satisfaction rated on the 5-point Likert scale was 4.22 ± 0.73
40 adolescents with cancer who used a smartphone app for 28 days ³³	App: Pain Squad+ OS: Apple iOS 6	Real-time pain management	• Pain	Self-report on surveys	• Statistically significant improvements in pain intensity, pain interference, and quality of life with app use (effect sizes range: 0.23–0.67)
32 adult patients diagnosed with cancer randomized to 12-week intervention with smartphone app vs. standard of care ²⁸	App: Runkeeper OS: Android or Apple iOS	Enhance physical activity	• Physical activity	Self-report on surveys	• 51 % increase in physical activity (medium estimated effect size $r = 0.40$) and 46% increase in total minutes of physical activity ($r = 0.37$) in patients using smartphone app
284 colon cancer survivors randomized to receive a smartphone with app vs. standard of care ²⁹	App: SurvivorCHESS OS: not specified	Enhance physical activity, quality of life and distress	• Duration of physical activity • QoL and distress items	Self-report on surveys	• Nonsignificant increase in moderate to vigorous physical activity at 6 months from baseline (19.4 min to 50 min vs 15.5 min to 40.3 min, $P = 0.083$)
102 colorectal cancer patients undergoing chemotherapy who underwent 12 weeks of smartphone aftercare ³²	App: mobile health app paired with wearable device OS: not specified	Improve physical capacity, treatment related symptoms, and health	• Strength • Cardiorespiratory endurance	Self-report on surveys	• Lower extremity strength and cardiorespiratory endurance were significantly improved after intervention ($P < 0.001$)

Patients	Smartphone Application and Supported Operating System (OS)	Purpose of Smartphone App	Patient Generated Health Data (PGHD)	Source of PGHD	Key Findings
356 breast cancer patients performing a 12-week regimen of aerobic and resistance exercise randomized to receive a pedometer with smartphone app vs. standard of care ³⁰	App: smart after care paired with pedometer OS: not specified	Enhance physical function, activity, and QoL	Step count	Self-report on surveys	Physical function, activity, and QoL scores were not significantly improved using smartphone app compared to conventional program
112 women diagnosed with breast cancer 5 years randomized to smartphone app mindfulness training vs. standard of care ³¹	App: HeadSpace OS: Android or Apple iOS	Enhance QoL through mindfulness training	QoL	Self-report on REDcap	Higher QoL reported among patients who used app from baseline to follow-up ($P < 0.01$)
30 breast cancer patients receiving chemotherapy using a smartphone app for 90 days during treatment ³⁵	App: Pit-a-Pat OS: Android or Apple iOS	Collection of patient reported outcomes	Sleep patterns Anxiety severity Mood status	Self-report on app	There was a 45% overall compliance rate for self-reporting sleep-disturbance data on the app Patient reporting rate was higher when self-report on the app occurred on the day immediately after enrollment compared to when there was a 2 day lag time (51.6% vs 29.6%, $P = 0.03$)
107 patients with stage II-IV breast or colorectal cancer and their spouses using a smartphone app for 14 days ³⁶	App: not specified OS: Android or Apple iOS	Collection of patient reported outcomes	Relationship satisfaction Communication	Self-report on app	Expressing one's feelings was unassociated with relationship satisfaction in couples with cancer while holding back from doing so was associated with relationship satisfaction in both patients and their spouses
101 patients undergoing routine chemotherapy who used a smartphone app during treatment at least once ³⁷	App: PRO-SMART OS: Android or Apple iOS	Toxicity monitoring	Symptomatic AEs associated with chemotherapy	Self-report on app	There was a significantly increased number of symptomatic AEs recorded in health record after introduction of app compared to usual practice (before PRO-SMART)(mean \pm standard deviation increased from 0.92 ± 0.80 to 2.26 ± 1.80 , $P < 0.0001$)
112 patients with lung, breast, or colorectal cancer randomized to use a smartphone app vs. standard of care ⁴⁸	App: not specified OS: not specified	Toxicity monitoring	Life-threatening symptoms	Self-report on app	There was a significantly increased grading of AEs with use of the app compared to usual practice (from 0.81 ± 0.69 to 1.00 ± 0.62 , $P = 0.029$). Patients reported improvements in communication with health professionals,

Patients	Smartphone Application and Supported Operating System (OS)	Purpose of Smartphone App	Patient Generated Health Data (PGHD)	Source of PGHD	Key Findings
100 prostate cancer patients who underwent surgery participating in a pedometer vs. smartphone based exercise program ²⁷	App: smart after-care paired with pedometer OS: not specified	Enhance physical activity	<ul style="list-style-type: none"> Physical status and function 	Traditional biometric measurements	and in the management and monitoring of their symptoms <ul style="list-style-type: none"> There were increases in physical function in patients using smartphone and pedometers There were no significant differences in uptake/adherence in the smartphone vs pedometer group

Abbreviations: AE, adverse event; OS, operating system; QoL, of quality, life.

Table 2
Clinical Studies in Cancer Patients Using Smartphone Apps With Embedded Sensors to Record PGHD

Patients	Smartphone Application and Supported Operating System (OS)	Purpose of Smartphone App	Patient Generated Health Data (PGHD)	Source of PGHD	Key Findings
72 patients with cancers who used a smartphone for 14 days ⁴⁰	App: Walkmeter OS: Apple iOS 10.2	Measure physical activity	<ul style="list-style-type: none"> Step count Distance traveled 	Smartphone global positioning system (GPS)-signal	<ul style="list-style-type: none"> Smartphones demonstrated excellent validity for step count when compared to a wearable accelerometer (ICC = 0.97, $P < 0.001$) and fair validity for fitness (ICC = 0.47, $P < 0.001$). Excellent test-retest reliability for step count (ICC = 0.91, $P < 0.001$).
40 patients aged 65 y starting first-line chemotherapy for solid tumors who used a smartphone for 1 cycle ⁴¹	App: GoogleFit OS: Android	Measure physical activity	<ul style="list-style-type: none"> Step count 	Smartphone accelerometer	<ul style="list-style-type: none"> Mean pretreatment daily steps was 311 60% of patients had toxicities management over the phone 27.5% of patients were sent for urgent medical attention and 15% were hospitalized
10 breast cancer survivors who participated in a 10-week pilot study with a smartphone app and health information delivery through Facebook ⁴²	App: MapMyFitness OS: Android or Apple iOS	Measure and enhance physical activity	<ul style="list-style-type: none"> Distance traveled Step count 	Smartphone global positioning system (GPS)-signal	<ul style="list-style-type: none"> Average daily moderate-to-vigorous physical activity and steps increased by 2.6 min and 1657, respectively Average weight and body fat percentage decreased (2.5 kg, 2.3%, respectively)
Cancer patients in a tertiary hospital who used a smartphone app with sensor ⁴³	App: My Cancer Diary OS: Android or Apple iOS	Patient self-management	<ul style="list-style-type: none"> Symptom management Cancer education 	Smartphone camera for patient log on	<ul style="list-style-type: none"> Sensor usage by patients to log into smartphone app gradually declined in the first 3 mo.

Abbreviation: ICC, interclass correlation coefficient.