

STUDY PROTOCOL

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Benefit of adding Cureety Techcare telemonitoring to usual care during injectable anticancer treatment: the OPTIMACURE multicentric French prospective randomized study

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Abstract

Background In routine oncology care, assessing a patient's suitability for injectable anticancer treatment involves several factors including blood tests and follow-up calls from hospital staff to review results and relevant factors. The OPTIMA program at the François Baclesse Comprehensive Cancer Center and the "Star" program at Foch Hospital in France have improved chemotherapy prescription accuracy and reduced wait times through structured calls and biological tests. However, these programs rely heavily on telephone calls, increasing staff workload. The Cureety digital telemonitoring platform could streamline this process by efficiently collecting and evaluating patient data, potentially reducing the number of outgoing calls. The OPTIMACURE study was implemented to assess whether integrating Cureety telemonitoring into usual care can decrease the workload on hospital staff compared to programs like OPTIMA.

Methods The main aim of this prospective, randomized, multicenter, open-label study is to assess the effectiveness of adding Cureety telemonitoring to usual care to reduce the number of outgoing telephone calls from the center during the first two months after randomization. Patients initiating injectable anticancer treatment will be randomly allocated in a 2:1 ratio to either usual care with Cureety telemonitoring or usual care alone (OPTIMA or equivalent program). Randomization will be stratified by treatment type, Eastern Cooperative Oncology Group performance status, administration frequency, and participating center. A total of 192 patients will be recruited over four months, with patient participation planned for two months, making the study duration six months from the first enrollment. An interim analysis is planned once 96 patients reach the two-month visit.

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Discussion This study aims to validate telemonitoring as a more efficient alternative, potentially enhancing data collection and patient monitoring while reducing healthcare staff workload. The research aims to improve oncology care efficiency by integrating Cureety telemonitoring, reducing staff workload and improving patient care. It seeks to enhance the patient's experience with timely data collection, leading to better quality of life, fewer emergency room visits, and potentially improved clinical outcomes.

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Keywords Anticipated prescription, Cancer, Chemotherapy management, Injectable anticancer treatment, Telemonitoring, Quality of care

Background

In usual oncology care, it is crucial to determine a patient's suitability for injectable anticancer treatment in the days preceding administration. This assessment typically involves conducting blood tests shortly before the planned treatment. A hospital staff member then calls the patient to evaluate their treatment eligibility, using the test results and other patient data, such as the presence of adverse events (AEs) and the Eastern Cooperative Oncology Group (ECOG) performance status, to decide whether the patient is fit for treatment or if it should be deferred.

In France, the François Baclesse Comprehensive Cancer Center in Caen (Normandy) launched the OPTIMA program in 2014 to optimize the prescription and preparation of chemotherapy in the hospital's ambulatory unit [1]. The OPTIMA program consists of three stages: first, nurses conduct structured phone calls with patients 2–3 days before their scheduled chemotherapy to collect data on adverse events and other relevant information. Second, patients undergo biological tests within 48 h before the appointment and send the results to the center. Finally, one day prior to the appointment, a physician reviews the data and decides whether to validate or defer the chemotherapy prescription.

A study validating the OPTIMA program found that chemotherapy prescriptions were accurate and patient wait times between the appointment and the initiation of chemotherapy were significantly reduced [1]. The OPTIMA program has since become part of the center's usual care. Similarly, the Foch Hospital in Suresnes (Île-de-France) launched the "Star" program to collect patient data within three days prior to chemotherapy [2] while the PROCHE program at the European Hospital Georges Pompidou in Paris (Île-de-France) started an oncology-monitoring program to reduce both patient wait time and chemotherapy wastage [3]. Patients provide data via a web-based platform or by telephone, which includes health status, adverse events, and blood test results. This information allows healthcare professionals to adapt or delay chemotherapy and offer necessary support,

resulting in increased patient throughput, decreased wait times, and reduced healthcare product wastage (Table 1).

Following the success of the OPTIMA and "Star" programs, several French healthcare centers have implemented similar initiatives. However, a significant portion of data collection still relies on outgoing telephone calls, increasing the workload of hospital staff. Since the deployment of these programs, more patients have requested a web-based application alternative to telephone calls, which can be inefficient due to unresponsive patients and difficulties for those with language or hearing issues.

Emergence of connected health has driven the development of remote monitoring solutions to support patient management. Remote patient monitoring (RPM) has the potential to support personalized therapy monitoring outside the hospitals using mobile health tools to capture patients' data. It has proven promise as supplementary methods to objectively and continuously assess the treatment and recovery of patients [4–6]. Various remote parameters were shown to correlate with relevant outcomes used in routine care, including adverse events and performance status [5, 7]. Evidence suggests that RPM can offer benefits such as early detection of adverse events, improved quality of life (QoL), fewer emergency room visits, longer chemotherapy adherence, and extended overall survival [4, 5, 7, 8]. In these conditions, RPM has the potential to streamline the process to assess suitability for injectable anticancer treatment by collecting blood test results and other necessary patient data [9–19]. Telemonitoring is thus helpful to identify patients requiring particular attention from hospital staff, allowing targeting outgoing calls to perform for oncology care.

Cureety is a digital telemonitoring platform designed to monitor disease progression and adverse events in cancer patients. This digital tool collects data on blood results, treatment-related information, and QoL. Patients respond to an electronic questionnaire based on NCI-CTCAE v5.0, with the Cureety TechCare algorithm classifying their state and advising appropriate actions. In preparation for injectable anticancer treatment, Cureety

Table 1 Overview of digital health studies in the landscape of oncological day care

Study program	Sponsor, participating sites	Intervention	Patients	Primary objective / Measurement	Secondary objectives / Measurements	Study outcomes
OPTIMA [1]	Centre François Baclesse, Caen, FR	OPTIMA program: nurse phone call and blood sample two days before the planned cancer treatment.	N=283 (step 1) N=294 (step 2)	Discrepancy rate between anticipated prescription and real prescription	Patients' waiting time Patients' satisfaction with care	Discrepancy rate: 8.7% Reduced waiting time (55 vs. 95 min, $p < 0.001$) High general care satisfaction score (80.2%)
Star program [2]	Foch Hospital, Paris, FR	Star oncology-monitoring program: call to patient 2 days before chemotherapy	N=382	Early preparation rate before/after implementation of the Star program	Destroyed preparation rate because of non-administration	Increase of early preparation rate of expensive drugs from 0 to 40% Decrease of destroyed preparation rate from 5 to 2%
PROCHE program [3]	Hôpital Européen Georges Pompidou, AP-HP, Paris, FR	Oncology-monitoring program: collection of data 2 days before chemotherapy	N=1037 in the Proche program N=513 controls before the Proche program	Patient waiting time	Chemotherapy wastage Patient care throughput Patient care outcomes	Waiting time decreased by 66 min Drug wastage reduced from 6% to 2% ($p < 0.0001$) Significant increase of bed occupancy rates Reduced pain incidence and fatigue severity
OPTIMACURE	Centre François Baclesse, Caen, FR Bligny hospital, FR Osny hospital FR	Cureety remote patient monitoring	N=192	Number of outgoing telephone calls from the center during the first two months	Patient management: duration of hospital-free survival, duration of treatment-free survival patient quality of life Satisfaction with care	NA

can collect the data necessary to evaluate whether patients are apt for treatment.

This study thus aims to evaluate the effectiveness of adding Cureety RPM to usual care for care management of patients initiating injectable anticancer treatment, as compared to usual care programs like OPTIMA.

Methods / design

The OPTIMACURE trial is a prospective, randomized, multicenter, open-label, interventional study (<http://clinicaltrials.gov/study/NCT06371911>). It addresses patients initiating injectable anticancer treatment (Fig. 1). The OPTIMACURE protocol and this manuscript have been written in accordance with standard protocol items, namely recommendations for interventional trials (SPIRIT).

Primary objective

The primary objective is to assess the effectiveness of adding Cureety telemonitoring to usual care to reduce the number of outgoing telephone calls from the hospital medical staff during the first two months after randomization.

The primary endpoint measurement is the number of outgoing telephone calls from the treatment centers to the patients receiving injectable anticancer treatments for two months after randomization. We have defined

outgoing calls considered for the primary endpoint as those related to the management of intercurrent events and to the validation or delay of the injectable anticancer treatment prescription.

Secondary objectives

Secondary endpoints will be used to assess the effectiveness of adding Cureety telemonitoring to usual care, concerning patient management, the organization of hospital services, and the overall satisfaction of Cureety telemonitoring.

Patient outcomes

Metrics to evaluate patient health and satisfaction post-randomization include: the duration of hospital-free survival (HFS), which measures the days a patient remains out of the hospital until death [20]; the HFS rate at two months; the duration of treatment-free survival (TFS), marking the days from randomization until a grade 3–4 non-hematological AE (grade using CTCAE v5.0), a hospitalization for safety reasons, or death, from any cause; and the TFS rate at two months. Additionally, patient QoL will be assessed using the EORTC QLQ-C30 self-questionnaire [21], both overall and by specific dimensions. Lastly, patient satisfaction with the healthcare provided will be evaluated using the EORTC OUT-PAT-SAT35-CT questionnaire [22].

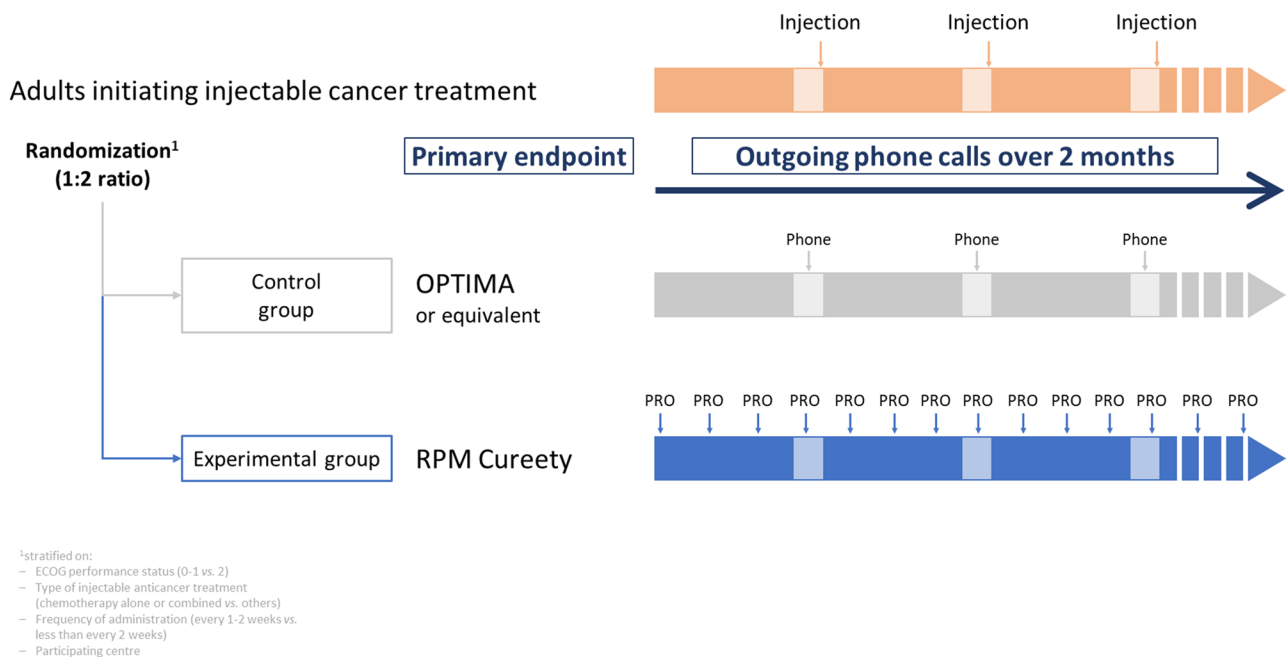


Fig. 1 Study design

Table 2 Eligibility criteria in the OPTIMACURE study

Inclusion criteria	Non-inclusion criteria
<ul style="list-style-type: none"> • Patients that have provided written informed consent for study participation before any trial-related activities • Patients aged 18 years or older. • Patients initiating injectable anticancer treatment (chemotherapy, immunotherapy, targeted therapies etc.) • Patients with the capacity, personally (e.g., language and capacity to use the application), and in terms of infrastructure (internet access, possessing a smart phone etc.) to perform Cureety telemonitoring • Patients affiliated to an appropriate social security system 	<ul style="list-style-type: none"> • Exclusive oral cancer treatment • Patients with dysphonia or difficulty communicating orally • Patients benefiting from injectable cancer treatment as part of a clinical trial • Inability to undergo trial monitoring for geographical, social or psychological reasons • Any associated medical or psychological condition that could compromise the patient's ability to participate in the study • Patients deprived of freedom or under guardianship

Organization of hospital services

The time interval between the validation of the injectable anticancer treatment prescription and administration will be assessed using three categories: <12 h, 12–24 h, and > 24 h.

Overall satisfaction of Cureety telemonitoring

A study-specific questionnaire will be used to assess patients', doctors', pharmacists', and nurses' satisfaction with Cureety telemonitoring.

Study population

The OPTIMACURE study will be conducted among patients initiating injectable anticancer treatment. Eligibility criteria are presented in Table 2.

Study site

The study is conducted in 3 French centers (<https://clinicaltrials.gov/study/NCT06371911#contacts-and-locations>).

Study experimental plan

Nurses or medical oncologists will inform eligible patients of the study and solicit their participation. Written study information will be given to patients who will then have the liberty to join the study or not. Should the patient wish to participate in the study, their informed consent will be obtained followed by the specific exams requested at the baseline visit before being included in the study. Patients' trial eligibility will be verified and then randomization will be performed on the eCRF portal. Patients will be randomly allocated in a 2:1 ratio to one of the following arms:

- Experimental arm: usual care with anticipated validation of injectable cancer treatment with Cureety telemonitoring.
- Control arm: usual care with anticipated validation of injectable cancer treatment (OPTIMA or equivalent program).

Randomization will be stratified by four criteria: type of injectable anticancer treatment (chemotherapy alone or combined versus others [immunotherapy, targeted therapies, etc.]), ECOG performance status (0–1 versus 2), frequency of administration (every 1–2 weeks versus less frequently than every 2 weeks), and the participating center.

Recruitment is planned for a duration of four months. While the Cureety telemonitoring intervention is planned for the duration of the cancer treatment, patient participation has been planned for two months.

Modalities of participation

For all enrolled patients, injectable cancer treatment and management will be initiated as per usual care. All treatments, therapies, and concomitant treatments according to the usual practice at the participating center and at the physician's discretion will be authorized.

Control arm: usual care with anticipated validation of injectable cancer treatment

Patients assigned to the control arm will be enrolled in the current OPTIMA or an equivalent program (without Cureety telemonitoring application), which consists of three stages.

The first stage consists of structured telephone calls made by the medical team to patients two to three days before the planned administration of injectable treatment. This allows for the monitoring of adverse events and other relevant data. Secondly, patients will undergo biological tests within 48 h of the appointment, and the results will be sent to the center by the laboratory. Then, the physician will assess the data to decide whether to defer or validate the prescription of injectable treatments.

Experimental arm: usual care with anticipated validation of injectable cancer treatment with cureety telemonitoring

For patients assigned to the experimental arm, the Cureety digital patient monitoring and management platform (including the medical device Cureety TechCare) will be used during the study. All device deficiencies (including malfunction, use error, and inadequate labeling) will be documented and reported by the investigator throughout the clinical investigation and appropriately managed by the sponsor.

Cureety, a digital telemonitoring platform, has been designed to facilitate the monitoring of signs and symptoms of treatment specific AEs and disease progression. It provides access to the Cureety TechCare medical device, a configurable classification algorithm that allows for the configuration of follow-up questionnaires specific to the treatment and pathology of each patient being monitored. At the institutional level, physicians and health staff involved are referenced on the Cureety

platform. The platform integrates an algorithm that is CE marked, Cureety TechCare, self-certified as a class I medical device according to the directive 93/42/CEE, and a class IIa medical device according to the Medical Device Regulation (MDR) 2017/745 (certification according to the MDR is under way).

Prior to initiating injectable anticancer treatment, patients allocated to Cureety telemonitoring will need to download the Cureety telemonitoring application (compatible with smartphone or tablet (Android or Apple system), or computer) and perform the required training. Dedicated, study-trained nurses and physicians working in participating ambulatory oncology centers will facilitate the implementation of Cureety telemonitoring for the patient. In accordance to French regulations [23], the health team in charge of telemonitoring is apt to ensure a standard management of patients or to refer them to health professionals for adequate standard care, if necessary. Patients will receive information on the therapeutic decision, at the same time they receive information of the telemonitoring modalities using the Cureety platform. If necessary, patients will be assisted to implement the Cureety web application on their smartphone. The health staff is in charge of creating a Cureety patient web account, indicating the cancer regimen that will be delivered to the patient and configuring the questionnaires based on the prescribed regimen. Patients will thereafter receive an email and a SMS permitting the activation of their Cureety account. During Cureety telemonitoring, the patient will be prompted by Cureety notifications (via SMS) to complete questionnaires on the platform.

All along cancer treatment in ambulatory care, during intervals between cancer treatment administration (inter-cycles period), patients will be asked to complete a questionnaire specifically designed for the drug class or treatment being administered via the platform (side effects, symptoms, intercurrent events, weight, etc.). According to responses, patients will be classified by the algorithm into four risk categories: “correct” (green), “compromised” (yellow), “state to be monitored” (orange), or “critical state” (red). The color code will not be transmitted to the patients, but, depending on the category, patients could be advised to take action. The dedicated health team will monitor patient alerts in real-time: health professionals have available real-time dashboards with various tabs, including one for patient telemonitoring and one for validation of injectable cancer treatment prescription (Suppl file 1). In case of minor symptoms (green or yellow categories), personalized advice will be given to the patients. Adversely, patients will be phoned by the telemonitoring nurses to explore the reported symptoms and adapt care management, in consultation with the day care medical oncologist, if requested. Each outgoing call is noted in real time in the patient medical

record, while precisizing the date, the contact mode (telephone call, remote audio or remote audio-video), the reason for outgoing call (clinical evaluation of the patient pre day care center, clinical evaluation of the patient pre day care center following toxicity report, clinical evaluation of the patient pre day care center following nonadherence on application, intercurrent toxicity, or other). The professional who realized the call is also recorded (physician, nurse, advanced practice nurse, medical assistant, or other).

In case of emergency outside normal outpatient service hours, patients will be advised to contact the emergency number.

Cureety RPM will also collect the following data:

- Treatment delays, dose reductions and compliance data.
- Compliance with the use of Cureety.
- QoL data using validated questionnaires such as the EORTC QLQ-C30 [21].
- Patient satisfaction with Cureety and care management.

Study evaluations

The trial assessments and procedures are fully described in Table 3.

Baseline

For patients in both arms, the following data will be collected: sociodemographic and disease characteristics, details of disease treatments, and information from a comprehensive clinical exam. Additionally, data on prior and concomitant medications will be gathered, including details of injectable cancer treatments (such as type, frequency, and treatment line) and concomitant treatments (including prophylactic treatments like growth factors and antihistamines). Patients' quality of life will also be assessed using the EORTC QLQ-C30 questionnaire.

For patients in the Cureety arm, we will also ensure proper downloading of and training concerning the use of Cureety.

During trial

For all patients, at one month (± 1 week) and two months (± 2 weeks) after randomization, the following data will be collected: a complete physical examination, ECOG status, vital signs, and symptoms. Current and concomitant medications, including injectable cancer treatments (type, frequency, and treatment line), will be documented. Adverse events will be recorded according to NCI-CTCAE v5, and patients' QoL will be assessed. Additionally, data on hospitalizations, the number of outgoing calls from hospital staff to patients undergoing

injectable anticancer treatment at the participating center and the validation of prescriptions prior to injectable cancer treatment (categorized as < 12 h, 12–24 h, or > 24 h) will be collected.

For patients in the Cureety arm, incidences related to the medical device will also be documented.

End of trial

Two months after randomization, the end-of-participation assessments will include an evaluation of patient satisfaction with care for all patients from both arms, using the self-reported EORTC OUT-PATSAT35-CT questionnaire. Additionally, for patients in the Cureety arm, the satisfaction of users with the Cureety system will be evaluated using the F-SUS self-reported questionnaire.

Follow-up

At the end of patient participation, hospitalizations and severe adverse events will be collected from medical records up for a maximum duration of six months after randomization.

Tools used for study assessments

Efficacy

The efficacy will be assessed using the number of outgoing calls, the time interval between the validation of the prescription for injectable anticancer treatment prescriptions and administration, HFS, and TFS.

Patient quality of life

The patient QoL will be assessed using version 3 of the EORTC QLQ-C30 questionnaire [21]. The core QLQ-C30 comprises 30 items across 9 scales: 5 functional scales (physical, role, cognitive, emotional, and social), 3 symptom scales (fatigue, pain, nausea and vomiting), and a global health and quality of life scale. Among the 30 items, 28 are scored using 4-point Likert scales (1 for "Not at all" and 4 for "Very much"). The remaining 2 items assessing overall health and quality of life are each scored from 1 ("Very poor") to 7 ("Excellent").

The patients will complete the questionnaire at baseline and then at 2 months (± 2 weeks) after randomization. The QoL will be compared overall and according to the dimension scales.

Patient's satisfaction with healthcare

The patient's satisfaction with the healthcare provided will be assessed using the standardized care EORTC OUT-PATSAT35-CT questionnaire [22], which is a 35-item and 13-scale questionnaire assessing outpatients' perception of the care provided by doctors and nurses, as well as organization and services provided [23]. The structure of the OUT-PATSAT35 questionnaire includes 12 multi-item scales organized in three areas: doctors,

Table 3 Overview of study flow and measurement timings in the OPTIMACURE study

	Screening (up to 7 days before Day 1)		Intervention al period (until month 2)	End of trial visit (month 2 ±2 weeks)	Follow-up (every month +/- 1 week) up to end of injectable treatment or 6 months after randomization
Study explanation and informed consent signature before any study procedures	✓	RANDOMIZATION 2:1 between: Experimental arm (CUREETY telemonitoring) or Control arm (OPTIMA or equivalent programs)			
Demographic, treatment, and cancer-related data <i>Complete physical examination, including weight, height (only at baseline), ECOG, vital signs and symptoms</i> <i>Medical history</i>	✓ ✓		✓	✓	
Prior and current concomitant medication including injectable treatments for cancer (type of treatment, frequency of administration, line of treatment)	✓		✓		
Safety data Incidence of adverse events (graded by NCI-CTCAE v5) For patient in Cureety group: Medical device-related incidences (Usual care with Cureety telemonitoring group only)			✓ ✓	✓ ✓	
Quality of life Quality of life data (EORTC QLQ-C30)	✓		✓*	✓	
Patient satisfaction with healthcare provided (EORTC OUT-PATSAT35-CT)				✓	
Satisfaction questionnaire (only for Cureety arm) • F-SUS • Patient satisfaction with Cureety telemonitoring (study-specific questionnaire*) Satisfaction of doctors, pharmacists, and nurses with Cureety telemonitoring (study-specific questionnaire*)				✓ ✓	
Hospitalization on patient medical file			✓	✓	✓
Severe adverse events on patient medical file			✓	✓	✓
Collection of data from hospital staff Number of outgoing calls Validation of prescription prior to injectable cancer treatment (<12 h, 12-24 h, or >24 h)			✓ ✓	✓ ✓	
Incidence of adverse events (graded by NCI-CTCAE v5)			✓	✓	
Medical device-related incidences (Usual care with Cureety telemonitoring group only)				✓	

*Questionnaire based on the PRO-TECT study by Basch et al (15,16,19)

nurses, services and care organization, each area containing four scales. It also has a global item on overall satisfaction. Responses are given on a five-level scale: “poor,” “fair,” “good,” “very good” or “excellent” [24]. The mean completion rate of the questionnaire is within 15 min.

Satisfaction with cureety telemonitoring

The experience and satisfaction of patients and health-care staff will be assessed at the end of the trial (2 months post-randomization).

The patients’ experience with the Cureety telemonitoring will be assessed using the French validated version of the System Usability Scale (SUS) self-questionnaire [25, 26]. This questionnaire includes 10 questions and aims to determine the level of satisfaction of users of a service (software, application). It evaluates frequency, complexity, easiness of use, user control, good integration of functions, inconsistency of functionality, speed of learning, cumbersome and confidence in the application. It measures the experience that patients and professionals have of the application by evaluating the “usability” or “user-friendliness” of the service. This experience is both subjective and polymorphous. This self-questionnaire is simple and quick (one minute).

The satisfaction of health professionals with the use of Cureety (Suppl file 2) will be based on the PRO-TECT study by Basch et al. [15, 16, 19].

Safety

Safety will be assessed in terms of the incidence and severity of AEs. The severity of AEs will be assessed using the NCI-CTCAE v5.0. For AEs not listed in the NCI-CTCAE, the severity will be assessed as follows:

- Grade 1 (mild): Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- Grade 2 (moderate): Minimal local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL.
- Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL.
- Grade 4: Life-threatening consequences; urgent intervention indicated.
- Grade 5: Death related to the event.

Statistical considerations

Sample size determination

A total of 192 patients needs to be enrolled in the study to achieve the desired statistical power. The sample population must include at least 128 patients receiving usual care with Cureety telemonitoring and 64 patients

receiving usual care alone (OPTIMA or equivalent programs). This distribution is designed to achieve 90% power to reject the null hypothesis of a zero-effect size, assuming a population effect size of 0.5 and a significance level (alpha) of 5%, using a two-sided two-sample equal-variance t-test. Thus, the study can detect an effect size higher than 0.5 corresponding to a mean decrease of the number of outgoing calls to patients performing injectable anticancer treatments during the first two months after randomization from 6 ± 4 calls in the control arm to 4 ± 4 in the experimental arm.

This sample size allows for group-sequential tests for two means with known variances ($\sigma=4$), including an interim analysis after 96 patients have reached the two-month visit (information proportion at 50%). Sequential testing will use two stages and boundary values calculated from the spending function of O’Brien-Fleming.

Statistical analyses

Quantitative variables will be described using numbers of filled and missing data, mean, standard deviation, median, first and third quartiles, as well as minimum and maximum. For comparison of quantitative variables, Student t-test will be used (with Satterthwaite correction if variances are unequal). Before using these tests, normality will be tested using Shapiro-Wilk test. If normality is rejected, a non-parametrical method (Wilcoxon ranks) will be used instead of the Student’s t-test.

Qualitative variables will be described using numbers of filled and missing data and, for each modality, the frequency and percentage (referring to filled data). For comparison of qualitative variables, Chi² test will be used. If hypotheses are not fulfilled, Fisher exact test will be used instead. In case of ordinal variable with less than five modalities, the Cochran-Mantel-Haenszel test will be used. The type I error will be 5% two-sided.

The final data will be transferred to the R Project for Statistical Computing SAS system for analysis, and coding will be done using MedDRA and WHO Drug Dictionary standards.

Primary endpoint analysis The main analytical approach involves estimating the effect of Cureety telemonitoring on the number of outgoing telephone calls. This will be done using an analysis of variance (ANOVA), with arm and randomization criteria as factors, taking into account all randomized patients. Least-squares means and their differences in each arm, along with 95% confidence intervals (CI) and p-values, will be provided. The study will be considered positive if the p-value for the primary endpoint is less than 5%. For sensitivity analysis, a Poisson regression will be conducted. This will include Poisson regression coefficients for the treatment effect,

along with standard errors, Wald Chi-Square statistics and intervals, and p-values for the coefficients.

Secondary endpoints analysis The time interval between the validation of the prescription for injectable anticancer treatment and its administration will be analyzed as a continuous variable using the same approach as the primary endpoint. Additionally, this interval will be categorized into < 12 h, 12–24 h, and > 24 h, and analyzed using a logistic regression model with arm and randomization criteria as factors. Satisfaction levels of patients, doctors, pharmacists, and nurses with Cureety telemonitoring will be assessed using a study-specific questionnaire.

Survivals (HFS and TFS) will be summarized for all randomized patients, using the Kaplan-Meier method and displayed graphically. Median event times for each arm and corresponding two-sided 95% CIs will be provided. Survival comparisons between arms will use a two-sided log-rank test stratified by randomization criteria, and a Cox regression model will provide hazard ratios and 95% CIs. Survival rate at two months will also be estimated.

QoL scores will be derived from the EORTC QLQ-C30 items, summarized by cycle and study arm, and assessed across multiple dimensions, including global health status, functional scales (physical, role, emotional, cognitive, social), and symptom scales (fatigue, nausea/vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, financial difficulties). Scores range from 0 to 100, with higher scores indicating better QoL. Absolute changes from baseline will be summarized, and means with 95% CIs will be plotted. Changes in scores from baseline until month four will be assessed using a mixed-effects model for repeated measures (MMRM) analysis, considering baseline score as a covariate and fitting patient as a random effect.

The OUT-PATSAT35-CT questionnaire will be analyzed similarly to the EORTC QLQ-C30. Items are rated on a 5-level Likert scale and scores are transformed to a 0-100 scale, with higher scores reflecting higher satisfaction.

Satisfaction with Cureety will be described without inferential statistics.

Data treatment and conservation

Data will be collected via electronic data capture (EDC) using electronic case report forms (eCRFs). Centers are responsible for data entry, and any discrepancies will be clarified electronically by the data manager. A validated electronic database will maintain an audit trail of all changes, ensuring traceability. Data security will be enforced through personal logins and passwords, restricting access to authorized personnel. After data

cleaning and before database lock, investigators will electronically sign eCRFs to confirm data accuracy. A copy of the completed eCRF will be archived at the study sites.

Early discontinuation of telemonitoring and patients lost to follow-up

Telemonitoring can be discontinued under the following circumstances: if the patient decides to revoke consent and withdraw from the trial, with all data collected up until the date of revocation being analyzed unless the patient requests otherwise; or if the investigator determines that continuing telemonitoring is not in the patient's best interest, in which case all collected data will be analyzed.

A patient will be considered lost to follow-up if the patient repeatedly fails to return for scheduled visits and is unable to be contacted by the center. The following actions must be taken if a patient fails to return to the clinic for a required trial visit:

- The center must attempt to contact the patient and reschedule the missed visit as soon as possible, counsel the patient on the importance of maintaining the assigned visit schedule and to assess whether the patient wishes to and/or should continue in the trial.
- Before a patient is deemed lost to follow-up, the investigator or a staff member at the center must make every effort to regain contact with the patient (where possible, by telephone calls, and if necessary, a certified letter to the patient's last known mailing address or local equivalent methods). These contact attempts should be documented in the patient's medical record.
- Should the patient remain unreachable, the patient will be considered to have withdrawn from the trial.

Discussion

The proposed research evaluates the integration of Cureety telemonitoring into usual oncology care, specifically assessing its effectiveness in reducing the number of outgoing telephone calls from treatment centers during the first two months following randomization. This study is based on the need to streamline the assessment process for determining a patient's suitability for injectable anticancer treatment, which traditionally relies on pre-treatment blood tests and subsequent phone evaluations by hospital staff. Current programs like OPTIMA and "Star" have demonstrated the benefits of structured pre-treatment evaluations, significantly reducing patient waiting times and improving the accuracy of chemotherapy prescriptions. However, these programs still rely heavily on outgoing telephone calls, increasing the workload for hospital staff and often facing inefficiencies due to patient unresponsiveness or communication barriers.

By leveraging telemonitoring through the Cureety platform, this study explores a digital alternative that could enhance data collection efficiency and reduce the dependency on phone calls. Cureety's digital tool is designed to monitor disease progression and adverse events, providing a more seamless and timely collection of critical patient data. If successful, the study could demonstrate that telemonitoring significantly reduces the number of outgoing calls, thus validating the integration of digital health solutions into routine oncology care. This research could provide a model for other healthcare centers to follow, driving advancements in patient monitoring and support, and ultimately contributing to the broader adoption of telemonitoring technologies in oncology care.

In terms of health impact, the proposed research aims to improve the efficiency and effectiveness of patient care in oncology settings through the integration of Cureety telemonitoring. By reducing the calls required for assessing a patient's suitability for injectable anticancer treatment, this study seeks to alleviate the workload on healthcare staff, allowing them to focus more on direct patient care and other critical tasks. Telemonitoring has the potential to enhance the overall patient experience by providing timely and accurate data collection, leading to earlier detection of adverse events, better quality of life, fewer emergency room visits, longer adherence to chemotherapy regimens, and potentially extended overall survival. The success of this study could lead to significant improvements in the patient care process, reducing waiting times and increasing the efficiency of pre-treatment assessments. Patients could benefit from a more streamlined and responsive care system, enhancing their satisfaction and trust in the healthcare system. Additionally, the broader implementation of telemonitoring technologies could result in more personalized and proactive patient care, ultimately leading to better clinical outcomes and improved health impacts for oncology patients. This research could thus mark a significant step forward in integrating digital health solutions into routine oncology care, providing a more efficient, effective, and patient-centered approach to cancer treatment.

A key strength of this study is its prospective, randomized, multicenter design, which enhances the reliability and generalizability of the findings across different healthcare settings. The participating centers are representative of sites treating cancer patients in France, namely comprehensive cancer centers, public hospitals, and private for-profit healthcare establishments. Additionally, the integration of telemonitoring through the Cureety platform offers a modern, digital approach that could significantly streamline patient monitoring and reduce healthcare staff workload. However, the study's reliance on electronic data capture and telemonitoring may exclude patients with limited digital literacy or

access to technology, potentially impacting the generalizability of the results. Furthermore, the relatively short follow-up period of two months may not fully capture the long-term benefits or potential drawbacks of the telemonitoring intervention.

Abbreviations

AE	Adverse event
CE	Conformité Européenne
CI	Confidence interval
CRA	Clinical research associate
CRF	Case report form
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic case report form
EDC	Electronic data capture
EORTC	European Organization for Research and Treatment of Cancer
FAS	Full analysis set
F-SUS	French-System Usability Scale
GCP	Good clinical practice
HFS	Hospital-free survival
HLT	High-level term
HLGT	High-level group term
ICF	Informed consent form
ICH	International Council for Harmonization
IEC	Independent ethics committee
IRB	Institutional review board
LLT	Lowest level term
MDR	Medical device regulation
MedDRA	Medical dictionary for regulatory activities
MMRM	Mixed-effects model for repeated measures
NCI-CTCAE	National Cancer Institute common terminology criteria for adverse events
PT	Preferred term
QLQ-C30	Quality of life questionnaire-C30
QoL	Quality of life
SAP	Statistical analysis plan
SAS	Safety analysis set
SMS	Short message service
SOC	System organ class
TFS	Treatment-free survival

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12913-025-13661-1>.

Supplementary Material 1: SPIRIT checklist

Supplementary Material 2: Dashboards available on Cureety platform for patient monitoring: Extract from the Cureety Instruction Manual.

Supplementary Material 3: Self-questionnaire for healthcare professionals experience with the remote patient monitoring system, based on the PROTECT study by Basch et al.

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Author contributions

AF, FG, BC, JMG, FM, TS, CP, FGC, and RR devised the study concept and design. TS, FG, and BC wrote the manuscript. FM was responsible for overseeing the statistical section. AF, CP, JMG, JB, AE, FG, LG, FGC, BC provided the administrative, technical, or material support. All authors (AF, FG, RR, JMG, AE, LG, JB, FM, TS, CP, FGC, and BC) have been involved in drafting the manuscript or revising it critically for important intellectual content. AF, FG, CP, FGC, JMG, RR and BC supervised the entire work. All authors have given final approval for this version to be published. Each author has participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study received ethical approval from the *Comité de Protection des Personnes Sud-Est VI* on March 3, 2024 (N° ID-RCB: 2023-A02762-43; Ref AU 1925). Although no patients were involved in the study design, it warrants noting that three members of the local ethics committee that approved the study were user representatives. All eligible patients will be proposed to participate by nurses or medical oncologists, who will give them an information file. All patients will give their written informed consent before any study procedure. The study will be conducted in accordance with European Regulation (EU) 2017/745 on medical devices, the law related to the protection of physical persons for the treatments of personal data and related to information technology, database and liberties, the Helsinki declaration, and Good Clinical Practices (GCP) for Medical Devices (ISO 14155).

Consent for publication

Not applicable.

Competing interests

AF declares advisory/consultancy fees (personal) for Cureety. FM declares advisory/consultancy roles (from eXSTAT) for Cureety and owns shares of Cureety. CP and FGC are employees and own shares of Cureety. JB, FG, RR, JMG, AE, LG, BC declare research grant/funding (institution) from Cureety. TS declares no competing interest.

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References

- Dos Santos M, Lequesne J, Dugué AE, Grellard JM, Ory C, Jaffré S, et al. Optimisation of chemotherapy prescription and Preparation in an ambulatory unit: validation of the OPTIMA program. *Eur J Cancer Care (Engl)*. 2019;28(3):e13015.
- Peyrilles E, Lepage-Seydoux C, Sejean K, Bonan B. [Implementation of a remote oncology-monitoring program for cancer patients in outpatient care unit: A major challenge for the different actors]. *Bull Cancer (Paris)*. 2018;105(4):357–67.
- Scotté F, Oudard S, Aboudagga H, Elaidi R, Bonan B. A practical approach to improve safety and management in chemotherapy units based on the PROCHE - programme for optimisation of the chemotherapy network monitoring program. *Eur J Cancer Oxf Engl*. 1990. 2013;49(3):541–4.
- Kos M, Brouwer CG, van Laarhoven HWM, Hopman MTE, van Oijen MGH, Buffart LM. The association between wearable device metrics and clinical outcomes in oncology: A systematic review with evidence synthesis and meta-analysis. *Crit Rev Oncol Hematol*. 2023;185:103979.
- Kos M, Pijnappel EN, Buffart LM, Balvers BR, Kampshoff CS, Wilmlink JW, et al. The association between wearable activity monitor metrics and performance status in oncology: a systematic review. *Support Care Cancer Off J Multinatl Assoc Support Care Cancer*. 2021;29(11):7085–99.
- Stuijt DG, Radanovic I, Kos M, Schoones JW, Stuurman FE, Exadaktylos V, et al. Smartphone-Based passive sensing in monitoring patients with cancer: A systematic review. *JCO Clin Cancer Inf*. 2023;7:e2300141.
- van den Hurk CJG, Mols F, Eicher M, Chan RJ, Becker A, Geleijnse G, et al. A narrative review on the collection and use of electronic Patient-Reported outcomes in cancer survivorship care with emphasis on symptom monitoring. *Curr Oncol Tor Ont*. 2022;29(6):4370–85.
- Low CA. Harnessing consumer smartphone and wearable sensors for clinical cancer research. *NPJ Digit Med*. 2020;3:140.
- Livingston PM, Heckel L, Orellana L, Ashley D, Ugalde A, Botti M, et al. Outcomes of a randomized controlled trial assessing a smartphone application to reduce unmet needs among people diagnosed with cancer (ACE). *Cancer Med*. 2020;9(2):507–16.
- Raghunathan NJ, Korenstein D, Li QS, Tonorez ES, Mao JJ. Determinants of mobile technology use and smartphone application interest in cancer patients. *Cancer Med*. 2018;7(11):5812–9.
- Fristedt S, Smith F, Grynne A, Browall M. Digi-Do: a digital information tool to support patients with breast cancer before, during, and after start of radiotherapy treatment: an RCT study protocol. *BMC Med Inf Decis Mak*. 2021;21(1):76.
- Valenti V, Rossi R, Scarpi E, Ricci M, Pallotti MC, Dall'Agata M, et al. Nurse-led telephone follow-up for early palliative care patients with advanced cancer. *J Clin Nurs*. 2023;32(11–12):2846–53.
- Morris BB, Rossi B, Fuemmeler B. The role of digital health technology in rural cancer care delivery: A systematic review. *J Rural Health Off J Am Rural Health Assoc Natl Rural Health Care Assoc*. 2022;38(3):493–511.
- Mir O, Ferrua M, Fourcade A, Mathivon D, Duflo-Boukoba A, Dumont S, et al. Digital remote monitoring plus usual care versus usual care in patients treated with oral anticancer agents: the randomized phase 3 CAPRI trial. *Nat Med*. 2022;28(6):1224–31.
- Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall survival results of a trial assessing Patient-Reported outcomes for symptom monitoring during routine cancer treatment. *JAMA*. 2017;318(2):197–8.
- Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom monitoring with Patient-Reported outcomes during routine cancer treatment: A randomized controlled trial. *J Clin Oncol Off J Am Soc Clin Oncol*. 2016;34(6):557–65.
- Grustam AS, Severens JL, De Massari D, Buyukkaramikli N, Koymans R, Vrijhoef HJM. Cost-Effectiveness analysis in telehealth: A comparison between home Telemonitoring, nurse telephone Support, and usual care in chronic heart failure management. *Value Health J Int Soc Pharmacoeconomics Outcomes Res*. 2018;21(7):772–82.
- Schmalz O, Jacob C, Ammann J, Liss B, Iivanainen S, Kammermann M, et al. Digital monitoring and management of patients with advanced or metastatic Non-Small cell lung cancer treated with cancer immunotherapy and its impact on quality of clinical care: interview and survey study among health care professionals and patients. *J Med Internet Res*. 2020;22(12):e18655.
- Basch E, Schrag D, Jansen J, Henson S, Ginos B, Stover AM, et al. Symptom monitoring with electronic patient-reported outcomes during cancer treatment: final results of the PRO-TECT cluster-randomized trial. *Nat Med*. 2025;31(4):1225–32.
- Murakawa Y, Ootsuka K, Abue M. The appropriate First-Line chemotherapy regimen for incurable pancreatic cancer in clinical practice: A consideration of patients' overall survival and quality of life. *J Pancreat Cancer*. 2021;7(1):48–56.
- Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European organization for research and treatment of cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst*. 1993;85(5):365–76.
- Poinsot R, Altmeyer A, Conroy T, Savignoni A, Asselain B, Léonard I, et al. [Multisite validation study of questionnaire assessing out-patient satisfaction with care questionnaire in ambulatory chemotherapy or radiotherapy treatment]. *Bull Cancer (Paris)*. 2006;93(3):315–27.
- Arrêté du 25 octobre 2023 relatif à la prise en charge anticipée numérique de certains dispositifs médicaux numériques à visée thérapeutique et certaines activités de télésurveillance médicale en application de l'article L. 162-1-23

- du code de la sécurité sociale - Légifrance [Internet]. [Internet]. 2024. Available from: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000048276427>
24. Ware JE, Hays RD. Methods for measuring patient satisfaction with specific medical encounters. *Med Care*. 1988;26(4):393–402.
 25. Brooke J. SUS-A quick and dirty usability scale. *Usability Evaluation Ind*. 1996;4–7.
 26. Gronier G, Baudet A. Psychometric evaluation of the F-SUS: Creation and validation of the French version of the System Usability Scale. *International*

Journal of Human-Computer Interaction [Internet]. 2021; Available from: <https://doi.org/10.1080/10447318.2021.1898828>

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