ISRCTN99091108 https://doi.org/10.1186/ISRCTN99091108

User experience study of digital tools to collect data on wellbeing and side effects in cancer patients

Submission date
05/03/2025

Recruitment status
No longer recruiting

Registration date
13/03/2025

Overall study status
Completed

Last Edited
16/12/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Side effects, or adverse events (AEs), arising from anticancer therapies result in reduced health-related quality of life (HRQoL). Inadequate symptom monitoring and reporting can lead to worsening AEs, emergency department visits, hospital admissions and increased impact on HRQoL. The capture of clinical data of side effects and HRQoL directly from patients can provide important and vital information and transform the patient's role in clinical trials. Over the past 10 years, studies have shown that patient involvement in reporting their symptoms has demonstrated differences between what patients identify as important to their QoL compared with physicians. Traditionally, the patient's QoL is assessed at different timepoints in a clinical study using a formally validated HRQoL instrument in the form of a paper questionnaire. Studies have shown that patient engagement and involvement in reporting symptoms and HRQoL enriches the clinical understanding and impact of new and existing cancer therapies. The high availability of low-cost smart devices and affordable broadband is enabling the development and use of new digital clinical applications to improve drug side effect and HRQoL monitoring outside of the hospital.

Two studies provide context for the development of this proposed research: the PRO-TECT study evaluating the implementation of electronic patient-reported outcomes (ePROs) demonstrated how ePROs improved discussions with and empowered patients, and physician decision making; and, the original PROACT study (PROACT 1.0 - Patient Reported Outcomes about Clinical Tolerability), which demonstrated a new way for patients to interact with technology whilst on a clinical trial. The PROACT application enabled the capture of additional information by facilitating communication between patients, their clinical team, and feedback to the Sponsor, on specific topics such as safety, dosage administration and study design, while also providing added and complementary information on drug tolerability. This study will build on both studies and incorporate the PROACT application and PRO-CTCAE digital questionnaire (a patient-oriented digital tool to collect AEs from patients in real time) into the new PROACT 2.0 system.

PROACT 2.0 is a new digital healthcare platform for patients to self-report feelings and function in a clinical trial via text, voice note, video or digital questionnaire. It can also transmit information related to the trial to patients and caregivers through its broadcast functionality. The feedback from patients and nursing staff has been very supportive and positive so far. With the PROACT 2.0 videos, patients are advised to discuss how they are feeling and what symptoms they may have. There is no script because the idea is to see what information patients freely provide; this was chosen as it is a new method to explore the capture of this kind of data. This feasibility study is the first time that the new PROACT 2.0 digital system will be implemented in a large heterogeneous clinical setting, focusing on two of the features of this digital tool – video and digital questionnaire - and the first time that the PRO-CTCAE digital questionnaire will be implemented in a large clinical patient cohort.

Who can participate?
All patients enrolled in phase I or II anticancer drug trials can take part as long as they provide written informed consent to participate in the study and are capable of using mobile phone applications, or have a carer who is willing to and able to use the applications on their behalf.

What does the study involve?
Patients that consent will go into a screening period for their treatment trial. During this period, patients will complete a questionnaire for this study that will ask about their quality of life. After the screening period and on the first day of their treatment, patients will be allocated to one of the three arms in the feasibility study:
1. PROACT 2.0 video
2. PROACT 2.0 digital questionnaire
3. Quality of Life monitoring.
After 4 weeks on the feasibility study, they will stop using the app (if using). Then, at the next hospital appointment, they will be asked to complete the standard quality-of-life questionnaire again, as well as an end of study questionnaire about how they have found their time on trial.

Patients allocated to the PROACT 2.0 video arm will be asked to use the PROACT app every day for 4 weeks. They will be asked to record videos to discuss how they are feeling during their treatment, including any side effects they are experiencing.

Patients allocated to the PROACT 2.0 digital questionnaire arm will be asked to use this every day for 4 weeks. This feature uses a questionnaire to understand any side effects patients may be experiencing. For this study, the questionnaire will be the same every day.

Patients allocated to the quality of life monitoring will be asked to complete a standard quality-of-life questionnaire at each hospital visit over a 4-week period.

What are the possible benefits and risks of participating?
There are direct benefits and no anticipated risks to taking part in this feasibility study.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?
January 2024 to December 2025

Who is funding the study?
The Horizon 2020 European Union Funding for Research & Innovation program.

Who is the main contact?
Debra Joy Hall; debrajoy.hall@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Ms Debra Joy Hall

Contact details
Cambridge Cancer Trials Centre
Cambridge University Hospitals NHS Foundation Trust
Box 279 (S4) Addenbrooke's Hospital
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223 216083
debrajoy.hall@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
333333

Central Portfolio Management System (CPMS)
65505

Study information

Scientific Title
User experience study of digital tools to collect data on wellbeing and side effects in cancer patients

Study objectives
This is a feasibility, non-CTIMP study (within the Cancer Core Europe Data Rich Clinical Trials project), designed to evaluate whether patients receiving anticancer treatment in phase I or II anticancer drug trials, executed in Cancer Core Europe Centres, will use digital applications to record Health Related Quality of Life data. It will conduct an assessment of the uptake of a tool, the compliance to schedule and the quality of the data collected. Additionally, it aims to better understand the experience of patients and healthcare professionals in the use of digital tools to collect clinical data on well-being and adverse events. The study will be conducted alongside the patient's standard care and will not interfere in their trial-specific treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/12/2024, South West - Cornwall & Plymouth Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 24/PR/1499

Study design
Feasibility study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
All patients enrolled in phase I or II anticancer drug trials

Interventions
Target population:
Patients enrolled in phase I or II anticancer drug trials.
All potential study participants will be seen and assessed against eligibility criteria whilst already enrolled (cannot have started treatment) or attending for consideration for participation in a phase I or II clinical trial. Study participants will be selected by treating physicians from several Cancer Core Europe centres participating in the DART Work Package 12 project.

Potential participants will be provided with a patient information sheet (PIS) by a research team member and provided with sufficient time to consider this and ask questions. Once potential participants have had sufficient time to consider the information in the PIS, they will be invited to consent for the study and will be provided a copy of the patient information sheet and informed consent form to take away.

Prior to C1D1 -
Patients who have provided written informed consent will enter the screening period. This will include assessing the patient against inclusion and exclusion criteria for the study.

After the screening period is complete and if the patient is confirmed as eligible, participants will be allocated to one of the three arms based on an allocation schedule assigned to the site, as follows:
1. PROACT 2.0 video
2. PROACT 2.0 digital questionnaire
3. Standard QoL monitoring.
The arm they are allocated to will be recorded. All arms will last for 4 weeks.
If allocated to an arm requiring the use of the app, participants will be provided with training on how to use PROACT 2.0.
This study will use a standard QoL monitoring questionnaire (EQ5D5L). Participants on all arms will complete a QoL questionnaire after consent but before C1D1.

Day 1-28 -
Participants on the two PROACT 2.0 arms (video arm or digital questionnaire arm):
Participants on the PROACT 2.0 arms will be required to use the application every day for the duration of the 4-week study. Patients on the video arm will be asked to record any information

on symptoms or impact of treatment – whether positive or negative - in video form. Participants on the digital questionnaire arm will answer questions about adverse events experienced in the previous 24 hours. Patients will be allocated to use the video or the questionnaire, not both.

Participants on the QoL questionnaire arm:
Participants on the QoL questionnaire arm will complete QoL questionnaires whenever they attend for a hospital visit over the four-week period.

End of Study -
After the 4-week study period, participants will attend for their end of study visit; this will be when they next attend for their drug trial visit. At the end of the study visit, all participants will be asked to complete a questionnaire to assess their experience of the study. Additionally, they will be required to complete one last QoL monitoring questionnaire. WHO performance status will also be collected from patients by the healthcare professional.

Intervention Type
Behavioural

Primary outcome(s)
1. The number of patients screened failing or withdrawing from the study measured using the screen failure and withdrawal data captured in the eCRF at the end of the study
2. The proportion of patients complying with the agreed scheduled use of the digital tools measured daily using data from the PROACT tool for 28 days

Adherence to agreed usage schedule of at least 75% would be considered acceptable for feasibility for assessment of the digital tools.

Key secondary outcome(s))
1. Health-related quality of life measured using the EuroQol 5-level EQ-5D version (EQ-5D-5L) questionnaire completed by patients at the end of the study
2. The experience of healthcare professionals with the PROACT app measured using data collected during semi-structured interviews with healthcare professionals at the end of the study

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patients in screening for participation in a phase I or II anticancer drug trial
2. Written informed consent to participate in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Not capable of using mobile phone applications, or no carer who is willing to and able to use the applications on the participants' behalf
2. Enrolled in a phase I or II anticancer drug trial that includes a QoL questionnaire, where inclusion of an additional QoL would interfere with the study’s intended QoL measurements. This is at the investigator’s discretion.

Date of first enrolment
17/03/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Sponsor information

Organisation
The Netherlands Cancer Institute

ROR
https://ror.org/03xqtf034

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 European Union Funding for Research & Innovation

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 11.0	10/04/2024	12/03/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes