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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON53241

Source
ToetsingOnline

Brief title
DART WP12

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Horizon 2020 European Union Funding for

Research & Innovation program

Intervention

Keyword: Digital tools, Phase 1/2, PROACT 2.0, Toxicity

Outcome measures

Primary outcome

To evaluate the feasibility of using digital tools to report effects of drugs

in patients on phase 1 or 2 anticancer drug trials.

Secondary outcome

To evaluate user experience of using different digital tools to self-report on

adverse events and quality of life.

Study description

Background summary

Precision cancer medicine has created a rapid evolution of clinical research, with new types of adaptive, basket and umbrella clinical trials, amongst others, currently being developed with the aim of optimizing the biomarker-drug co-development process tailored to each disease setting. However, all too often, cancer patients receive treatments which can be toxic, ineffective, or both. Since cancer treatments often have a narrow therapeutic index, it is more important than ever to conduct smarter clinical trials which more effectively identify toxicities that significantly impact a patient*s quality of life so we can truly deliver the right drug, for the right patient, at the right time, with the right tolerability profile.

Study objective

This is a feasibility designed to investigate the feasibility of collecting QoL information from patients via digital tools. By feasibility, we mean the assessment of the uptake of the tool, the compliance to schedule and the quality of the data collected. Additionally, we aim 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.

Study design

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 1 or 2 clinical trials. 60 patients will be enrolled in this trial. After the screening period is complete, participants will be allocated to one of the three arms: 1. PROACT 2.0 video, 2. the PROACT 2.0 digital questionnaire, and 3. standard QoL monitoring.

Intervention

Participants will be allocated to one of the three arms: 1. PROACT 2.0 video, 2. the PROACT 2.0 digital questionnaire, and 3. standard QoL monitoring. All arms will last for 4 weeks.

Study burden and risks

A potential risk from this study is the potential for a data leak. To mitigate this risk, data will be pseudonymised and linked only by a trial ID.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Screening for participation in a phase 1-2 anticancer drug trials.
2. Written informed consent to participate in the study.

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 1-2 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2024
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	08-08-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-04-2024
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84155.041.23