Pilot study of the eHealth application *Cancer Patients Better Life Experience*

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To compare health-related quality of life, specifically fatigue, in melanoma patients treated with immunotherapy who use or do not use a patient-centered mobile coaching and monitoring system (CAPABLE). We expect that by using the CAPABLE eHealth...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON51454

Source
ToetsingOnline

Brief title
CAPABLE study

Condition

- Skin neoplasms malignant and unspecified

Synonym
melanoma skincancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Europese Unie (Horizon2020)

Intervention

Keyword: eHealth, immunotherapy, melanoma, quality of life

Outcome measures

Primary outcome

Main study parameters are the fatigue symptom scale of The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-core 30 (EORTC QLQ-C30). The EORTC QLQ-C30 is a self-reported questionnaire, specifically developed for patients with cancer who are receiving cancer treatment. The EORTC-QLQ- C30 is widely accepted and validated in clinical studies and is the most common quality of life instrument used in melanoma studies.

Secondary outcome

Feasibility

• Recruitment rate: number of included patients relative to the number of invited patients: recruitment rate will be calculated by the percentage of included patients compared to the total number of eligible patients contacted. An overall recruitment rate of 36 patients will be considered feasible.

• Patient compliance to the system will be evaluated by system interaction and data from the CAPABLE operational logs:

o Users* interactions logs;

o Component interaction data;

o Recommendations and messages generated by the system for the clinician and patient.

• Patient retainment: number of patients finishing the study: Patient

retainment will be calculated as the number of patients retained in the study for the full first three months as a percentage of the number of patients who started the study

Additional patient-reported outcomes (PROMs)

Secondary study parameters include outcomes of questionnaires regarding health-related quality of life outcomes, anxiety and depression, melanoma-specific HRQoL, immune-related adverse events and information needs in high risk and advanced melanoma patients treated with immune checkpoint-inhibitors.

* The EuroQoL-5D (EQ-5D-5L). The EQ-5D is a standardised 5-level, 5-dimensional multi-attribute utility questionnaire that measures mobility, self-care, usual activities, pain/discomfort and anxiety/depression, using a five dimension scale. This questionnaire is currently being used in the hospital according to clinical practice.

* Of the FACT-M, we use the Melanoma Subscale and the Melanoma Surgery Subscale, items specific to quality of life in melanoma patients. High scores show a high quality of life. Testing has shown that the FACT-M is a reliable and valid instrument to assess quality of life in patients with melanoma. This questionnaire is currently used in the hospital according to clinical practice.

* Psychological distress will be assessed with the Hospital Anxiety and Depression Scale (HADS). The HADS, a 14-item questionnaire, assesses symptoms of mood disturbance, yielding separate scale scores for anxiety and depression, as well as a total score. Numerous studies have applied the HADS to assess

distress among cancer survivors and the questionnaire has been validated for use in the Dutch population.

* Immunotherapy-specific questionnaire. In assessing quality of life in cancer patients, it is recommended to use a generic and cancer-specific measure of quality of life plus a treatment-specific questionnaire. However, to date the available validated measurements do not include the problems and symptoms of immunotherapy. Therefore, we identified, based on literature and expert opinion, 19 symptoms and created a symptom list based on items of the EORTC item Library [EORTC Item Library, qol.eortc.org/item-library].

* Fulfilment of information needs will be measured by the EORTC QLQ-INFO25 questionnaire. This validated 25-item questionnaire incorporates four information provision subscales: perceived receipt of information about the disease, medical tests, treatment and other care services.

Symptom monitoring

The severity of reported symptoms according to CTCAE v.5 grade. The number and severity will be collected from the EHRs and the CAPABLE system.

Additional secondary parameters

For the secondary objectives, data collected during the study:

o Data from the physician web application:

* Patient details entered at the time of enrolment;

* Patient-specific settings (which Virtual Capsules are available for this patient);

* Clinician*s responses to recommendations (accept or decline).

o Data from the patient app:

* Symptom reporting data;

* Patient*s selection of Virtual Capsules;

* Patient*s actions in the app and responses to prompts;

* Patient*s app preferences and settings;

o Sensor data collected using the ASUS smartwatch;

o From the EHR:

* Information on comorbidities

* Clinical data (disease, treatment details, adverse events);

* Medication prescriptions;

* Hospitalizations;

* Referrals to additional care;

Study description

Background summary

The most convincing data for web-based applications monitoring cancer patients, exists on patients receiving chemotherapy and less is known about symptom monitoring during immunotherapy. Melanoma patients treated with immune-checkpoint inhibitors have extensive needs for supportive care, information provision and symptom management, regardless of information and services already provided by the hospital. Patients believe that the use of eHealth applications, facilitating information gathering and symptom management, would increase their self-management skills, which would contribute to patients* autonomy. All of these were seen as positive drivers for quality of life. Therefore, we believe that more research is needed to explore the use and feasibility of eHealth applications in melanoma patients during immunotherapy. One example is a system like CAPABLE to support, monitor and coach cancer patients during systemic/ICIs treatment in order to maintain or improve quality of life (functioning and fatigue).

Previous pilot studies only focused on eHealth interventions affecting symptom monitoring. This study will introduce the more extensive CAPABLE eHealth tool: a clinical decision support system (DSS) dedicated to patients and healthcare professionals (HCPs). CAPABLE will support its users by providing evidence-based recommendations that are extracted from clinical practice guidelines and best practice knowledge, and formalised into computer interpretable guidelines (CIGs).The CAPABLE system serves three main goals for the patient: symptom monitoring, information needs fulfilment and interventions to improve mental- and physical wellbeing. These are available to the patient as a smartphone application that is connected to a smartwatch to monitor activity, blood pressure, sleep and heart rate. The CAPABLE system is accessible by healthcare professionals through a web application. They can closely follow up the patient and have access to all patient-reported outcomes and patient-generated data. The healthcare professionals involved in the present study include oncologists, nurse practitioners, psychologists and nutritionists. This study can therefore be considered as a first phase in exploring the use and feasibility and acceptability of this eHealth tool in melanoma patients treated with ICIs. Especially, in this study we will explore the effect of using CAPABLE on HRQoL outcomes as fatigue, physical- and role functioning, and patients* acceptability of using a system as CAPABLE.

Study objective

To compare health-related quality of life, specifically fatigue, in melanoma patients treated with immunotherapy who use or do not use a patient-centered mobile coaching and monitoring system (CAPABLE). We expect that by using the CAPABLE eHealth tool, patients' fatigue worsens less significantly (10 points) in the first 3 months of treatment than observed in usual care.

Study design

This is a prospectively enrolling, explorative cohort study in melanoma patients, eligible for treatment with ICI therapy. The explorative cohort receives the CAPABLE smartphone application and a multi-sensorial smartwatch. Patients will be asked to use the system for minimum of three to maximum of six months after enrolment. Figure 1 shows the timeline of the CAPABLE study. Questionnaires will be administered to the patients on baseline (T0) and every three months (T1 and T2). Quantitative user experience studies will be done at 3 months and at the end of the individual follow-up period with the CAPABLE system (T3). Outcomes of this study will be the exploration of changes in the health-related quality of life outcomes such as fatigue and physical- and role functioning in melanoma patients when using an eHealth tool during ICIs. Secondary, an explorative comparison with a historical cohort consisting of melanoma patients (P20MEL; NL75996.031.20) with the same inclusion criteria as this study population, but receiving standard care (e.g. without the CAPABLE app) will be done.

Study burden and risks

An extensive risk analysis is done, and added in the attached Data Protection Impact Assessment (DPIA). NKI*s Data Protection- and Security Officers approved the DPIA. Usage of an eHealth tool that monitors symptoms, provides information, and allows patients to work on their well-being from home can be experienced positively. However, a patient might find it too confronting to use the app after a while. Furthermore, it will take the patient time to fill in research-related questionnaires (3 times 30 minutes) and using the CAPABLE app.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* >18 years of age
* Sufficient understanding of the Dutch language
* Participants or their caregiver can use a smartphone (upon patient*s consent)
* Histologically confirmed melanoma (high-risk resectable stage III and stage IV and unresectable stage III) patients indicated to receive treatment with immune checkpoint-inhibitors, according to the clinical guidelines.

Exclusion criteria

Included in experimental clinical trial (with medication)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2023
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	CAPABLE
Registration:	No

Ethics review

Approved WMO Date:	28-12-2022
Application type:	First submission
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	NL81970.000.22