App Supported toxicity Surveilance using non-Invasive wearables during Systemic cancer Treatment.

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The objective of this study is to:1) explore the feasibility (recruitment, adherence, and absence of major technical problems) of using both medical-grade and consumer grade wearables for continuous measurement of physical activity, posture, balance...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON54204

Source
ToetsingOnline

Brief title
ASSIST

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
advanced melanoma, Head-neck cancer, non small cell lung cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cancer, Toxicity, Wearable technology

Outcome measures

Primary outcome

The main study endpoints relate to feasibility of study conduct and data collection, as well as to feasibility of a future full-scale study.

1) 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 60% at the end of the study will be considered sufficient feasibility.

2) Patient adherence to wear-time Fitbit and Corsano at the designated time periods: Patients will be asked to wear the Corsano and Fitbit 24 hours per day for 12 weeks. Adherence to the designated wear-time will be calculated through the number of hours data gathered compared to the expected amount of data per individual patient in percentages. The average percentage of this parameter provides an overall measure of adherence of the wear-time. We do not set an a-priori feasibility criterion in terms of % adherence, since one of the goals of the preliminary data analysis is to establish how much data is needed to generate potentially useful prediction models. This also applies to endpoints 3 and 4.

3) Technical feasibility of continuous measurements: percentage data loss and gap durations: Data loss may occur due to problems of uploading to the phone or measurement problems. We will compare gathered data in bytes with the expected amount of data corrected for loss data due wear-time and express this number for the individual patient in percentages.
Since the amount of acceptable data-loss is dependent, in part, on the possibility to deal with such missing data in the analysis, we do not set an a priori criterion for this outcome. However, extended data loss due to technical malfunction (i.e., Corsano or fitbit not transmitting data for an interval >4 hours, battery failure) should not happen more than once per patient during phase 1.
Gap duration will be calculated in time of the interval between continuous measurement points. The duration will be categorized in durations less than 15 minutes, less than 1 hour, or 4 hours or longer.

4) Patient retainment: number of patients finishing the study: Patient retainment will be calculated as 1) the number of patients retained in the study for the full 12 weeks as a percentage of the number of patients who started the study 2) the number of patients retained in the study until they have experienced an event, as a percentage of the number of patients who started the study.

5) PRO-CTCAE adherence rate: Compliance with weekly digital PROMS questionnaire is calculated by the number of completed questions on Castor. The

average value of this parameter provides an overall measure of compliance with online symptom monitoring over a period of 12 weeks. Feasibility is accepted when no individual patients fall below 70% adherence while still in the study.

Secondary outcome

1) Patient acceptance and experience. After the treatment period, subsequently included participants will be interviewed about their experiences with the use of Corsano and the Fitbit, and about their views about being continuously monitored during treatment. A short, structured interview guide will be prepared. The interview will be audio recorded. Recordings will be transcribed verbatim and qualitative analysis methods (i.e., coding and aggregating) will be applied to analyse the data using appropriate software for qualitative data analysis. Data collection will end once data saturation has been achieved (i.e., when no new viewpoints emerge), while keeping an eye on gender and diagnosis balance.

2) Usability Acceptability/satisfaction. Usability of both devices is assessed by the system usability scale (SUS) which is comprised of 10 statements, rated on a 5-point Likert scale, regarding the usability of an electronic device or platform. Based on previously published studies, a mean SUS score of 68 is chosen as cut point to determine the usability of the system.

3) Treatment-toxicity outcomes: number and grade according to CTCAE of all treatment related toxicity, number and nature of adverse events such as unplanned hospitalisation, unplanned adaptation of treatment plan, visits to

the ER, and admission to the ICU, including dates of occurrence. The PRO-CTCAE is a patient reported outcome (PRO) measurement system developed to evaluate symptomatic toxicity in patients on cancer clinical trials. It was designed to be used as a companion tot the Common Terminology Criteria for Adverse Events (CTCAE), the standard lexicon for adverse event reporting in cancer clinical trials. The questionnaire items evaluate the symptom attributes of frequency, severity, interference, amount and presence/absence. Each symptomatic adverse event is assessed by 1-3 attributes. PRO-CTCAE responses are scored from 0 to 4 (or 0/1 for absent/present). Specific items will be selected that apply to the three patient groups.

4) Health related quality of life outcomes: EORTC QLQ-C30 is a cancer specific, self-administered structured questionnaire designed for use in clinical trials. It contains 30 questions 24 of which are aggregated into 9 multi-item scales: 5 functioning scales (physical, role, cognitive [CF], emotional, and social); 3 symptom scales (fatigue, pain, and nausea and/or vomiting); and 1 global health-status scale. The remaining six single items assess symptoms of dyspnea, appetite loss (AP), sleep disturbance, constipation, diarrhea, and financial impact. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level. A high score for a functional scale represents a high / healthy level of functioning, a high score for the global health status / QoL represents a high QoL, but a high score for a

symptom scale / item represents a high level of symptomatology / problems.

5) Appropriateness of chosen time windows of monitoring using the wearables.

This endpoint will be measured at the end of the study comparing the toxicity

rate determined by the clinical specialist, compared to the toxicity determined

by the Kaiku-app .

6) Any action taken by the treating physician or nurse specialist in response

to toxicity.

Study description

Background summary

People treated for cancer are often exposed to highly toxic treatments. Treatment-induced toxicities can be dose-limiting, and can even be life-threatening. They can also lead to adverse events, including, for example, hospital admissions or emergency room visits.

Currently, the assessment of toxicity and functioning of patients is based on physician or nurse judgement, rather than on objective measurements, and is not performed in real time but during consultations. Recently it has been shown that routine monitoring of symptoms by self-report toxicity grading via a mobile app (and subsequent action) decreased adverse events, decreased the number of emergency room admissions, improved quality of life, and possibly even impacted positively on survival in patients with cancer. However, these patient-reported measures still reflect manifest toxicity, whereas the identification of subclinical signs of toxicity might be even more beneficial.

The current developments in wearable sensor technology enable continuous and extensive measurement of physiological functions and physical functioning. The rich data collected via wearables could provide valuable input for clinical prediction models for toxicity-related adverse events.
However, aside from challenges with data analysis, there are challenges related to feasibility and patient acceptance of data collection via wearables. These challenges may differ over different clinical populations, dependent not only

on the type of treatment and toxicity involved, but also on health literacy, technological readiness, age and socio-economic status. Before a larger study can be undertaken the feasibility of collecting high quality data using wearables must be established as well as patient experiences and acceptance.

Study objective

The objective of this study is to:

1) explore the feasibility (recruitment, adherence, and absence of major technical problems) of using both medical-grade and consumer grade wearables for continuous measurement of physical activity, posture, balance disturbances, and physiological parameters (heart rate, respiratory rate, skin temperature, and electrocardiogram), alongside web/app based PROMS for treatment specific toxicity during systemic cancer treatment with chemoradiation or immune therapy in three distinct clinical populations.

2) to explore patients experiences with and views about the use of wearable data and to correlate the collected wearable data to treatment toxicity outcomes and apply preliminary machine learning models

Study design

Prospective obsevational:

We will carry out a prospective study with patients receiving chemoradiation therapy for advanced head and neck cancer, immune therapy or targeted therapy for advanced melanoma who start treatment, and patients treated with chemo-radiation or chemo-immuno therapy for non-small cell lung cancer (NSCLC) at the Antoni van Leeuwenhoek or University Medical Centre of Utrecht. The study will be performed in two phases. First, we will enroll 10 patients for each diagnosis group. During this phase the main focus will be on early feasibility outcomes (recruitment, adherence, and absence of major technical problems, see 6.1 in C.1) (phase 1).
If these feasibility endpoints are met, we will upscale the study to include a total of 100 consecutive consenting patients (phase 2), to allow for collection of sufficient data for preliminary analysis of relationships of the sensor data with clinical outcomes.
In both phases, we will collect physiological and physical activity data using both medical-grade (Corsano) and consumer-grade (Fitbit) wearables. Each participant will wear both types of sensors, to enable direct comparisons. In addition, we will collect self-reported toxicity using a web-based survey (Castor). This data collection is based on patient reported translations of the common toxicity criteria for adverse events (PRO-CTCAE). We will also collect toxicity gradings as recorded in the medical files.

Study burden and risks

The risks associated with this study are negligible.

Missing data: Biosensor data could be missed due to patients forgetting/not being able to connect the Corsano bracelet to their phone. The software on the biosensor smartphone will send a notification to the main server when this happens. The researcher will check the data collection daily on the main server and contact the patients when data input is being missed. This daily checking of data input and contacting patients will also be done for the data collection of the Fitbit and Kaiku-app/Castor websurvey. Due to the remote nature of the wearables and applications, missing data can be easily spotted and addressed.

Privacy and data storage: The collected data by the wearables will be temporarily stored on the Google cloud Firebase on EU based servers. These are highly secured and conform to GDPR. We will make this explicit in the patient information.

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

- Patients with advanced head and neck cancer starting concurrent cisplatin-based chemo-radiation therapy or bioradiationtherapy
- Patients with stage III or stage IV melanoma who start with either immunotherapy (pembrolizumab, cemplimab, nivolumab (flatdose), ipilimumab - nivolumab). Or targeted therapy (dabrafenib-trametinib, encorafenib-binimetinib)
- Patients with locally advanced NSCLC stage III or NSCLC stage IV treated with low dose cisplatin and radiation therapy or treated with platinum-doublet chemotherapy with checkpoint inhibition.
- Sufficient mastery of the Dutch language
- Ambulatory without the use of walking aids
- Have an understanding, ability and willingness to fully comply with study procedures and restrictions
- > 18 years
- Ability to consent

Exclusion criteria

- Known history of heart-rhythm disorder
- Incapability of using digital devices
- Allergic to surgical steel or elastomer / rubber
- Permanent or temporary changes to the skin at locations where the sensors should be worn, (I.e., scar tissue) that might impact sensor performance

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2022
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	11-03-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-11-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-12-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-03-2023
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	NL79232.031.21