Development and evaluation of an online platform for advanced cancer patients who obtain durable response to immunotherapy or targeted therapy in co-creation with patients, psychologists and service providers.

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Developing and evaluating an online platform for stage 4 cancer patients with a durable response to immunotherapy or targeted therapy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Adjustment disorders (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON56652

Source
ToetsingOnline

Brief title
IMPRESS platform

Condition

- Adjustment disorders (incl subtypes)

Synonym
distress symptoms, Psychological distress

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: KWF Kankerfonds

Intervention

Keyword: Immunotherapy, Online platform, Psycho-oncology, Targeted therapy

Outcome measures

Primary outcome

The aim of this study is to develop and evaluate an online platform for advanced cancer patients who obtain durable response to IT or TT in co-creation with patients, psychologists and service providers. Endpoints will be studied in the evaluation phase.

We will examine the feasibility of the platform by assessing patients* usage of the platform during the first month they gained access to it. We will assess login frequency and activity on the platform using Google Analytics. Frequency refers to the number of visits per patient during the 1-month period of access to the platform. Activity refers to the number of opened ingredients (information, tasks, tests, videos) per patient. We will assess usability (i.e. the appropriateness of the platform to its purpose) via a self-reported outcome, the so-called System Usability Scale (SUS), which has often been used to assess the usability of websites and categorizes them as either poor, okay, good or excellent. This gives an indication of how easy to use and satisfactory the platform is and how likely patients are to return. Moreover, we will assess the extent to which the information and content by employing a custom made

questionnaire. This questionnaire will inquire about the coverage of essential topics relevant to patients within the platform.
We will track how many people who meet the eligibility criteria and are referred to the study by healthcare professionals and how many of them want to participate in the study and test the platform.

Qualitative semi-structured interviews will provide us with additional information about experiences of patients (and potentially of their close others) with using the platform, and if so, how it was helpful to them.

Secondary outcome

In order to examine the effects of utilizing the platform, participants will be required to fill out baseline and follow-up questionnaires related to their levels of anxiety, depressive symptoms, and resilience. Anxiety and depressive symptoms will be measured using the Hospital Anxiety and Depression Scale, containing 14 items. Resilience will be measured with the Brief Resilience Scale, which consists of 6 items exploring the extent to which patients in general quickly recover from adverse events.

Study description

Background summary

Getting a diagnosis of advanced melanoma or advanced lung cancer can have a huge impact on everyday life. First, patients are told that the cancer is (most likely) incurable. Then immunotherapy or targeted therapy appears to be successful, extending life for an unknown period of time. We do know that the resilience of these patients is repeatedly challenged. The confrontation with a poor prognosis, followed by the news of treatment options that can prolong

their life for an uncertain amount of time can be a lot to take in. They need to adjust to a new way of life in which death is a continuous threat, while being repeatedly confronted with uncertainties and other stressors. Several effective psychological therapies are available for cancer patients suffering from psychopathology. But can we also support this specific group of patients early in their medical treatment to deal with the continuously present stressors? We aim to offer this group of patients psychological support early in their medical treatment through an online platform in which feelings are normalized and acknowledged and practical tools are offered.

Study objective

Developing and evaluating an online platform for stage 4 cancer patients with a durable response to immunotherapy or targeted therapy.

Study design

In the development-phase (stage 3), we will make use of an observational cohort study design. Data will be collected through think-aloud and semi-structured interviews with 12 participants. As user feedback is gained, changes can be made to the online platform and then further interviews can be conducted to check whether the changes made are suitable. The development phase is therefore best viewed as an iterative cycle moving between user feedback and changes to the online platform.

In the evaluation-phase (stage 4), we will use a pre-post intervention design. Data will be collected through questionnaires and interviews with respectively 45 and 15 participants. These participants did not take part in the development-phase.

Study burden and risks

- Participation will cost time:
• Participating in the development phase will cost patients at least 130 minutes, excluding time they will spent using the platform (questionnaire: 10 minutes; Think-aloud interview: maximum 60 minutes; use prototype; interview about experiences with prototype: maximum 30 minutes each time).
• Participating in the evaluation phase will cost patients approximately 40 minutes, excluding time they will spent using the platform (baseline questionnaire: 20 minutes; use platform; follow-up questionnaire: 20 minutes; and for 15 out of 45 participants an interview about experiences with platform: maximum of 60 minutes).
- Although the use of the platform can give patients insight into their situation, recognize and normalize possible difficulties and provide tools on how to deal with the challenges, it is possible that this can evoke emotions. For this reason, participants receive instructions to contact their healthcare

provider and a phone number of the researcher is provided in the invitation letter and the questionnaire to discuss how/where the participant can receive appropriate care.

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 are diagnosed with stage IV cancer with confirmed response to or long-term stable disease while on immunotherapy or targeted therapy.
We consider a response confirmed after the second scan shows that patients respond well (i.e. RECIST at least partial response or >1 year of stable disease) to one of both therapies.

Exclusion criteria

- <18 years of age;
- not able to sufficiently use and understand the Dutch language;
- have no internet access.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2024
Enrollment:	57
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	19-03-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-11-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL85889.028.23