

# IMPRESS: predictors of daily life resilience in advanced cancer patients

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1) To identify factors that predict resilient functioning.2) To study whether (in line with Fredrickson's broaden & built theory) the ability to experience positive emotions in response to a pleasant event predicts few psychosocial...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric and behavioural symptoms NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON54145

### Source

ToetsingOnline

### Brief title

IMPRESS

### Condition

- Psychiatric and behavioural symptoms NEC

### 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:** Experience Sampling Method, Immunotherapy and Targeted Therapy, Metastatic Cancer, Psychological Resilience

## Outcome measures

### Primary outcome

A week before participants start with ESM, they will complete several baseline questionnaires. During a two-week period participants are asked to complete ESM eight times per day via an app on their phone. Positive affect, negative affect, daily life events, predictors (i.e. fatigue, pain, emotion regulation and coping), and contextual predictors (i.e. location and company) will be measured in these ESM items. Analyses will be conducted separately for two resilience outcomes (recovery and reward experience). For each model, potential predictors (baseline predictors, momentary predictors, contextual predictors) will be entered as moderators.

### Secondary outcome

The secondary objective in this study is to explore whether reward response despite adversity (i.e. advanced cancer diagnosis) predicts low psychosocial distress (symptoms of depression and anxiety) and more illness acceptance, tolerance of uncertainty, mindfulness, optimism and perceived social support a year after measuring resilience in daily life. To explore this, participants will complete a follow-up questionnaire approximately a year after completing the ESM items. This questionnaire contains items about psychosocial distress, illness acceptance, tolerance of uncertainty, mindfulness, optimism, and perceived social support.

# 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 to handle these continuing stressors and potentially prevent psychopathology? Improving patients\* resilience will offer a valuable first step in patients\* mental healthcare.

## Study objective

- 1) To identify factors that predict resilient functioning.
- 2) To study whether (in line with Fredrickson's broaden & built theory) the ability to experience positive emotions in response to a pleasant event predicts few psychosocial complaints, more acceptance of illness, more experienced social support, more optimism, more mindfulness and more uncertainty tolerance one year after measuring resilience in long-term responders.

## Study design

For this intensive longitudinal observational study we will gather quantitative data using Experience Sampling Method (ESM).

## Study burden and risks

Participating in the study could provide insight for participants in what factors help them to function resiliently. By participating, patients are able to help future patients to function resiliently. Potential burden is that it costs participants quite some time (approximately five hours in total). Additionally, the information and ESM items could evoke emotions for some participants. Therefore, participants will be provided with the researcher\*s contact details, with whom they can discuss where and how they can receive appropriate care in case necessary.

## Contacts

### Public

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Nijmegen 6541ZT  
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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- diagnosed with stage IV melanoma with confirmed response to or long-term stable disease while on immunotherapy;
- or stage IV lung 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 smartphone or internet access.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 18-01-2022

Enrollment: 70

Type: Actual

## Ethics review

Approved WMO

Date: 03-12-2021

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 21-03-2023

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	NL78416.028.21

## Study results

Date completed:	17-02-2024
Actual enrolment:	70