

# Fear of progression in advanced cancer patients with prolonged survival on ongoing cancer treatment in an era of personalized medicine

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The aim of this study is to investigate the concept of fear of progression among advanced incurable cancer patients on ongoing systemic treatment.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Metastases
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON51095

### Source

ToetsingOnline

### Brief title

PERSPECTIVES

### Condition

- Metastases
- Anxiety disorders and symptoms

### Synonym

Advanced cancer, fear (of progression), psychosocial wellbeing

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum

**Source(s) of monetary or material Support:** KWF

## **Intervention**

**Keyword:** Advanced cancer, Fear of progression, Psycho-oncology

## **Outcome measures**

### **Primary outcome**

Fear of progression

### **Secondary outcome**

Uncertainty

## **Study description**

### **Background summary**

Fear of progression (FoP) can be described as a reactive, consciously perceived fear that develops from a serious, potential life-threatening or disabling disease or its treatment. Dealing with this fear of cancer spreading is reported as one of the most common unmet needs for help among patients. This fear manifests itself along a continuum ranging from an appropriate, adequate response to a clinical problem. It is characterized by chronic worry, excessive body checking and/or seeking of medical reassurance, avoidance of cancer reminders, intrusive thoughts and images about progression, and future planning difficulties. Elevated levels of FoP that become a serious problem, i.e., affecting treatment adherence, quality of life or social functioning, are in need for treatment. Until now, FoP research in oncology has largely been limited to those who have been curatively treated with conventional cancer therapies. Hardly any research on fear is done in the growing group of advanced cancer patients who are on ongoing cancer treatment, like targeted therapies or immunotherapy, also including patients who are confronted with a rare cancer. FoP is assumed to be different between advanced cancer patients and cancer survivors. Iatrogenic factors that are associated with novel therapies are assumed to contribute to FoP. More specifically, the extended treatment duration and the monitoring for signs of progression associated with evaluation of treatment effects, such as imaging, biomarkers and liquid biopsies during novel therapies, as well as the increased availability of information to predict individual treatment response or risk of recurrence, are hypothesized to contribute to high FoP and may contribute to growing numbers of patients being vulnerable to FoP in future decades.

Until now, no research on FoP has been done in the growing group of incurable patients with advanced cancer on ongoing treatment. In order to help patients suffering from elevated levels of FoP, main tasks in research on FoP in this population are: 1) to investigate, adapt and elaborate on the definition and measurement of clinical levels of FoP; 2) to better understand the relevance of illness-related and intrapersonal as well as interpersonal factors for high FoP. With more knowledge on these topics further development, elaboration and evaluation of psychological treatments for clinical FoP will be possible.

### **Study objective**

The aim of this study is to investigate the concept of fear of progression among advanced incurable cancer patients on ongoing systemic treatment.

### **Study design**

A longitudinal observational study with an estimated 200 patients filling in monthly (digital) assessments on FoP during one year.

### **Study burden and risks**

The burden for patients mainly consists of the time it takes to fill in the questionnaires, and possible emotional burden of sharing their personal experiences with these questionnaires. If patients experience prolonging emotional distress as a consequence, they will be offered a consult with one of the psychologistst from the Medical Psychology department of Radboudumc.

## **Contacts**

### **Public**

Selecteer

Reinier Postlaan 4  
Nijmegen 6525GC  
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### **Scientific**

Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Adult patients with any type of advanced/metastasized/incurable cancer;
- Receiving (ongoing) palliative systemic treatment (chemotherapy, hormonal therapy, targeted therapy, immunotherapy);
- Prognosis > 12 months;
- Able to fill in digital questionnaires;
- Sufficient command of Dutch language.

### Exclusion criteria

- The inability to give informed consent;
- Too ill to participate;
- Concurrent participation in another questionnaire study on quality of life/psychological functioning.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 09-12-2021  
Enrollment: 200  
Type: Actual

## Ethics review

Approved WMO  
Date: 22-07-2021  
Application type: First submission  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO  
Date: 18-08-2021  
Application type: Amendment  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO  
Date: 29-09-2021  
Application type: Amendment  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO  
Date: 12-01-2022  
Application type: Amendment  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO  
Date: 11-04-2022  
Application type: Amendment  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL77208.091.21