

# Mechanisms explaining psychological Distress In CErvical cancer patients and partners (DICE): a population-based prospective study

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1. What is the level of psychological distress among cervical cancer patients over time?2. What is the role of characteristics of the individual, characteristics of the environment, biological function, overall quality of life, functional status and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive neoplasms female malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON54494

### Source

ToetsingOnline

### Brief title

DICE

### Condition

- Reproductive neoplasms female malignant and unspecified
- Cervix disorders (excl infections and inflammations)

### Synonym

cervical cancer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit van Tilburg

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

## Intervention

**Keyword:** cervical cancer, observational study, psychological distress

## Outcome measures

### Primary outcome

psychological distress

### Secondary outcome

Characteristics of the individual, characteristics of the environment, biological function, overall quality of life, symptoms, functional status, and general health perceptions.

## Study description

### Background summary

A growing number of cervical cancer patients live years beyond their cancer diagnosis and ultimately survive their disease. Cervical cancer patients report higher levels of psychological distress compared to other (gynecological) cancer types, resulting in physical and psychosocial limitations. The mechanisms explaining why some patients do, and others do not experience persistent psychological distress after cervical cancer remain unclear.

### Study objective

1. What is the level of psychological distress among cervical cancer patients over time?
2. What is the role of characteristics of the individual, characteristics of the environment, biological function, overall quality of life, functional status and general health perceptions, in explaining psychological distress among cervical cancer patients?
3. What is the impact of cervical cancer on distress of partners of patients?

## Study design

This observational study is a population-based study in which we include cervical cancer patients and their partners shortly after diagnosis and follow them until 10 years after diagnosis. The patients and their partners are asked to complete questionnaires directly after diagnosis, after 6 months, and after 1, 2, 5 and 10 years. Moreover, patients are asked to wear a Fitbit at 6, 12 and 24 months after diagnosis. Patients who complete the questionnaire online, are additionally asked to complete an online nutrition diary \*De Eetmeter\*. In a subsample additional measurements will be executed. These measurements will include; drawing blood and analysing a hair sample.

## Study burden and risks

The burden of this study is the completion of the questionnaires, which takes about 30 to 60 minutes and wearing a Fitbit. For the subsample, the additional burden is to draw blood and to take a hair sample.

## Contacts

### Public

Universiteit van Tilburg

Warandelaan 2  
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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Newly diagnosed with stage I-III cervical cancer
- Being at least 18 years of age.

### Exclusion criteria

- Cognitive impairment
- Not able to read or write Dutch.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-11-2020

Enrollment: 520

Type: Actual

## Ethics review

Approved WMO

Date:	01-03-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	07-10-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	31-10-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	23-12-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	11-03-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	22-07-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	20-10-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	30-11-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	28-04-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	04-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	20-07-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	04-03-2024
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	NL67509.028.18