# Treating fear of cancer recurrence in primary care

No registrations found.

**Ethical review** Positive opinion **Status** Recruiting

Health condition type -

**Study type** Interventional

# **Summary**

#### ID

NL-OMON24438

Source

NTR

**Brief title** 

**BLANKET** 

**Health condition** 

Fear of cancer recurrence

## **Sponsors and support**

**Primary sponsor:** Helen Dowling Institute

Source(s) of monetary or material Support: KWF

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

Severity of fear of cancer recurrence, as measured by the severity scale of the FCRI-NL

#### **Secondary outcome**

FCR-related distress, healthcare uptake, healthcare costs

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# **Study description**

#### **Background summary**

Many successfully treated cancer patients suffer from fear of cancer recurrence (FCR), affecting their quality of life and their physical, emotional, cognitive and social functioning. Effective psychological interventions for FCR exist, but are not widely available, as they are usually exclusively offered by specialized psycho-oncology professionals and institutes. Concurrently, the role of primary care in cancer and survivorship care is increasing. Therefore, there could be a role for general practitioners (GP) and mental health workers (MHW) working in primary care in supporting patients with FCR. In the current study the effectiveness of a primary care delivered FCR intervention will be evaluated, using a cluster randomized trial. The primary outcome will be FCR severity; secondary outcomes will be FCR-related distress, healthcare uptake and healthcare costs. Participating primary care practices will be stratified by size and socio-economic status and randomly placed in the intervention or the control arm. In the control arm, practices will provide care as usual. In the intervention arm, practices will offer a cognitive behavioural FCR intervention.

#### **Study objective**

Severity of fear of cancer recurrence (FCR) will reduce more with the current intervention than with usual care

#### Study design

baseline, 3 months after baseline, 12 months after baseline

#### Intervention

Primary care FCR intervention

## **Contacts**

#### **Public**

Helen Dowling Instituut & UMC Utrecht Yvonne Luigies

0644923480

#### Scientific

Helen Dowling Instituut & UMC Utrecht Yvonne Luigies

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# **Eligibility criteria**

#### Inclusion criteria

Being registered at a general practice that is participating in the study; Being 18 years or older; Having finished successful curative cancer treatment between 3 months and 10 years ago; Desiring support for FCR; Having sufficient Dutch reading and writing skills.

### **Exclusion criteria**

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# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Double blinded (masking used)

Control: Active

#### Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 15-04-2019

Enrollment: 244

Type: Anticipated

## **IPD** sharing statement

Plan to share IPD: No

# **Ethics review**

Positive opinion

Date: 25-02-2019

Application type: First submission

# **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

NTR-new NL7573

Other METC Utrecht: METC 18/879

# **Study results**