BLANKET: Treating fear of cancer recurrence in primary care

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Ethical review	Approved WMO
Status	Completed
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON49012

Source
ToetsingOnline

Brief title
BLANKET

Condition

- Anxiety disorders and symptoms

Synonym
Fear of cancer recurrence

Research involving
Human

Sponsors and support

Primary sponsor: Helen Dowling Instituut
Source(s) of monetary or material Support: KWF

Intervention

Keyword: fear of cancer recurrence, mental health worker, primary care, psycho-oncology

Outcome measures

Primary outcome

The main parameter is the decrease in FCR severity as measured by the FCRI severity scale, between baseline and T1 (three months after baseline).

Secondary outcome

Secondary parameters are difference in distress, FCR health care use and costs, usual care, and satisfaction of patients and practitioners with the intervention.

Study description

Background summary

One third of successfully treated cancer patients suffer from fear of cancer recurrence (FCR). Effective treatments exist, but are not widely available. At the same time, the role of primary care in cancer care and survivorship care is increasing. Therefore, general practitioners (GP) and mental health workers (MHW) working in primary care could play a role in supporting patients with FCR.

Study objective

The primary objective of the study is to measure the effect of a primary care intervention for fear of cancer recurrence (FCR), on the severity of FCR of patients who desire support for FCR, as compared to care as usual. Secondary objectives are to measure the effect of a primary care intervention for FCR, on FCR-related distress, healthcare use and healthcare costs. Furthermore we will qualitatively analyse the experience of patients, trained mental health workers (MHW; in Dutch: POH-GGZ) and general practitioners (GP) with the FCR intervention, and describe usual care for patients with FCR.

Study design

The BLANKET-study is a cluster randomized trial. GP practices will be invited to participate in the study. Participating practices will be stratified by practice characteristics and randomly placed in the intervention or the control arm. In the intervention arm, practices will offer the FCR intervention; in the control group, practices will provide care as usual.
Patients will be recruited through their GPs. Practices participating in the study will send an invitation letter to patients registered at their practice, who were curatively treated for cancer. Patients will be invited in rounds, starting with those who most recently finished curative treatment. Patients who desire support for FCR are asked to participate. After filling out the baseline questionnaires, they visit the GP for a consultation on FCR support. Patients also fill out questionnaires 3 months (T1) and 12 months (T2) after the baseline. In addition, qualitative interviews are held after 3 months with a selection of participants and data is collected from patients* Electronic Health Records (EHR).

Intervention

In the intervention group, patients receive the FCR intervention. This intervention follows a protocol that consists of five sessions with the MHW, which focus on psycho-education, normalization and self-management. The sessions are supported by intervention materials, which are available online or on paper. The control group receives care as usual.

Study burden and risks

During the study, all patients fill out questionnaires three times at home (20 min each time). After the first questionnaire, patients are invited for an intake with their GP about FCR care. In the intervention group, care will include 5 sessions with the MHW, following a protocol. After three months, some patients are invited for voluntary participation in qualitative interviews with the researcher about the FCR intervention.

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

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

Exclusion criteria

Exclusion criteria for general practitioners (GP) and mental health workers (MHW):
In some cases there are complex clusters where, for example, one GP works in two practices, and a MHW in one of those practices works in a third practice, as well. In these cases the practice where both the GP and the MHW work is excluded to prevent contamination.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-04-2019
Enrollment:	244
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-07-2019
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	25-07-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-09-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL66988.041.18

Study results

Date completed:	24-01-2023
Results posted:	27-10-2023
Actual enrolment:	235

First publication
27-10-2023