Effect evaluation of Oncokompas 2.0.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28918

Source
NTR

Brief title
-

Health condition

Cancer, cancer survivors
Kanker

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: KWF Kankerbestrijding, Alpe d'HuZes

Intervention

Outcome measures

Primary outcome

Patient Activation Measure (PAM)

Secondary outcome

Self efficacy, patient empowerment, need for supportive care, mental adjustment to cancer, health related QoL, costs

Study description

Background summary

Background: Cancer survivors have to deal with a wide range of physical symptoms and psychological, social, and existential concerns related to cancer and its treatment. Supportive care in cancer addresses survivors' symptoms and concerns. Oncokompas2.0 was developed to meet cancer survivors' individual supportive care needs. A RCT will be conducted to determine the reach, efficacy and cost-utility of Oncokompas2.0 as a self-management application in cancer survivors.

Methods/design: Adult patients diagnosed with breast, colorectal, head and neck cancer or lymphoma, who have been 3 months – 5 year after curative treatment will be included. In total 544 cancer survivors are randomly assigned to the intervention group or a waiting list control group. Primary outcome measures are patient empowerment and self-efficacy. Secondary outcomes include need for supportive care, mental adjustment to cancer, QOL, and costs. Questionnaires will be administered at baseline, 1 week post-intervention, and at 3, 6, and 12 months follow-up. Participants in the control group get access to Oncokompas2.0 after 6 months.

Discussion: This study evaluates the reach, efficacy, cost-utility of Oncokompas2.0 among cancer survivors. Evaluation of Oncokompas2.0 will take place using the RE-AIM framework.

Study objective

The use of Oncokompas2.0 will be superior to care as usual regarding self-efficacy, patient empowerment and costs.

Study design

T4 – 12 months follow-up

Intervention

Access to Oncokompas 2.0.

Contacts

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Eligibility criteria

Inclusion criteria

Patients diagnosed with breast, colorectal, head and neck cancer or lymphoma, age ≥ 18 years (no upper limit), 3 months – 5 years after treatment with curative intent (all treatment modalities) and with accessibility to the internet.

Exclusion criteria

Severe cognitive impairment, insufficient mastery of Dutch language, or insufficient basic internet skills.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	544
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL4910
NTR-old	NTR5774
Other	METc VUmc : 2015.523

Study results

Summary results
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