Effect evaluation online application Oncokompas for partners

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23995

Source
Nationaal Trial Register

Brief title
-

Health condition

informal caregiver, incurable cancer

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Caregiver Strain Index +

Secondary outcome

General Self-Efficacy, health related quality of life, costs

Study description

Background summary

Background: In the Netherlands more than 100.000 patients are diagnosed with cancer and 45.000 patients die of cancer each year. Cancer not only affects patients, it also has impact on their partners, family members, and other people around them. Partners often help patients with personal care and provide practical and emotional and support to patients. Although caring for a loved one can be rewarding, informal caregiving responsibilities are also associated with physical, emotional, social and financial difficulties. Nowadays, cancer is increasingly recognized as a chronic illness, which challenges partners of cancer patients to manage the patient's and their own care and quality of life to an increasing extent of time. To support partners in monitoring their quality of life and finding optimal supportive care, we extended the existing eHealth self-management application "Oncokompas". Oncokompas could help partners of patients with incurable cancer to identify their unmet needs and take actions to meet these needs. This will help partners to be more effective in managing the care of their loved one, with less negative consequences for their own health and quality of life.

Methods: A monocenter prospective randomized controlled trial with two parallel groups will be carried out. Partners will be randomly assigned to the intervention group (direct access to Oncokompas), or the control group (a waiting list condition of 3 months) which receives care as usual. The control group will have access to Oncokompas 3 months after randomization. 136 partners of patients with incurable cancer (who no longer have curative treatment options and face a prognosis of at least 3 months), will be included. Participants will be asked to complete a questionnaire at the time of inclusion (t0), 2 weeks after randomization (t1) and at 3 months follow-up (t2). The primary outcome is caregiver burden. Secondary outcomes are general self-efficacy and health-related quality of life. To investigate the cost-utility we will use different cost questionnaires. Partners randomized in the control group will have access to Oncokompas after 3 months.

Study objective

The main hypothesis is that use of Oncokompas will be superior to care as usual to reduce caregiver burden and to improve self-efficacy and quality of life, and it is expected that Oncokompas will improve quality-adjusted life years (QALYs) at acceptable costs compared to care-as-usual.

Study design

T0 - baseline

T1 - 2 weeks follow-up

T2 - 3 months follow-up

Intervention

Access to the eHealth self-management application Oncokomas

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• Partner of a patient with incurable cancer (no curative treatment options, but not yet in the last phase of their life)

• Have access to the internet and have an e-mail address

• Age of 18 years and older

Exclusion criteria

• Severe cognitive impairments

• Psychotic behavior (delusions and hallucinations)

• Poor understanding of the Dutch language (and thereby not able to complete a Dutch questionnaire)

• Not willing to participate

• No informed consent

• Partners who have had cancer themselves and used Oncokompas as a patient

• Partners whose partner with cancer participates in the RCT to determine the efficacy and

cost-utility of Oncokompas among patients with incurable cancer

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	136
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-11-2018
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	NL7411
NTR-old	NTR7636
Other	: 2018.517 METc VUmc

Study results

Summary results

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