Efficacy and cost-utility of eHealth application 'Oncokompas' for patients with incurable cancer.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48895

Source
ToetsingOnline

Brief title
Effect evaluation of online application Oncokompas

Condition

- Other condition

Synonym
cancer, malignancies

Health condition

oncologische aandoeningen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: effect evaluation, Oncokompas, palliative care, self-management

Outcome measures

Primary outcome

The primary outcome measue is patient activation (PAM).

Secondary outcome

Secondary outcomes are general self-efficacy (GSE), quality of life (EORTC

QLQ-C15-PAL). To investigate the cost-utility we will use different cost

questionnaires (iMCQ and iPCQ) and the EQ-5D.

Study description

Background summary

Each year over 40.000 patients die of cancer. Although discussing palliative care options improves quality of life in patients, this often often occurs at a late stage of the advanced cancer trajectory. Nowadays it is expected that patients adopt an active role in the management of their own care to improve the access to palliative care. Since the past decades there is a growing interest in self-management and eHealth as means to improve (the access to) care. Research has shown that patients benefit from self-management interventions in terms of patient activation and self-efficacy. An eHealth self-management application monitoring the quality of life and providing personalized advice and guidance to palliative care services, could be a solution to meet the palliative care needs of individual patients with incurable cancer.

Study objective

The goal of this study is to investigate the efficacy and cost-utility of Oncokompas among patients with incurable cancer compared to care-as-usual.

The main hypothesis is that use of Oncokompas will be superior to care as usual to improve patient activation, 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.

Furthermore, a qualitative follow-up study (PAMQOL-study) will be conducted to explore to which extent patients feel activated by using the online self-management tool Oncokompas and which role they think Oncokompas plays in their health-related activities.

Study design

A monocenter prospective randomized controlled trial with two parallel groups. Patients are randomly assigned to either the intervention condition, direct access to Oncokompas, or the waiting list condition receiving care-as-usual.

The PAMQOL-study will be a qualitative study among patients who participated in the RCT and gave their consent that they could be approached for follow-up research regarding Oncokompas.

Intervention

The intervention investigated in this study is the online self-management application Oncokompas. Oncokompas is an integrated eHealth self-management application to monitor the different domains of quality of life and to provide personalized information on quality of life to patients. Oncokompas supports patients in finding optimal supportive care, adjusted to their quality of life and personal preferences.

In this study, care-as-usual is defined as care provided by the oncological team or by other health care professionals and includes all medical and supportive care that patients receive regardless of their participation in this study.

Study burden and risks

The main burden for participants is to fill in the questionnaires for the study. Participants will be asked to fill in questionnaires at three moments in time. Patients in the intervention group will also spend time on using Oncokompas.

Risks are negligible. In case of positive results, participating patients will probably benefit immediately from the online self-management application.

The interviews of the PAMQOL-study will take up to an hour of the participants'

time to minimize the burden for participants.

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

Inclusion criteria of the RCT:
- Incurable cancer; no curative treatment options;
- A prognosis of at least 3 months;
- Awareness of the incurability of the cancer.

Additional criteria of the PAMQOL-study:
For the qualitative study additional inclusion criteria are that a patient must have completed the RCT and gave his/her permission on the informed consent form

of the RCT that he/she could be approached for the follow-up study.

Exclusion criteria

- Not having access to the internet and not having an e-mail address;
- Severe cognitive impairments;
- Psychotic behaviour (delusions and hallucinations);
- Poor understanding of the Dutch language (and thereby not able to complete a Dutch questionnaire);
- Younger than 18 years;
- Patients too ill to participate;
- Not willing to participate;
- No informed consent;
- Patients who participated in the randomized controlled trial of the ICT4CANCER project (as a cancer survivor), but who are now diagnosed with incurable cancer;
- E-mail address of patient is already registered in Oncokompas (this means that this patient is familiar with using Oncokompas);
- Patients of which their physician/nurse thinks participation in another study will be too much of a burden.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2019
Enrollment:	136
Type:	Actual

Medical products/devices used

Generic name:	eHealth self-management application Oncokompas
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL66307.029.18