Effect evaluation of the online application Oncokompas.

Gepubliceerd: 24-09-2018 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22607

Bron
NTR

Verkorte titel
-

Aandoening

Incurable cancer, cancer, cancer patients

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient Activation Measure (PAM)

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Each year over 40.000 patients die of cancer. Although discussing palliative care options in time significantly improves quality of life of patients, this often occurs at a late stage of the advanced cancer trajectory. Patients with incurable cancer often have unmet informational and care needs and are uncertain where they can go for advice and guidance. 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 shows 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.

Methods: A monocenter prospective randomized controlled trial with two parallel groups will be conducted. Patients are randomly assigned to either the intervention condition, direct access to Oncokompas, or the waiting list condition receiving care-as-usual. 136 adult patients with incurable cancer (lung cancer, breast cancer, colorectal cancer, head and neck cancer, lymphoma or glioma), 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 patient activation (PAM). Secondary outcomes are general self-efficacy (GSE) and 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. Patients randomized into the control group will have access to Oncokompas after 3 months.

Doel van het onderzoek

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.

Onderzoeksopzet

T0 - baseline

T1 - 2 week follow-up

T2 - 3 months follow-up

Onderzoeksproduct en/of interventie

Access to the eHealth self-management application Oncokompas.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Incurable cancer; no curative treatment options;

- Diagnosed with lung cancer, breast cancer, colorectal cancer, head and neck cancer, lymphoma or glioma;

- A prognosis of at least 3 months;

- Awareness of the incurability of the cancer.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not having access to the internet and not having an e-mail address;

- Severe cognitive impairments;

- Psychotic behavior (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 a patient is familiar with using Oncokompas);

- A patient of which his/her physician thinks participation in another study will be too much of a burden for this particular patient (because this patient is also participating in other studies).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	136
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7285
NTR-old	NTR7494
Ander register	METc VUmc : 2018.224

Resultaten

Samenvatting resultaten

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