

Eigen regie van mensen met gevorderde kanker en hun naasten: het Leven met Kanker programma

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We hypothesise that the Living with Cancer programme will improve the wellbeing of patients with advanced cancer and their relatives, through improving their self-efficacy and self-management behaviours.

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

Samenvatting

ID

NL-OMON24393

Bron

NTR

Verkorte titel

The SMART study

Aandoening

Advanced cancer

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: Dutch Research Council (NWO, VIDI)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

This is a mixed-methods study. Various quantitative and qualitative measures will be used to evaluate the effect of and experiences with the programme. Quantitative measures include: self-management behaviours (primary outcome), self-efficacy, quality of life, pain, fatigue, depression, anxiety, loneliness, and healthcare utilization. Qualitative measures include: experiences of participants regarding the content, value and working mechanism of the programme.

Toelichting onderzoek

Achtergrond van het onderzoek

Background

It is known that patients with advanced cancer need to deal with considerable emotional, psychosocial and lifestyle consequences of their disease and its treatment. Most of the time, patients, together with their relatives, need to manage a huge part of their care and lives themselves, at home. This can be highly complex and many are unprepared to do this. Interventions to support patients and their relatives in their self-management have barely been developed and studied. Therefore, we developed an online self-management support programme for patients with advanced cancer and their relatives. The acceptability and feasibility of this online self-management support programme for patients with advanced cancer and their relatives were assessed and confirmed in the SMART pilot study with 12 participants.

Study design

The programme will be offered through a non-randomized stepped wedge design, with outcomes evaluated at baseline, after 8 weeks and after 16 weeks. In addition qualitative measures, including logbooks and recording of the meetings will be evaluated.

Population

The study population consists of patients with advanced cancer (defined as having no curative treatment options available) and their relatives.

Doel van het onderzoek

We hypothesize that the Living with Cancer programme will improve the wellbeing of patients with advanced cancer and their relatives, through improving their self-efficacy and self-management behaviours.

Onderzoeksopzet

- At baseline (T0)
- 8 weeks after baseline (T1)
- 16 weeks after baseline (T2)

Onderzoeksproduct en/of interventie

The online Living with Cancer programme is a peer-led self-management programme designed to support patients with advanced cancer and their relatives in their confidence and skills to better manage the consequences of the illness. The programme consists of six 1,5 hour video-based group meetings of 8 to 12 participants. Two peer-facilitators facilitate the meetings of the programme; there is also one person available for technical support. Essential information of the themes as discussed in the programme will be provided in short audio clips with supported text, to allow participants to prepare for the meetings. Essential information (principles or explanations about a theme) of the themes will be given in short audio clips with supported text. Participants will be invited to watch these before each meeting, to prepare. In addition, participants will receive a digital syllabus. The meetings will support participants in developing their self-management skills: action-planning, problem-solving, effective communication and decision-making. The meetings address relevant themes such as dealing with fatigue, dealing with emotion, living with uncertainty and adapting lifestyle. An important component of the programme is self-tailoring, which means that participants can decide which problems they want to focus on. The primary aim of the meetings is that participants share their experiences and best practices in brainstorm and support each other. Participants will receive a syllabus for additional readings. The programme will be facilitated by 2 facilitators. They will introduce the themes and start the conversations. There will be a moderator available, who is responsible for technical support.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients

- Having advanced cancer (defined as having no curative treatment options available)
- Access to a computer or laptop
- Internet access

Relatives

- Relative of a patient with advanced cancer
- Access to a computer or laptop
- Internet access

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients and relatives

- Younger than 18 years of age
- Unable to provide consent
- Unable to read and speak the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	20-10-2021
Aantal proefpersonen:	162
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 20-10-2021

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	NL9806
Ander register	METC Erasmus MC : MEC-2021-0347

Resultaten