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

No registrations found.

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

Summary

ID

NL-OMON24393

Source
NTR

Brief title
The SMART study

Health condition

Advanced cancer

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Dutch Research Council (NWO, VIDI)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

See Primary outcome

Study description

Background summary

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 addtion 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.

Study objective

We hypothesis 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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2021
Enrollment:	162
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	20-10-2021
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	NL9806
Other	METC Erasmus MC : MEC-2021-0347

Study results