

Self-management of persons with advanced cancer and their relatives (SMART): the Living with Cancer Programme

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To evaluate the effectiveness of a peer-led, video-based self-management support programme for patients with advanced cancer and their relatives. The programme aims to improve the wellbeing of patients with advanced cancer and their relatives,...

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51125

Source

ToetsingOnline

Brief title

The SMART study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

Advanced cancer and relatives

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: NWO;VIDI vernieuwingsimpuls

Intervention

Keyword: Advanced cancer, Peer-support, Relatives, Self-management

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 study parameter/outcome of the study.

Study description

Background summary

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 objective

To evaluate the effectiveness of a peer-led, video-based self-management support programme for patients with advanced cancer and their relatives. The programme aims to improve the wellbeing of patients with advanced cancer and their relatives, through improving their self-efficacy and self-management behaviours.

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.

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.

Study burden and risks

This study does not apply any invasive physical procedures. Some of the topics of the Living with Cancer programme may be perceived as

emotional and confronting. However, previous experiences with the programme and our results of the pilot study indicate that participants find it pleasant and useful to discuss their difficulties, challenges, and experiences with peers in a safe and supportive environment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Patients

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

Relatives

1. Relative of a patient with advanced cancer

2. Access to a computer or laptop
3. Internet access

Exclusion criteria

Patients and relatives

1. Younger than 18 years of age
2. Unable to provide consent
3. Unable to read and speak the Dutch language

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 02-08-2021

Enrollment: 162

Type: Actual

Ethics review

Approved WMO

Date: 22-07-2021

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 02-05-2022

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL77374.078.21