Pilot study of the Living with Cancer Programme

Published: 25-02-2020
Last updated: 10-04-2024

Based on the Chronic Disease Self-Management Programme, we developed the Living with Cancer programme: a self-management support programme aimed to improve the wellbeing of patients with advanced cancer and their family caregivers. According to the...

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

Summary

ID

NL-OMON49086

Source
ToetsingOnline

Brief title
the SMART pilot

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Advanced cancer and family caregivers

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, Family caregivers, Programme, Self-management

Outcome measures

Primary outcome

Evaluation of the content of the programme, the organisation (dates/timing),

the procedures and the measurement instruments (home diary and questionnaire).

And to evaluate whether video communication is suitable and acceptable for

participants, concerning receiving the programme content, peer support and

online information.

Secondary outcome

See Primary study parameter/outcome of the study

Study description

Background summary

Patients with advanced cancer have to live with the prospect of impending death and are increasingly unable to continue their daily activities and fulfil their usual social roles, they need to deal with considerable emotional, psychosocial and lifestyle consequences. They do this in the face of increasing multidimensional symptoms, such as fatigue, pain, anxiety, and depression. Most of the time, patients, together with their family caregivers, need to manage a huge part of their care and lives themselves. This can be highly complex and many are unprepared to do this. We want to study how we can support patients and their family caregivers.

Study objective

Based on the Chronic Disease Self-Management Programme, we developed the Living with Cancer programme: a self-management support programme aimed to improve the wellbeing of patients with advanced cancer and their family caregivers.
According to the Medical Research Council guidelines on development and evaluation of a new complex intervention, in this pilot study we will test the programme, the procedures, the measurement instruments (diary and

questionnaires), and assumptions about recruitment and retention.

Study design

This is an explorative pilot of the online Living with Cancer programme. The feasibility of the programme will be evaluated and adapted before delivering in the main study.

Intervention

The online Living with Cancer programme is a community based, peer-led self-management programme designed to help patients with advanced cancer and their family caregivers gain the confidence and skills to better manage the consequences of the illness, and living their daily life with advanced cancer.
The Living with Cancer Programme concerns a 6 week self-management support programme. The programme consist of 6 meetings through video communication, each of 1 hour (with a break) per meeting and approximately 6 to 12 participants. Essential information (principles or explanations about a theme) of the themes will be provided as homework, by short videos and readings.

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 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 so called *pair and share* exercises, 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

Burden:
The programme consiste of 6 online meetings, 1 hour per meeting. An individual meeting of approximately 30 minutes for explanation and testing the videoconference application. Homework, by short videos and readings, 15 to 30 minutes each week.
Filling in a home diary about healtcare ulitilization and a weekly evaluation of the meetings, 6 times. Filling in the home diary will take approximately 5 to 10 minutes.
Participants are asked to complete a questionnaire after the programme. Completion of the questionnaire will take approximately 20 tot 30 minutes.

Participants will be interviewed after the programme. The interview will take 30 to 60 minutes.

Risks:
The themes of the programme of this pilot study may be perceived as emotional and confronting. However, facilitators are trained to handle such situations. Previous experiences show that participants find it pleasant and useful to discuss their difficulties, challenges and experiences with peers in a safe and supportive environment.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients
1. Advanced cancer (with no curative treatment options available)
2. WHO performance status of 0, 1 or 2
3. Acces to internet

Family caregivers
1. Involved in the care for a patient with advanced cancer
2. Acces to internet

Volunteers
1. Health care professionals (e.g. nurses, physicians, social workers, psychologists, chaplains) or volunteers, currently or previously involved in the care for patients with advanced cancer
2. Acces to internet

Exclusion criteria

1. Younger than 18 years of age
2. Patients with WHO performance status of 3 or 4
3. Unable to provide consent
4. 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:	Recruitment stopped
Start date (anticipated):	14-09-2020
Enrollment:	12

Type:	Actual

Ethics review

Approved WMO Date:	25-02-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-09-2020
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	NL72308.078.19