Evaluation of Dyadic Psychoeducational Interventions for People with Advanced Cancer and their Informal Caregivers (DIAdIC): An international randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52263

Source
ToetsingOnline

Brief title
DIAdIC-trial

Condition

- Other condition

Synonym
advanced cancer, cancer

Health condition

oncologische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Horizon2020

Intervention

Keyword: advanced cancer, informal caregivers, Palliative care, supportive care

Outcome measures

Primary outcome

The primary endpoints are emotional functioning and self-efficacy of both the

person with advanced cancer and the family caregiver at t1.

Secondary outcome

The secondary endpoints are: quality of life of the patient and caregiver,

benefits of illness, coping, dyadic communication, ways of giving support at

t1. All listed primary and secondary outcomes at t2 and formal healthcare use

and costs at t1 and t2

Study description

Background summary

Despite the serious problems that advanced cancer involves for patients and their family caregivers, there are few interventions that target both the patient and the family caregiver to self-manage these problems. Dyadic interventions, i.e. targeting the patient and family caregiver together, are more likely to result in better outcomes for both parties than single target interventions and are more cost-effective.
Consequently, interventions focusing on the quality of life of both the patient and the family caregiver (i.e. the dyad) are necessary to promote their well-being, reduce their burden and avoid unnecessary economic costs of

end-of-life cancer care.

Study objective

The overall aim of this project is to evaluate the effectiveness, cost-effectiveness and mechanisms of action of two psychoeducational interventions: a face-to-face nurse-led intervention called FOCUS+ and an eHealth intervention called iFOCUS. These interventions are aimed at improving the emotional function and self-efficacy of patients with advanced cancer and their family caregivers.
Specific objectives:
(1) To compare the face-to-face FOCUS+ intervention and the iFOCUS web intervention with care as usual in terms of their:
- Effect on the emotional functioning and self-efficacy of patients with advanced cancer and their family caregivers (primary outcomes),
- Effect on participants appraisal of the illness, uncertainty, hopelessness, coping, dyad communication, quality of life and healthcare resource use
- Cost-effectiveness
- Effects on vulnerable subgroups (particularly women and those with a of lower socioeconomic status)
- Effectiveness in different healthcare systems
(2) To evaluate the implementation process of the interventions in terms of the acceptability, feasibility, usefulness as perceived by patients, family caregivers and healthcare staff in each country, and their mechanisms of action.

Study design

This study is an international multicenter three-arm randomized superiority trial.

Intervention

The face-to-face intervention: FOCUS+
Delivery mode and dose
This intervention will be provided to patient-caregiver dyads after they completed the baseline measurement (T0) and were randomly allocated to the face-to-face intervention. The face-to-face FOCUS+ intervention is a home-based intervention consisting of two 90-minute home visits and one 30-minute telephone session, conducted by a trained intervention nurse over a period of 12 weeks (4 weeks between each session).
The web-based intervention: iFOCUS
Delivery mode and dose
This intervention will be provided to patient-caregiver dyads after they completed the baseline measurement (T0) and were randomly allocated to the web-

intervention. The web-based iFOCUS intervention is a self-managed psycho-educational intervention that is completed autonomously by the patient-caregiver dyads. It encompasses four sessions over a period of 12 weeks (3 weeks between each session).

Study burden and risks

The DIAdIC protocol is non-invasive and does not involve known risks of protocol-related injury. It is a psycho-educational intervention focused on the provision of information; it is not intended to be a therapeutic or cognitive/behavioral intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The study population will consist of patients with advanced solid organ cancer (except brain cancer) and their primary family caregiver.

Inclusion criteria
Patient
Diagnosis of cancer: solid organ (lung, colorectal, breast, prostate and other)
No longer receives curative treatment (only life-prolonging or palliative treatments)
Written informed consent
Lives within 100 km for intervention nurses to travel
Family caregiver
Written informed consent
Primary informal caregiver as determined by the patient
Lives within 100 km for intervention nurses to travel
Dyad
Patient and/or family caregivers has access to and is familiar with use of internet

Exclusion criteria

Exclusion criteria
Brain cancer, brain metastases, non-solid cancers
Prognosis of less than 3 months
Has no informal caregivers
< 18 years old
Unable to participate in available languages
Family caregiver
Unable to physically or mentally participate
Cancer diagnosis in the last 12 months
<18 years old
Unable to participate in available languages

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2022
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-09-2022
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	NL75241.078.20