CHOICE: CHOosing treatment together In Cancer at the End of life

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44961

Source
ToetsingOnline

Brief title
CHOICE: CHOosing treatment together In Cancer at the End of life

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
Metastasized and inoperable tumours; incurable cancer

Health condition

Uitgezaaide, niet-operabele tumoren

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ALpe d'HuZes/KWF Kankerbestrijding

Intervention

Keyword: communication skills training, palliative chemotherapy, patient participation, shared decision making

Outcome measures

Primary outcome

The primary outcome is the level of SDM as observed in the consultation. To

this end, we will audiotape the consultation.

Secondary outcome

o Observed SDM in a simulated patient encounter (effect training only)

o Patients* perceived efficacy in communication before the consultation

o Patient and oncologist satisfaction with communication and decision making

o Congruence between patients* preferred and perceived role in decision making

o Patients* attitudes towards striving for quantity (length) or quality of life

o Patients* evaluation of the decision made

o Patients* quality of life

o Patients* trust in the oncologist

o Patients* anxiety

o Patients* fighting spirit

o Consultation time

o The treatment decision made

o Patients* use of the *Gesprekswijzer*

o Patients*evaluation of the *Gesprekswijzer*

Study description

Background summary

Disease-targeted treatment for metastasized or inoperable tumours offers uncertain and sometimes little benefit while treatment burden can be high. Hence, treatment decisions cannot be solely based on evidence and patients* clinical status, but should incorporate patients* values and preferences This requires shared decision making (SDM), an approach whereby clinician and patient exchange information and jointly deliberate to come to an agreed-upon decision. Evidence shows that SDM is not standard practice in consultations about palliative systemic treatment.

Study objective

We aim to test the effectiveness of a patient-targeted preparatory tool (*Gesprekswijzer*) and an oncologist-targeted communication skills training to enhance shared decision making in consultations about palliative systemic treatment.

The primary research questions are:
1. Do both the *Gesprekswijzer* and the training independently improve observed SDM in consultations about palliative systemic treatment?
2. Is the combination of both interventions more effective in improving observed SDM than targeting only one party?

The secondary research questions are:
3. Do the interventions affect:
a. Observed SDM in a simulated patient encounter (effect training only)
b. Patients* perceived efficacy in communication
c. Patient and oncologist satisfaction with communication and decision making
d. Congruence between patients* preferred and perceived role in decision making
e. Patients* attitudes towards striving for quantity (length) or quality of life
f. Patients* evaluation of the decision made
g. Patients* quality of life
h. The treatment decision made
i. Patients* trust in the oncologist
j. Patients* anxiety
k. Patients* fighting spirit
l. Consultation time
4. How do patients use the *Gesprekswijzer*?

5. How do patients evaluate the *Gesprekswijzer*?

Study design

A pragmatic multi-center randomised controlled design with four parallel arms will be adopted. Medical oncologists (n=24) will be randomised to the training or the care as usual condition. Patients (n=192; within oncologists) will be randomised to either receive the QPL or care as usual.

Intervention

The CHOICE skills training is based on a four-step model of SDM and on techniques known from behavior change theories. The training is provided in small groups (n=3-5) by a professional trainer and actor. It consists of a reader, two half days of training making use of modeling videos and role play, a booster session and a consultation room tool.
The *Gesprekswijzer* consists of a Question Prompt List and Value Clarification Exercises, i.e., two known methods to empower patients in communication and decision making. The booklet compirses (1) an explanation that, when cure is no longer an option, treatment decisions are highly dependent on individual preferences, (2) example question patients may wish to pose in the upcoming consultation with the oncologist and (3) questions to help patients think about their values.

Study burden and risks

Oncologists will be randomized to receive the skills training (total 17 hours) or not. The skills of all participating oncologists will be assessed in simulated patient encounters at two time points. Furthermore, consultations with participating patients will be audiotaped and oncologists will be asked to fill out a one page questionnaire after the consultation. Patients will be randomized to receive the *Gesprekswijzer* or not. All participating patients will fill out questionnaires at baseline, right before the consultation, 1 week after and at 3 and 6 months post-consultation (total 2,5 hours).
Participation is without risks. We estimate the physical burden to be negligible. We are aware of a potential emotional/psychological burden for patients. Patients randomized to the intervention condition may experience benefits from using the Gesprekswijzer. The direct aim of this study is to improve the care for patients with advanced cancer.

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

Patients
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. diagnosed with metastasized or locally irresectable cancer
2. not eligible for treatment with curative intent
3. median life expectancy of <1 year without systemic treatment, and a median survival benefit of systemic treatment of <6 months. This includes, but is not limited to:
a. patients with metastases or locally irresectable tumors of the pancreas, esophageus, stomach, liver, gall bladder, and bladder, and patients with metastatic sarcoma or melanoma
b. patients with advanced cancer, irrespective of tumour type, who have experienced progression under first line palliative systemic treatment.
4. scheduled for a consultation with a participating medical oncologist in which decisions about the start, (dis)continuation or adjustment of palliative systemic treatment will be made. This includes consultations in which:
a. a decision to start, forego or postpone a (new line of) systemic treatment will be made
b. current systemic treatment is evaluated after a fixed number of cycles and a decision to (dis)continue and/or adjust systemic treatment will be made;Oncologists
Eligible are all medical oncologists (in training) treating the eligible patient population with an

appointment of at least 1 year after the start of the trial.

Exclusion criteria

Patients
A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. insufficient mastery of Dutch, i.e., inability to understand the 'Gesprekswijzer' as well as the questionnaires as judged by either the physician or the researcher
2. cognitive disabilities or a psychiatric disorder that hinder understanding of the 'Gesprekswijzer' as well as the questionnaires as judged by either the physician or the researcher
3. not enough time (<2 days) to make sure the Gesprekswijzer is received before the consultation in which decisions are made
4. a primary brain tumor or brain metastasizes which significantly affect cognitive functioning;Oncologists
Excluded will be oncologists involved in the design of the content of the interventions.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-03-2016
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22913
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL48722.018.15

Register	ID
OMON	NL-OMON22913