Shared decision making (SDM) in oncology: Developing and validating cancer patient and oncologist questionnaires for realization of SDM*

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47781

Source
ToetsingOnline

Brief title
Shared decision making in oncology.

Condition

- Other condition

Synonym
cancer, carcinoma

Health condition

kanker

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cancer, instrument, shared decision making

Outcome measures

Primary outcome

The psychometric properties of the I-SHARE questionnaire to measure SDM in

oncology; this will consist of a version for patients and a version for

doctors.

Secondary outcome

Not applicable

Study description

Background summary

There is growing recognition that shared decision making (SDM) is important, particularly in oncology: clinicians and patients make decisions together using the best available evidence. It is expected to lead to better experiences of care, less overtreatment, and better patient outcomes. However, evidence shows that available observational instruments to assess SDM do not correlate well with patient self-report methods, and the most used self-report measure of SDM does not seem to capture decisional roles in a valid way. Further, many clinicians report they routinely adhere to SDM whereas observation and patient reports show this not to be the case. Ideas about what constitutes a SDM process thus seem to differ significantly among patients, clinicians, and observers, and valid self-report instruments are lacking. Further, instrument development and validation have mostly been carried out in primary care and instruments lack components relevant to oncology. These methodological shortcomings need urgently to be addressed, in order to gather evidence on the realization of SDM, on barriers and facilitators to its realization, and, in

turn, on the outcomes of SDM in oncology practice.

Study objective

Aims of the study are to 1) further clarify the construct of SDM for oncology; 2) find ways to operationalize SDM-realization and formulate drafts of a patient and oncologist version of a SDM-realization questionnaire; 3) validate the questionnaires by testing acceptability, (test-retest) reliability, validity and finalize the questionnaires.

Study design

An observational study in experts, 16 members of the general population, 16 disease-free patients, 5 nurse practitioners, approximately 326 patients and 64 doctors, from several (academic and peripheral) hospitals and departments, to get a representative sample. Furthermore, experts on the project group, international SDM experts and experts on questionnaire development, will participate in interviews and expert meetings.

The study will consist of the following phases:

The study will consist of the following phases: 1) Three systematic literature reviews, one or two qualitative studies (taping of consultations, interviews, (optional) focus group meetings), focus group meetings, online consultation of experts and an expert meeting to clarify the construct of SDM in oncology. In this phase 32 patients and 16 doctors will participate in the taping of consultations and interviews. Also 16 members of the general population and 16 disease *free patients will participate in interviews. In the focus group meetings 16 patients and 12 doctors will participate. In total at least 48 patients and 28 doctors will participate in this phase.

2) Interviews to draft and pilot the questionnaires.
In the interviews about the items 16 patients and 12 doctors will participate. In the cognitive interviews 12 patients and 6 doctors will participate. In total 28 patients and 18 doctors will participate in this phase.

3) Administering questionnaires and an expert meeting to validate the questionnaires.
In this phase 250 patients and 50 doctors will participate. The doctors may have participated in earlier phases of the study. The patients will fill in the I-SHARE questionnaire twice.

Study burden and risks

The risk of participation in this study is negligible. Patients may experience it as a token of interest to be asked for their opinion regarding the way in

which decisions about their treatment were made and as gratifying to provide input for scientific research relevant to other patients. The burden depends on the part of the study in which the patient participates and every patients participates in one part only:
* The consultation is audiotaped and the patient participates in an interview which will last approximately 1 hour and will take place within a few days after the consultation. The interview will take place at the patient*s home or will be combined with an appointment at the hospital. This interview will be audiotaped. It could be confronting for patients to hear their own consultation and to talk about their experiences and opinions.
* The member of the general population participates in an interview in the LUMC, which will last approximately 1 hour. This interview will be audiotaped.
* The disease-free patient participates in an interview, which will last approximately 1 hour. This interview will be audiotaped and will take place at the patient*s home or in the LUMC. It could be disturbing for disease-free patients to talk about their experiences and opinions.
* The patient participates in a focus group meeting of at most 2 hours. This focus group meeting will be audiotaped. It could be disturbing for patients to think about their own consultation and it could be challenging to talk about the different constructs that are of interest in this study.
* The patient is interviewed for approximately 1 hour, at the patient*s home or combined with an appointment at the hospital. This interview will be audiotaped. It could be disturbing for patients to think about their own consultation and it could be challenging to reflect on the items of the questionnaire.
* The patient completes the questionnaire draft and talks out loud while doing so, with a research assistant present to take notes and discuss any issues related to the questionnaire that could help to improve it. This interview will take approximately 1 hour and will take place at the patient*s home or combined with an appointment at the hospital. This interview will be audiotaped. It could be disturbing for patients to think about their own consultation and it could be taxing to talk out loud while completing the questionnaire.
* The patient fills in the questionnaire at home; this includes the I-SHAREpatient questionnaire and questionnaires for validation (approximately 45 minutes) and fills in the I-SHAREpatient questionnaire for the second time, one to two weeks after the first time (approximately 5 minutes).
* The patient fills in the questionnaire at home; this includes the I-SHAREpatient questionnaire and questionnaires for validation (approximately 45 minutes).

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

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
* Be diagnosed with cancer
* Age > 17
* Life expectation > 3 months
* Able to speak and write in Dutch
* Having recently had a decisional consultation, which means that in the consultation a decision to start, stop, change or forego a treatment was discussed (this criterion is necessary for qualitative study 1, and for aim 3, but not for the other studies). For aim 3, we aim to include patients who have faced preference-sensitive decisions.In order to be eligible to participate in an interview, a disease-free patient must meet all of the following criteria:
* Be diagnosed with cancer
* Be free of disease
* At least 6 months after the last treatment for cancer ended (except for hormone therapy)
* Age > 17
* Life expectation > 6 months

* Able to speak and write in DutchIn order to be eligible to participate in an interview, a member of the general population must meet all of the following criteria:
* No experience with oncology consultations
* No cancer diagnosis in significant others in the last 6 months
* No medical profession
* Age > 17
* Able to speak and write in Dutch patiënt

Exclusion criteria

N/A

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2015
Enrollment:	358
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO
Date: 11-08-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 29-09-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 17-12-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 13-09-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 01-12-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 30-04-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	31-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL50551.058.14