

Do communication training and patient education improve discussions about treatment restrictions?

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

Summary

ID

NL-OMON45935

Source

ToetsingOnline

Brief title

CONTACT

Condition

- Other condition
- Gender related factors

Synonym

advanced care planning, Treatment restrictions

Health condition

Het effect van interventies ophet gesprek over behandelbeperkingen

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Communication, Education, Patient participation, Treatment restrictions

Outcome measures

Primary outcome

Primary study outcome is patient satisfaction about the conversation with their doctor, the received information and the patient-doctor relationship. This will be measured with three questions on satisfaction using a 11-point Likert scale.

Moreover, the doctor-patient relationship will be further assessed with the Patient Doctor Relationship questionnaire (PDRQ-9), and doctors will receive a questionnaire that will assess satisfaction as well.

Secondary outcome

Quantitative analysis: decisional conflict (Decisional Evaluation Scale), shared decision-making (SDM-9-Doc), gender differences in previously mentioned outcomes

Qualitative analysis: quality of the conversation on treatment restrictions, gender differences in communication styles regarding the conversation on treatment restrictions

Study description

Background summary

Timely discussing treatment restrictions with patients is important in order to

prevent difficult situations at, for example, the emergency department. Nowadays, patients are often uninformed about the possibilities and consequences of resuscitation, mechanical ventilation and intensive care admission. This makes it hard or even impossible to decide about whether these interventions should be performed whenever they become necessary, especially in an urgent medical situation. Doctors, however, find it difficult to discuss potential treatment restrictions with patients. We hypothesize that routinely discussing potential treatment restrictions with patients at the outpatient clinic, in a less stressful environment with their *own* physician, leads to better informed patients, more patient and doctor satisfaction about this conversation and more shared decision-making. Furthermore, it is important to gain more insight in the role of gender differences in communication style regarding the discussion on potential treatment restrictions.

Study objective

Our aim is to improve patient and doctor satisfaction and quality of the discussion about potential treatment restrictions by introducing a digital information and conversation aid for patients and training for doctors. Moreover, we aim to provide more insight into gender differences regarding this subject.

Study design

This is a randomized controlled trial with a mixed methods design.

Intervention

Patients will receive a digital information brochure and conversational aid. Doctors will be trained with simulated patients and an e-learning module.

Study burden and risks

No extra diagnostic or therapeutic actions will be performed for this study. Discussing treatment restrictions at the outpatient clinic is considered good clinical practice. The *burden* associated with study participation for patients only involves questionnaires and the video recording of the patient-doctor conversations. Moreover, half of the patients will receive extra information on resuscitation, mechanical ventilation and intensive care unit admission. Beside this, patient will receive regular care at the outpatient clinic. Doctors will all participate in a training on discussing treatment restrictions and will complete questionnaires.

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

All new patients or known patients (>18 years) with whom potential treatment restrictions have not been discussed, that are scheduled for a visit at the internal medicine outpatient clinic are eligible for inclusion. Moreover, internal medicine residents and internists who did not participate in the treatment restrictions communication training before will be asked to participate in this study.

Exclusion criteria

Patients with insufficient Dutch language ability in order to be able to complete the patient information files and questionnaires, inability to give informed consent and patients with whom treatment restrictions have been discussed previously will be excluded.

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:	Recruitment stopped
Start date (anticipated):	25-09-2018
Enrollment:	244
Type:	Actual

Ethics review

Approved WMO	
Date:	02-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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

CCMO

ID

NL65774.041.18