Effects of Advance Care Planning on Patient Empowerment, Perception of Care and Healthcare Utilization in Older Patients with Multimorbidity: a Feasibility Pilot of a Randomized Controlled Trial

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The primary objective of our pilot study is to assess trial feasibility. Our secondary pilot objectives are to collect data on patient experience of healthcare, patient engagement, cost-effectiveness, and other data that might inform the design of a...

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

Summary

ID

NL-OMON52742

Source
ToetsingOnline

Brief title
Effects of ACP in Older Patients with Multimorbidity: a Feasibility Pilot

Condition

- Other condition
- Age related factors

Synonym
healthcare utilization, Patient empowerment

Health condition

zorggebruik

Research involving
Human

Sponsors and support

Primary sponsor: Department of Public Health, Section Care and Decision Making at the End of Life
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Advance Care Planning (ACP), Healthcare Utilization, Multimorbidity, Patient Empowerment

Outcome measures

Primary outcome

Trial-feasibility is defined as the successful inclusion of 50 patients in total, timely administration of the intervention in 25 patients, adherence to follow-up procedures and identification of problems or barriers during recruitment, inclusion, intervention administration and follow-up.

Secondary outcome

Our main outcome for cost-effectiveness is total duration and number of hospital admissions, as a proxy for both costs and effects (iMCQ). In order to inform a possible cost-effectiveness analysis (CEA), data on health-related quality of life (EQ5D-5L) will also be collected. Our outcomes for patient assessment of care and patient empowerment are the PACIC questionnaire, the ACP Engagement Survey and the appointment of a surrogate decision maker and/or the documentation of advance directives. Other data that will be collected to

describe our population is daily activities (ADL and iADL) and destination at

discharge (if admitted).

Study description

Background summary

A recent study into the patient perspective of patients with multiple chronic conditions in the Netherlands underlines the strain multimorbidity can put on people. Most patients would appreciate more coordination from and communication with their care providers. This call for better coordination of needs and preferences ties into the concept of Advance Care Planning (ACP). ACP is a structured process of communication in which patients and physicians discuss and, if applicable, document health preferences and goals of patients regarding their last phase in life. Most ACP studies have been performed amongst older, terminally ill patients with the main aim of establishing patients' preferences before they lose capacity. We want to investigate the potential of ACP to increase patient empowerment in a population of competent patients with multimorbidity, who are not necessarily in their last phase of life.
The distribution of healthcare expenditure among the population requiring care is skewed. In the Netherlands the top-10% most cost incurring patients account for 68% of expenditure. Many of these patients receive unnecessary or ineffective care, with a recent study estimating preventable spending at 10%. High-Need High-Cost patients comprise a very heterogeneous group, yet one common denominator explaining high cost is the high prevalence of multiple chronic conditions. Both overtreatment and conflicting treatment are legitimate concerns within this population. As multimorbidity and frailty increase with age, the older patient with multimorbidity is especially at risk. Targeted care programmes have been developed under the assumption that better coordination will lead to a reduction in healthcare utilization. However, although care might be identified as preventable or inefficient from a medical point of view, this is not necessarily the case from a patient perspective. We are interested how patients experience such care and thereby if better coordination would indeed lead to a reduction in utilization.
Because ACP supports patients in timely recognition and better expression of their needs and preferences, we hypothesize that care will address those needs and preferences more adequately, which will result in improved patient assessment of care. We further hypothesize that patient empowerment will enable better planning of care and decision making, which can result in less unwanted or preventable interventions. As a consequence healthcare utilization might decrease. However, another possibility is that rather than leading to a decrease, improved empowerment may lead to an increase in utilization because care which is deemed superfluous from a medical perspective might not be

perceived as such by patients.

Study objective

The primary objective of our pilot study is to assess trial feasibility. Our secondary pilot objectives are to collect data on patient experience of healthcare, patient engagement, cost-effectiveness, and other data that might inform the design of a full-scale RCT.

Study design

Randomized Controlled Trial feasibility pilot

Intervention

One of the most well-researched ACP programs is the Respecting Choices Program. In this program, a trained facilitator encourages patients to reflect on their goals, values and beliefs, to discuss and document their future choices, and to appoint a surrogate decision maker. The program was translated to the Dutch context in previous studies in the nursing home setting and oncology care. Patients randomized to receive ACP will have two meetings with a trained facilitator within two months.

Study burden and risks

A possible disadvantage is that participants will be invited to discuss topics which might make them feel uncomfortable. However, the intervention is very sensitive to such situations and, moreover, people are not by no means obliged to participate in the study. This research can deliver useful information on the experienced quality of care and wishes of patients suffering multimorbidity as well as informing strategies for cost-reduction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

patients >= 65 years of age with polypharmacy who gave informed consent and had 2 or more hospitalizations, day clinic admission or individual ER admissions in the last year

Exclusion criteria

Patients with serious cognitive impairment (MMSE score < 16), patients with a limited life-expectancy (<6mo) and/or who are not fluent in Dutch

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:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	22-04-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved Date:	06-02-2023
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	NL72101.078.20