Improving Medication Prescription in the Context of Advanced Care Planning for Patients Receiving Nursing Home Care

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29679

Source
NTR

Brief title
IMPETUS

Health condition

Prescribing practice for elderly nursing home patients with a limited life expectancy; medication appropriateness; appropriate prescribing; medication review; advance care planning; nursing home patients; geriatric palliative care

Sponsors and support

Primary sponsor: VU University Medical Center, department of General Practice and Elderly Care Medicine
Source(s) of monetary or material Support: ZonMw, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Unless otherwise indicated, all outcome variables will be measured at T0-T3 both in the intervention group and the control group.

Outcome name: change in prescription of preventive/chronic medication from: (among others) ATC main groups N (central nervous system), A (alimentary tract and metabolism) and C (cardiovascular System). Medication use per ATC (Anatomical Therapeutical Chemical Classification) group, number of DDD (daily defined dose) will be derived from the computer system of the NH pharmacists.

Timepoint: T0-T3 (18 months after T0 inclusion)

The study will focus on longitudinal change in individual medication use (allowing for intra patient comparisons), as well as on change in medication use of residents of a ward.

To support data registration, online forms will be developed as part of a special electronic patient record-tool.

Secondary outcome

1. Quality of life: measured with the EuroQoL (EQ-5D) proxy version. Timepoints: T0-3

2. Social wellbeing will be measured with the RISE (Revised Index for Social Engagement), derived from the RAI-LTCF (Resident Assessment Instrument for Long-Term Care Facilities). Timepoints: T0-3

3. Pain, measured with RAI-LCTF. Timepoints: T0-3

4. Experienced involvement in decision-making about medications by patients/surrogates will be measured by a questionnaire based on the SDM-Q9 for decision-making. Time-points T0-3

5. Frequency of falls in the last 90 days, measured with RAI-LCTF. Timepoint: T0-T3

6. Hospitalizations: cause, length of stay in days, derived from the electronic patient records. Timepoint: at T3 or when patient terminates the study (any cause)

7. Deaths (any cause). Timepoint: any timepoint

8. Appropriateness of medication prescription. This will be assessed by an expert panel consisting of members from the research team, supported by members of Ephor. Assessment will be on the basis of the following (anonymous patient) data: medical diagnoses, renal function, pain, overriding care goal (see secondary outcomes and additional measurements), and will be scored using the medication appropriateness indicators list developed in the

Delphi study and the guidelines of the professional organization of elderly care physicians.

Timepoint: T1-T3, after every SMMR.

Additional measurements (including possible confounders):

- Socio-demographic variables (sex, age) and length of stay in NH, from electronic patient records. Timepoint: T0

- Overriding care goal (geriatric-palliative care or other, from electronic patient records, Timepoint: T0-3

- Medical diagnoses, including recent renal function (GFR), from electronic patient records, Timepoint: T0-3

- Decisional capacity, measured with the RAI-LCTF. Timepoint: T0-3

- Demographic data on nursing home staff (physicians, pharmacists, nurses): age, sex, years of experience in nursing home setting. Timepoint: T1

Study description

Background summary

Patients in Nursing homes are generally (very) old and suffer from complex multi-morbidity. For many patients, the treatment goals change from a focus on prevention and curation, to a more Geriatric-palliative care (GPC) approach with a focus on quality of life and symptom treatment. However, this change is not yet seen in medication prescription: medication appropriateness is highly prevalent in nursing home patients. The literature had identified many barriers, for example the lack of clear incentives and a structured method to discuss medication appropriateness.

OBJECTIVE: The objective of the IMPETUS study is to align medication prescribing with the principles and practice of GPC, by means of an advance care planning (ACP)-working method. The aim is to implement and evaluate ACP discussions integrated with a structured multidisciplinary medication review (SMMR) based on the GPC paradigm and supported by a list of medication appropriateness indicators and tailored START/STOPP criteria.

STUDY DESIGN:
Cluster randomized controlled trial, in 2 x 20 long term care wards of university affiliated NH. After the trial, a qualitative process analysis will be performed.

STUDY POPULATION: NH residents admitted for long term care with an indication for a GPC approach based on the SPICT.

INTERVENTION: SMMR combined with ACP discussions with residents and/or their surrogates (ACP+) versus usual care.

PRIMARY OUTCOME: Change in preventive/chronic medication

SECONDARY OUTCOMES:

Falls, hospitalizations/acute referrals, mortality, quality of life, patient/surrogate satisfaction with
involvement in decision-making, appropriateness of prescription

HYPOTHESES:

It is hypothesized that the working Method increases the prescribing of appropriate medication in the target population. It will result in a reduction of chronic and preventive medications in favor of prescriptions for pain and symptom management, without adverse effects, such as falls, increased mortality or acute care referrals, and without negative effects (or even with positive effects) on quality of life. A positive effect on patient and surrogate satisfaction with (involvement in) decision-making is also expected.

FEASIBILITY STUDY IN PRIMARY CARE: In addition to the main study a pilot evaluating the ACP+ intervention in 'SPICT-positive' community dwelling older patients with complex multi-morbidity will also be conducted as part of the collaboration between GPs and ECPs at the University Practice for Elderly Care Medicine of VUmc.

This study is a collaboration between the Amsterdam Public Health/EMGO+ Institute for Health and Care Research at VU University Medical Center Department of general practice & elderly care medicine.

Study objective

This study aims to implement and evaluate an advance care planning (ACP) intervention for elderly nursing home patients with a limited life expectancy. The intervention consists of ACP discussions integrated with a structured multidisciplinary medication review (SMMR) based on a geriatric-palliative care paradigm and supported by a list of medication appropriateness indicators.

The hypothesis is that this intervention increases the prescribing of appropriate medication,

resulting in a reduction of chronic and preventive medications in favor of prescriptions for pain and symptom management, compared to usual care.

The intervention is expected not to cause an increase in adverse effects like falling, hospital admission, increased mortality, and to have a positive effect on the quality of life, satisfaction with (involvement in) decision-making and health-care costs.

Study design

Inclusion

Baseline T=0

Intervention (for intervention group) between T0 and T1

6 months T=1

Intervention (for intervention group) between T1 and T2

12 months T=2

Intervention (for intervention group) between T2 and T3

18 months T=3 = endline

Intervention

All NHs (intervention and control group) will be instructed in the inclusion procedure and the use of the online data registration tool.

Before the trial, a Delphi consensus study will be conducted to develop a list of medication appropriateness indicators, by adjusting the current START/STOPP criteria to the target population.

Intervention

The Advance Care Planning (ACP+) intervention is a working method, aimed to stimulate prescribing practice based on the multidisciplinary guideline “Polypharmacy in the elderly”.

Physicians, pharmacists and nursing staff will be trained in the intervention.

The ACP+ working method consists of a combination of a structured multidisciplinary

medication review (SMMR) and an ACP discussion. Firstly, experiences questions and wishes of the patient in regards to his/her medication will be explored. Secondly, the physician and pharmacist conduct an SMMR. During this SMMR, the appropriateness of a patient's medication is reviewed on the basis of key elements from the guideline "polypharmacy in the elderly", medication appropriateness indicators, and the geriatric-palliative algoritm.

The recommendations from this SMMR are then discussed with the patient and/or representatives in an ACP discussion.

This SMMR and ACP working method will be repeated every six months (between T0 and T1, between T1 and T2, and between T2 and T3), three times for each patient during the study.

Control:

The control group will receive care as usual which likely includes mostly unstructured MR (both in time and in methodology, as the multidisciplinary guideline "Polypharmacy in the elderly" is not yet widely implemented in Dutch nursing homes), and ACP without discussion about medication treatment plans (as this approach is completely new in the field). At the end of the study, the training programme (adjusted on the basis of the study findings) will also be offered to the control group.

Contacts

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Eligibility criteria

Inclusion criteria

- Elderly patients (age >=65 years)

- Residing in (University-affiliated) Nursing home, nursing home uses Ysis as Electronic medical Record

- Patients residing on a long-term NH ward for somatic or psychogeriatric care

- Having a permanent residence indication (¡Ã6 months, until the end of life)

- Having an indication for geriatric-palliative care based on the Supportive & palliative Care Indicators Tool (SPICT)

OR: Having a clear wish for a geriatric-palliative approach.

- Written informed consent can be obtained (consent is given by the patient him-/herself or through a legal representative in case of legal incapability)

Exclusion criteria

- Having an short-stay indication of less than six months

- Being admitted for geriatric rehabilitation or hospice care (terminal care).

- Patients residing on special care wards (e.g. mentally handicapped ward, young dementia ward, Acquired Brain Injury-ward, wards for specific diseases (Parkinson, Huntington, Korsakov)

Study design

Design

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

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	480
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-08-2017
Application type:	First submission

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
NTR-new	NL6466
NTR-old	NTR6644
Other	Dossier number ZonMw: quality in health care program : 80-83910-98-13122

Study results

Summary results
N/A