Discontinuing Inappropriate Medication in Nursing Home Residents (the DIM NHR study): a cluster randomized controlled trial.

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This study aims to examine the efficacy and cost-efficacy of multidisciplinary systematic medication reviews.

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

Summary

ID

NL-OMON40684

Source
ToetsingOnline

Brief title
DIM NHR Study

Condition

- Other condition

Synonym
polypharmacy; use of multiple drugs at the same time

Health condition

polyfarmacie

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Inappropriate Prescribing, Nursing Home Residents, Polypharmacy, Systematic Medication Reviews

Outcome measures

Primary outcome

The difference in the proportion of residents for whom inappropriate medication

will be discontinued (intervention group versus control group).

Secondary outcome

Underprescribing; Exposure to anticholinergic and sedative medication; side

effecs of medication; neuropsychiatric symptoms; cognitive function; quality of

life; hospital admissions; mortality risk.

Study description

Background summary

Nursing home residents are a frail patient group who often have multimorbidity which results in use of multiple drugs at the same time or polypharmacy. Polypharmacy may reflect inappropriate prescribing e.g. overprescribing but also underprescribing. Polypharmacy increases the occurence of side effects, increases the fall risk, hospital admission, health care utilization and mortality. Multidisciplinary systematic medication reviews provide an opportunity to decrease inappropriate prescribing. However, the efficacy and cost-efficacy of medication reviews have not yet been examined in the Dutch nursing home setting.

Study objective

This study aims to examine the efficacy and cost-efficacy of multidisciplinary

systematic medication reviews.

Study design

A cluster randomized controlled trial in nursing homes. Randomization takes place at the level of the ward. The nursing home wards form the custers. Data will be collected at baseline and at follow-up or four months after the medication review has taken place.

Intervention

Multidisciplinary systematic medication reviews are the interventions that will be examined in this study.These medication reviews are based on multidisciplinary guidelines of the Dutch association of general practitioners and the Dutch association of elderly care physicians. Multidisciplinary systematic medication reviews are carried out by a elderly care physician and a hospital pharmacist. On clinical indication, a medical specialist will be consulted.

Study burden and risks

Participants or their legal representatives will be informed about the study. Informed Consent will be asked from every participant or his/her legal representative. Data will be processed anonymously. Only the physician and the researcher will have acces to the data. If required, the Dutch Inspection of Healthcare will also be granted access to the data for inspection. The burden of participation will be constrained to a minimum by trying to retrieve as much information from patients' medical records as possible and by using questionnaires and tests that were specifically developed for the nursing home population. In our opinion, participation does not involve risks. Multidisciplinary systematic medication reviews are aimed at improving the advice to the elderly care physician. Final decisions concerning treatment will rest with the elderly care physician though.Medication reviews have much to offer to frail nursing home residents as they have the potential to reduce inappropriate prescribing i.e. overprescribing as well as underprescribing. Polypharmacy, possibly resulting from overtreatment and inappropriate prescribing, is a significant problem in this group of patients. Polypharmacy increases the occurence of side effects, increases the fall risk, hospital admission, health care utilization and mortality. We expect medication reviews to improve nursing home residents' health and quality of life significantly.

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

Nursing Home Ward Level:;• Long stay ward.
• Capability and commitment to perform a multidisciplinary multistep medication review in the way as outlined in paragraph 4.1 Treatment of the study protocol. ;Nursing Home Residents Level:;• A life expectancy of >4 weeks as judged by the treating elderly care physician.
• IC provided by patients themselves or provided by a legal representative of incapacitated patients.

Exclusion criteria

Nursing Home Ward Level:;• Short stay, revalidation or observation wards as including these will inflate the rate of patients who are lost to follow-up.
• Specialized ward where patients with an atypical etiology e.g. lifespan psychiatric illness, alcohol dementia, AIDS, and mental disability are cared for.
• Elderly care physicians who have recently received or who are to receive recertification at

short notice with regard to systematic medication review methodology.
• Participation in other studies aimed at improving the quality of drug prescription (in the past 12 months).;Nursing Home Residents Level:;• Refusal of treatment with medicines.
• Having received a multidisciplinary systematic medication review in the past 6 months.
• Being terminally ill and having a life expectancy <= 4 weeks as judged by the treating elderly care physician.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2014
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO

Date:	01-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01876095
CCMO	NL48091.042.14