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A collaborative approach to optimise medication use for older people in nursing homes: a cluster controlled trial

Submission date
10/11/2015

Recruitment status
No longer recruiting

Registration date
18/11/2015

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ageing has become a worldwide reality and presents new challenges for the health care system. Research has shown that the prescription of potentially inappropriate medications (PIMs) happens a lot for older people, especially in nursing homes (NH). The use of PIMs is associated with bad side effects (or adverse drug events (ADEs)), hospitalizations, death and healthcare costs.
The Come-On study aims to investigate the effect of a complex, multifaceted intervention (that is, a programme with many different features), including training, local concertation (partnerships) and multidisciplinary case conferences (conferences covering cases involving a number of diseases), on whether the use of medicines for older people in Belgian nursing homes is appropriate.

Who can participate?
Nursing home residents that are at least 65 years old, living in a participating nursing homes under the care of a participating general practitioner (GP).

What does the study involve?
Participating nursing homes are randomly allocated into one of two groups. Those in group 1 (intervention group) hold four-monthly case conferences between the nurse, the GP and the pharmacist for each resident. Additional case conferences can be organized after hospitalization or upon entry in palliative care. In each case, a review of the medication that the resident is taking is done in order to optimize their medication profile (i.e. make sure that they are on the best combination of medications). A web application, built for this purpose, supports data collection and data sharing between health care professionals (HCPs) in the intervention arm. It also supports the documentation and follow-up of drug-related problems (DRPs) and related interventions/treatments. Education and training, both through e-learning and on-site sessions is provided to participating health care professionals from the intervention group. Furthermore, nursing homes in the intervention group work together in discussing and coming to an agreement on the appropriate use of two types of medication (antidepressants and lipid-lowering drugs).Nursing homes in group 2 (control group) deliver usual care.

What are the possible benefits and risks of participating?
The main benefit for participants in this study is the evaluation and the optimization of their medication profile. The information of this study can contribute to an improved medication policy for other nursing home residents, not included in the study. This study contains no risks for participating residents.

Where is the study run from?
A total of 63 nursing homes where recruited in this study. It is organized by KU Leuven and the University in Louvain-la-Neuve (Belgium).

When is the study starting and how long is it expected to run for?
January 2015 to June 2016

Who is the funding body of the study?
National Institute for Health and Disability Insurance (NIHDI) of Belgium

Who is the main contact?
1. Professor Veerle Foulon (scientific)
2. Professor Anne Spinewine (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
s57145

Study information

Scientific Title
A Collaborative approach to Optimise MEdication use for Older people in Nursing homes (the COME-ON study): a cluster controlled trial

Acronym
COME-ON

Study objectives
A complex, multifaceted intervention that consists of a multidisciplinary medication review, supported by training and local concertation, will improve the appropriateness of use of medicines for older people in Belgian nursing homes (NHs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the University Hospitals Leuven, 21 October 2014, reference number: s57145 (ML11035)

Study design
Multi-centre cluster controlled trial using parallel groups

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Optimization of medication

Interventions
The intervention is considered as a complex multifaceted intervention that is built up from three main components (for the intervention arm of the trial):
1. Education and training
Education and training, both through e-learning and on-site sessions, will be provided to participating health care professionals (HCPs). An e-learning platform is specifically designed to support this component.
2. Local concertations
Two meetings (i.e. local concertations) will be held on the level of the nursing home to discuss and generate consensus on the appropriate use of two specific medication classes (antidepressants and lipid-lowering drugs), and to stimulate collaboration.
3. Multidisciplinary case conferences
Four-monthly scheduled multidisciplinary case conferences between nurse, general practitioner and pharmacist will be conducted on a resident-level over a period of 12 months. Additional case conferences can be organized after hospitalization or upon entry in palliative care. Case conferences will facilitate a structured medication review in order to optimize the residents' medication profile.

Two additional components should facilitate the intervention. First, using a web application that has been developed for data collection, will allow health care providers in the intervention group to share data and to prepare the medication review. Moreover, the web application provides the opportunity to document and follow-up drug-related problems and interventions. Second, a financial incentive will be provided to participating healthcare professionals for data collection and participation to case conferences.

Qualitative analysis will be incorporated in the study to provide insight into the intervention delivery and the acceptability of the intervention to different HCPs .

Nursing homes allocated to the control group will deliver usual care and will be paid for data collection.

Intervention Type
Other

Primary outcome measure
The primary outcome measure relates to appropriateness of prescribing. It considers:
1. Proportion of residents with improvement in Potential Inappropriate Medication (PIM) / Potential Prescribing Omission (PPO) (overall score) between baseline and end of study
2. Median number of PIMs/PPOs per patient (difference between baseline and end of study) .

PIMs/PPOs will be identified by the research team from a pre-defined list of explicit criteria that includes STOPP-START (version 2) and Beers criteria.

Secondary outcome measures
Resident level:
1. Appropriateness of prescribing:
1.1. PIMs and PPOs: prevalence per explicit criteria at baseline, middle and end of study

1.2. On a random subsample of patients and using an implicit approach for the evaluation of appropriateness:
1.2.1. Prevalence of PIMs/PPOs that can be considered as actually inappropriate on an individual basis
1.2.2. Appropriateness of prescribing at baseline and end of study using the Medication Appropriateness Index (MAI)
2. Medication use: median number of drugs per resident and classes of medications (ATC) at baseline, middle and end of study
3. Process of case conferences: number of case conferences per resident and per nursing home, reason for case conference, number of participating health care providers and duration of case conference at each case conference
4. Outcome of case conferences: characteristics of drug-related problems (DRPs) leading to treatment changes and proportion of modifications implemented at the next case conference
5. Clinical outcomes / residents' status: death, hospital admissions, visits to emergency department, GP visits and consultations with specialists
6. Cost of medication, cost of medical care and cost of intervention

Nursing home level:
1. Facilitators and barriers, satisfaction of caregivers by semi-structured interviews and/or focus groups at the end of the study
2. Process analysis / fidelity to the intervention
2.1. Participation rate for educational sessions / e-learning at month 3 and at the end of the study
2.2. Number of local concertation meetings organized at each NH
2.3. Proportion and types of HCPs participating to local concertation

Overall study start date
01/01/2015

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Participating nursing homes:
The National Institute for Health and Disability Insurance (NIHDI) of Belgium launched a call in July 2013 to all Belgian nursing homes to apply for participation to the Come-On study. In total, 72 nursing homes were considered as eligible candidates. After the exclusion of duplicates (in case of the same coordinating physician, the same pharmacist or the same board of directions), 63 submission files were restrained.
In agreement with NIHDI we decided to use the resulting 63 files to generate an intervention group of 30 NHs (as stipulated in the call launched by NIHDI in July 2013) and a control group of 33 NHs.
Because of political reasons, it was decided on beforehand that each 'entity' in Belgium (12 in total: five Flemish provinces, five Walloon provinces, German-speaking community and Brussels-Capital Region) would have at least one NH in the intervention group.
The number of NHs to be selected from each of the eight remaining entities was calculated on the number of inhabitants. We further stratified, within these entities, for experience with case

conferencing and type of delivering pharmacy (hospital pharmacy versus community pharmacy). This resulted in 17 groups.
Randomization within the groups was performed with SPSS.

2. Participating nursing home residents:
2.1. Resident of participating nursing home
2.2. Participating GP
2.3. 65 years and older
2.4. A signed informed consent

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
Recruitment of 63 nursing homes and 2205 nursing home residents (63 clusters; in each nursing home 35 residents included)

Total final enrolment
1804

Key exclusion criteria
1. Short stay or revalidation
2. Receiving palliative care (according to GP's evaluation)
3. Refusal of resident to participate

Date of first enrolment
01/01/2015

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Belgium

Study participating centre
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Study participating centre
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-
-
Belgium
-

Sponsor type
Not defined

Website
http://www.kuleuven.be/english

ROR
https://ror.org/05f950310

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Disability Insurance (NIHDI) of Belgium

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/03/2016		Yes	No
Results article	results	01/11/2019	14/08/2019	Yes	No
Other publications	process evaluation	11/12/2019	13/12/2019	Yes	No
Results article	Drug–drug interaction results	08/01/2023	09/01/2024	Yes	No