Impact of a complex intervention on the appropriateness of prescribing for nursing home residents: results of a cluster controlled trial (COME-ON study)

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Introduction

The **COME-ON study** (Collaborative approach to Optimize Medication use for Older people in Nursing homes) aimed to investigate the impact of a complex intervention on the appropriateness of prescribing for Belgian nursing home residents (NHRs)[1].

Methods: intervention

A multicenter, cluster controlled trial was set up. The complex intervention consisted of **blended training**, **local concertation** (discussion on the appropriate use of specific medication classes on the nursing home (NH) level) and repeated **interdisciplinary case conferences (ICC)** (involving the GP, the pharmacist and the nurse) to perform medication review for each NHR (see figure 1). Control NHs delivered usual care.

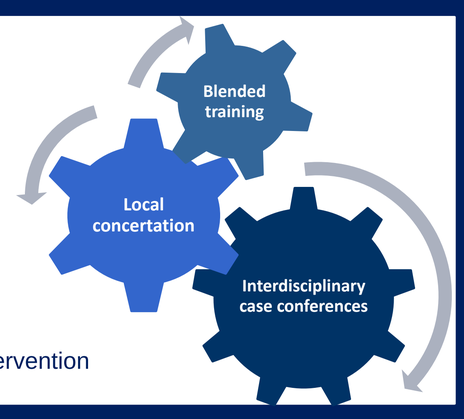

Figure 1: the COME-ON intervention

Methods: outcome measures and analysis

- The primary outcome measure related to the **appropriateness of prescribing** at the resident level and was considered successful when **≥ 1 potentially inappropriate medication (PIM) or potential prescribing omission (PPO)** that was present at baseline had been **solved** at end of study *(outcome A),* and when there was **no new PIM or PPO** at end of study compared to baseline *(outcome B).* **Additional analyses** were conducted in the **middle of the study.** Detection of PIM and PPO occurred via an **automatic algorithm** based on explicit tools (STOPP/START v2 and BEERS 2015)[2].
- A binary logistic mixed effects model was applied to evaluate the intervention effect on the primary outcome. A **three-level mixed effects model** was used to account for the clustering of the data: NHRs were nested within their GPs, and the GPs in their turn were nested within NHs. Stratification variables used for allocation of NHs to intervention or control arm were included as covariate.
- A **multiple imputation strategy** on all 1804 NHRs was followed for the primary outcome to avoid analyzing only the complete cases, which entails a risk for biased estimates of the intervention effect if the missingness is not at random.
- A **logistic regression model** or **a regression model** for count data (depending on the type of data) was used for analysis of the secondary outcomes (taking into account clustering, stratification variables and other confounding variables).

Results

- 54 NHs (24 intervention and 30 control) and 1804 NHRs (847 intervention, 957 control) participated in the study.
- The median age of NHRs was 87 (82-92) and the majority was female (69.7%).
- The median number of medications at baseline was 9 (6-12), the median number of PIMs and PPOs at baseline was 2 (1-4) and 2 (1-3) respectively.
- A **significant effect** (p=0.021) **in favor of the intervention** on the **primary outcome measure (A+B)** was observed, for both comparison of end and middle data vs. baseline (p<.0.001) (see table 1).
- The effect was strongly in favor of the intervention for outcome A, but not for outcome B (see table 1).
- The number needed to treat for a successful outcome A+B at end of study (calculated using data after imputation) was 18.
- **Clinical outcomes** did not significantly differ between groups, except for the mortality rate that was significantly higher in the intervention group than in the control group (see table 2). The median number of medications did not change over time within the two groups (see table 2).

Table 1: odds ratios for a successful primary outcome A+B, outcome A and B for comparison of end data versus baseline (primary outcome) and for comparison of middle data versus baseline.

COMPARISON END DATA versus BASELINE		
Variable	**Odds ratio (95% CI)**	**P-value**
Primary outcome (outcome A+B)		
Intervention effect	1.479 (1.062-2.059)	0.021*
Outcome A		
Intervention effect	2.666 (1.784-3.983)	<.001*
Outcome B		
Intervention effect	0.664 (0.458-0.961)	0.03*
COMPARISON MIDDLE DATA versus BASELINE		
Outcome A+B		
Intervention effect	2.194 (1.49-3.23)	<.001*
Outcome A		
Intervention effect	3.311 (2.075-5.282)	<.001*
Outcome B		
Intervention effect	0.561 (0.383-0.821)	0.003*

Table 2: impact of complex intervention on mortality and number of medications at end of study among NHRs .

Variable	Intervention group	Control group	Ratio (95% CI)	P-value
Death, *n (%)*	226 (26.7%)	207 (21.6%)	1.462 (1.076;1.987)	0.0153*
Number of medications at end, *median (IQR)*	9 (6-12)	9 (6-12)	1.011 (0.936;1.092)	0.7857

Key conclusions

The complex intervention tested in the COME-ON study **was successful in improving appropriateness of prescribing** in NHRs.

1. Anrys P, Strauven G, Boland B, Dalleur O, Declercq A, Degryse J-M, et al. Collaborative approach to Optimise MEdication use for Older people in Nursing homes (COME-ON): Study protocol of a cluster controlled trial. Implement. Sci. 2016;11.
2. Anrys P, Boland B, Degryse JM, De Lepeleire J, Petrovic M, Marien S, et al. STOPP/START version 2-development of software applications: Easier said than done? Age Ageing 2016;45:590–3.

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The Come-On project is funded by the Belgian National Institute for Health and Disability Insurance (INAMI-RIZIV)