Opportunities and Limits to Deprescribing in Nursing Homes: Quality Circle Deprescribing Module (QC-DeMo)

Statistical Analysis Plan

OLD-NH-QC-DeMo

Type of Research Project:	Research project using anonymous health-related data
Risk Categorisation:	Not applicable
Project Identifier:	OLD-NH-QC-DeMo-2017
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Problem to be studied:	Effect of a deprescribing-specific quality-circle module on the use of potentially inappropriate medication in nursing homes of Vaud and Fribourg.
Project Duration	December 2017 – March 2019 (possible extension to March 2020)
Plan Version and Date:	V1, 07.08.2018
Registration number	NCT03688542

ACCESS TO RESEARCH DOCUMENTS
All essential documents of promoter and investigators will be stored in study folders, whose management and archival are conform to the Principles of Good Clinical Practices (GCP).

Study objectives

1) To evaluate the effect of a deprescribing-specific interdisciplinary quality circle module on the use of potentially inappropriate medication in nursing-home residents.

2) To determine the effective strategies to reach and implement deprescribing consensus resulting of said quality circle module.

Outcomes

Primary outcome

The overall proportion of galenic units considered inappropriate (possibly and probably inappropriate) will be computed for each NH using the following formula:

$$\frac{(total\ number\ of\ inappropriate\ galenic\ units\ used\ during\ the\ period)}{(total\ number\ of\ galenic\ units\ used\ during\ the\ period)}$$

The difference between baseline and 12 months will then be computed for each NH.

Secondary outcomes

Difference in proportion of probably inappropriate galenic units and of possibly inappropriate galenic units: the baseline to 12-month difference in the proportion of possibly inappropriate drugs and of probably inappropriate drugs will be computed for each NH using the same method as for the primary outcome.

Difference in proportion of probably inappropriate DDDs and of possibly inappropriate DDDs: for each data line, the number of DDDs will be computed by multiplying the number of galenic units with the number of DDD per galenic unit. The latter is present in the database used created by the CPC for the monitoring of the cantonal PAPs. The change in proportion of possible inappropriate DDDs and probably inappropriate DDDs will then be computed as for the primary outcome.

Number of hospital days per mean resident and per year: for each year, NH will report the total number of days spent in the hospital (i.e. days spent outside of the NH for medical reasons). The total number of days spent in the NH will be provided by the CPC monitoring team; the mean number of days in hospital per year and per mean resident will then be computed using the following formula:

$$(total\ number\ of\ days\ in\ hospital)/(total\ number\ of\ days\ spent\ in\ NH)/365$$

Mortality rate: NH will report the number of residents having died during each year. The annual mortality rate will then be computed for each NH using the following formula:

$$(total\ number\ of\ deaths)/(total\ number\ of\ days\ spent\ in\ NH)/365$$

Number of falls per mean resident and per month: for each year, NH will report the number of falls. The monthly number of falls per mean resident will then be computed for each NH using the following formula:

$$(total\ number\ of\ falls)/(total\ number\ of\ days\ spent\ in\ NH)/365$$

Number of restraints measures per mean resident and per month: for each year, NH will report the number of restraint measures episodes enacted. The number of falls per mean resident and per year will then be computed for each NH using the following formula:

$$(total\ number\ of\ restraint\ measures\ episodes)/(total\ number\ of\ days\ spent\ in\ NH)/365$$

Statistical analysis

The treatment groups were randomly allocated among nursing-homes (NH). The analyst will be blinded with regard to the allocation.

Analyses will be performed at NH level, the NH being the unit of analysis (i.e. there is one data point per NH per variable).

Data preparation

The data of 2017 and 2018 will be pooled for the analysis.

Data will be transferred to the statistician in an Excel spreadsheet and then imported into the Statistical package Stata (StataCorp LLC, College Station, Texas, USA). All data preparations and analyses will be performed on Stata.

The presence of missing values will be checked and the number of missing values quantified for each variable.

The overall proportion of galenic units considered inappropriate (primary outcome) will be calculated with the formula above. The probability distribution of the difference between

baseline and 12 months (primary outcome) will be checked by means of a histogram and the calculation of skewness and kurtosis. If normality cannot be assumed, data will not be transformed (see Data analysis). The same will be done for all the secondary outcomes listed above.

Descriptive analysis

All descriptive statistics will be reported separately for the two study groups.

The overall proportion of galenic units considered inappropriate will be described at baseline and 12 months by its mean, standard deviation (SD), median, interquartile range (IQR), minimum and maximum values. The same statistics will be reported for the difference between 12 months and baseline.

The very same procedure will be applied to describe the proportion of probably inappropriate galenic units and of possibly inappropriate galenic units (two variables), and the proportion of probably inappropriate DDDs and of possibly inappropriate DDDs (two variables) plus these variables' differences between baseline and 12 months.

The same statistics will be calculated for: number of hospital days/mean resident/year; mortality rate; number of falls/mean resident/month; number of restraint measures/mean resident/month. These variables have no longitudinal structure.

NH population will be described by the number of residents, sex ratio, and mean resident age.

Inferential analysis

The analysis will follow the intention to treat approach. However, it is expected that all NH comply with the intervention group they have been randomized into.

No formal statistical tests will be applied to compare NH groups for the variables measured before randomization.

If the primary outcome follows a normal distribution and variances between intervention groups are equal, NH groups will be compared by means of linear least-square regression under adjustment for baseline. In case of heteroscedasticity, a robust estimation of the variance will be applied. If the outcome does not follow a sufficiently normal distribution, a generalised linear model (GLM) will be applied with the most appropriate distribution and link function. Residual diagnostics will be used to check the quality of the statistical model. If it is not possible to find an acceptable model, the two NH groups will be compared by means of a Mann-Whitney test without baseline adjustment.

The same procedure will be used to compare the differences between baseline and 12 months for the proportion of probably inappropriate galenic units and of possibly inappropriate galenic units (two variables), the proportion of probably inappropriate DDDs and of possibly inappropriate DDDs (two variables) and for mortality rate.

The number of hospital days/mean resident/year, number of falls/mean resident/month; and number of restraint measures/mean resident/month, being counts, are likely to follow a Poisson distribution. Therefore, a GLM with family Poisson and logarithmic link function will be applied first.