

Switzerland - Standardised brief geriatric evaluation versus routine care for preventing functional decline in general practice: a pragmatic cluster-randomised trial, AGE3

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Overview

Identification

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10.16909-DATASET-23

Version

VERSION DESCRIPTION

Version 1.0

PRODUCTION DATE

2020-04-20

Overview

ABSTRACT

Objective. To determine whether a systematic geriatric evaluation performed by general practitioners (GPs) that includes a brief assessment of geriatric syndromes and a management plan can prevent functional decline in older patients.

Design. Controlled, open-label, pragmatic cluster-randomised trial, randomising at the GP level.

Setting. 42 GP practices, western Switzerland.

Participants. Participating GPs had to work at least 20 hours per week as GPs in French-speaking Switzerland, and were expected to enroll ten community-dwelling adults at least 75-years-old, able to understand French, and having visited their GP at least twice in the prior year.

Intervention. Yearly assessment by the GP of eight geriatric syndromes associated with ad hoc management plans.

Main outcome measures. The primary outcome was, at individual participant level, the proportion of patients losing at least one instrumental activity of daily living (IADL) over two years, compared by a generalised 2-level mixed model with a logit regression. Secondary outcomes were losses in basic ADLs and quality-of-life (WHOQOL-OLD) scores. After complete case analysis, predefined sensitivity analyses were performed with last observation carried forward and considering patients who died or were institutionalized as having lost an IADL.

Randomization and masking. The randomisation unit was the GP, with GPs assigned on a 1:1 ratio to the intervention or usual care arm, based on a computer-based randomisation list, using uneven block sizes. GPs were allocated to their respective arm after patient enrolment. The study staff performing the main outcome measures (telephone interviews), study coordinator and study statistician were blinded to the allocation.

Results: 42 GPs recruited 429 participants of mean age 82.5 years (SD 4.8) at inclusion, 63% women, with 217 participants allocated to the intervention and 212 to the control arm. The proportion of patients losing at least one IADL during the course of the study was 43.6% and 47.6% in the intervention and control arms, respectively ($p=0.476$). Mean reduction in quality-of-life score was -0.12 and 0.74 ($p=0.331$). There was no difference between arms in any of the outcomes considered. Concerning adherence to the intervention, 85.7% (186/217) of patients in the intervention arm had at least one assessment and GPs adhered to 43.4% of the recommendations in the management plans.

Conclusion. A yearly geriatric evaluation associated with a management plan conducted systematically among community-dwelling, ≥ 75 -year-old patients in GP practices does not lessen functional decline.

Trial registration. The trial was registered in ClinicalTrials.gov with identifier NCT02618291.

UNITS OF ANALYSIS

429 individuals from 42 clusters

KEYWORDS

Functional decline, geriatric assessment, geriatric syndrome, activities of daily living, primary care, general practice

Coverage

GEOGRAPHIC COVERAGE

Western Switzerland (cantons of Vaud, Neuchâtel, Fribourg)

UNIVERSE

family medicine patients aged 75 years and older

Producers and Sponsors

PRIMARY INVESTIGATOR(S)

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FUNDING

Name	Abbreviation	Role
Swiss National Science Foundation	SNF	

OTHER ACKNOWLEDGEMENTS

Name	Affiliation	Role
Viret, Ophélie	Center for Primary Care and Public Health (Unisanté), University of Lausanne, Switzerland	Data acquisition
Cornuz, Jacques	Center for Primary Care and Public Health (Unisanté), University of Lausanne, Switzerland	input into the study conception
Büla, Christophe	CHUV	input into the study conception
Price, Mélanie		English editing

Metadata Production

METADATA PRODUCED BY

Name	Abbreviation	Affiliation	Role
Center for Primary Care and Public Health (Unisanté), University of Lausanne, Switzerland	Unisanté		Data publisher

DDI DOCUMENT VERSION

Version 1.0 (November 2020)

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Sampling

Sampling Procedure

Consecutive enrolment or random sampling at family physician level

Questionnaires

Overview

eCRF (secuTrial)

Data Collection

Data Collection Dates

Start	End	Cycle
2016-08-12	2020-01-31	N/A

Data Collection Mode

phone interview, data extraction from medical file

Data Collection Notes

Questionnaires

eCRF (secuTrial)

Data Processing

Data Editing

Electronic and central data validation

AGE3 data are collected via secuTrial.

Predefined checks incorporated in secuTrial concern mainly:

- Respect of the time intervals between annual study visits.
- Height (≥ 120 and < 220 cm)

Secutrial software has an inbuilt data management tool allowing investigators to produce queries. Each form is revised by a member of the study staff. After solving of the pending queries, each form is locked, preventing further modification.

Completion status of each section was predefined during database development. The secuTrial system includes visual aid to inform of data entry completion.

Monthly exports of the data as .csv files were performed by the data manager and stored in her personal folder. Data were then transformed to respect anonymisation (excluding Contact information) and blinding of study coordinator (_4_egb and _10_plansoins forms unlinked to study ID), and stored in .dta format for further management within Stata.

The study coordinator performed monthly data monitoring, to identify missing items or discrepancies, in which case an electronic query was made in secuTrial to the person responsible of data entry for this section.

Source data validation (when applicable) was performed by the study assistant during his/her annual visits to each practice ("review A"). These visits were also an opportunity to solve all remaining queries.

A final data validation took place when data entry was considered complete. The database was locked after all study data had been validated and monitoring review had been completed.

Data Appraisal

No content available