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BMJ Open Efficacy of nurse-led and general practitioner-led comprehensive geriatric assessment in primary care: protocol of a pragmatic three-arm cluster randomised controlled trial (CEpiA study)

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The protocol was presented in part at the Collège National des Généralistes Enseignants (CNGE) congress in November 2016.

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ABSTRACT

Introduction Older patients raise therapeutic challenges, because they constitute a heterogeneous population with multimorbidity. To appraise this complexity, geriatricians have developed a multidimensional comprehensive geriatric assessment (CGA), which may be difficult to apply in primary care settings. Our primary objective was to compare the effect on morbimortality of usual care compared with two complex interventions combining educational seminars about CGA: a dedicated geriatric hotline for general practitioners (GPs) and CGA by trained nurses or GPs.

Methods and analysis The Clinical Epidemiology and Ageing study is an open-label, pragmatic, multicentre, three-arm, cluster randomised controlled trial comparing two intervention groups and one control group. Patients must be 70 years or older with a long-term illness or with unscheduled hospitalisation in the past 3 months (750 patients planned). This study involves volunteering GPs practising in French primary care centres, with randomisation at the practice level. The multifaceted interventions for interventional arms comprise an educational interactive multiprofessional seminar for GPs and nurses, a geriatric hotline dedicated to GPs in case of difficulties and the performance of a CGA updated to primary care. The CGA is systematically performed by a nurse in arm 1 but is GP-led on a case-by-case basis in arm 2. The primary endpoint is a composite criterion comprising overall death, unscheduled hospitalisations, emergency admissions and institutionalisation within 12 months after inclusion. Intention-to-treat analysis will be performed using mixed-effects logistic regression models, with adjustment for potential confounders.

Ethics and dissemination The protocol was approved by an appropriate ethics committee (CPP Ile-de-France IV, Paris, France, approval April 2015;15 664). This study is conducted according to principles of good clinical practice in the context of current care and will provide useful knowledge on the clinical benefits achievable by CGA in primary care.

Trial registration number NCT02664454; Pre-results.

Strengths and limitations of this study

- Pragmatic multifaceted intervention using a patient-centred approach to improve management of older patients with chronic conditions.
- Thorough adaptation of the comprehensive geriatric assessment (CGA) procedure to the primary care setting.
- Three-arm trial design to assess the influence of the stakeholder conducting the CGA.
- Time-consuming procedure whose actual usability in real-life setting still needs to be confirmed.

INTRODUCTION

The ageing population observed in most industrialised countries imposes new challenges on society that require healthcare systems to rapidly adapt and develop new solutions.¹ The proportion of people ≥65 years old was 18.5% in the European Union in 2014, a number projected to reach almost 30% by 2080, with the percentage of ≥80 years old expected to increase from 5% to 12% over the same period.² Older patients raise therapeutic challenges, because they constitute a heterogeneous population with various combinations of geriatric syndromes, disabilities and comorbidities. Such heterogeneity relates to the concept of frailty, a clinical syndrome reflecting a decrease in physiological reserve capacities and altered adaptive mechanisms to stress.³ Frailty has been linked to increased risk of falls, hospitalisations, disability, long-term care and death.⁴⁻⁹

To appraise complexity in the older population, geriatricians have developed a thorough assessment method: the comprehensive geriatric assessment (CGA). The CGA is a multidimensional, multidisciplinary assessment

designed to evaluate functional ability, physical health, cognition and mental health, and socioenvironmental circumstances for detecting unidentified and potentially reversible problems. The CGA allows to develop a coordinated and integrated plan for treatment and follow-up through implementation of a personalised care plan (PCP).¹⁰ It has been found useful to characterise functional and health impairments in older patients, particularly in the geriatric oncological setting.^{11 12} However, a large implementation of geriatrician-led CGA at the population level may prove difficult due to feasibility constraints, thus requiring the involvement of non-geriatricians health professionals.

Despite its hypothetical benefits, the CGA is still underused in the primary care setting and not fully integrated in the medical routine of general practitioners (GPs) who assess and manage older patients with frailty factors and comorbidities on a daily basis.¹³ Depending on the definition, estimates of the prevalence of multimorbidity in older people range from 50% to 90% in primary care.^{14–16} Limits to wider diffusion of CGA are not fully known but may include the time-consuming aspect or the limited perceived added value of the CGA by GPs. Also, the evidence base for managing multimorbidity and preventing disease complications is still mostly based on a disease-specific approach as opposed to patient-centred approaches.¹⁴ Thus, promoting a more global and comprehensive view of the patient by use of the CGA could be desirable for managing frail older patients in their full complexity.^{14 17–20}

Limited and conflicting evidence is available on the clinical impact of CGA in primary care, with varying findings depending on the study population and how the CGA was implemented. Home CGA programmes and CGA performed in the hospital have been found beneficial for several health outcomes, but conflicting results were observed for posthospital discharge CGA programmes, CGA-based in patient geriatric consultation services and outpatient CGA consultations.²¹ Regarding overall survival, most studies conducted in primary care did not find significant benefits^{21–26} but a moderate reduction in mortality for patients at high risk of falls²² and in those <78 years old.^{26 27} A recent study showed that inhome CGA performed by trained medical students for patients >70 years old could reduce mortality by 20%.²⁸ As for other outcomes, there is moderate evidence that CGA may reduce the risk of functional decline,^{22 26 28} institutionalisation^{26 28} and admissions.^{28 29}

Several key factors may limit the efficacy of CGA in primary care and contribute to such conflicting results, including the difficulty to target the appropriate eligible population from community-dwelling older subjects to postdischarge frail patients, lack of pluriprofessional collaborations, training of health professionals and integration of health and social services and compliance and monitoring of the PCP.³⁰ In France, despite a CGA adapted to the primary care setting recently recommended by the French health authority, Haute Autorité de Santé (HAS),

no randomised study has yet assessed the impact of such a CGA-based complex intervention. There is a need to further assess the feasibility, potential barriers to implementation and clinical interest of CGA in primary care.

Hypothesis and study aims

We hypothesised that a complex intervention including a CGA adapted to primary care, educational training and specialised geriatric phone support to GPs is more effective for morbimortality than routine medical care for patients ≥70 years old with long-term health conditions.

Our primary objective with a composite outcome, including 1-year all-cause mortality, emergency admissions, unplanned hospitalisations and institutionalisation, is to assess the effect of two complex interventions combining (1) a 1-day multiprofessional educational seminar about CGA for GPs and nurses, (2) a dedicated geriatric hotline for GPs and (3) a systematic nurse-led CGA for one arm and a GP-led CGA on a case-by-case basis for the second arm. Those interventions will be compared with a control group (usual care) and between themselves.

Secondary objectives are to (1) assess the effect of the interventions on each component of the composite primary criteria; (2) assess the effect on quality of life, prevention of functional decline and polypharmacy; and (3) describe GPs' and nurses' satisfaction with the intervention in its two modalities.

METHODS AND ANALYSIS

Study design

The Clinical Epidemiology and Ageing (CEpiA) study is an open-label, pragmatic, multicentre, three-arm, cluster randomised controlled trial with a 12-month follow-up. Two experimental groups are compared with a control group and between themselves. The patient flow chart is shown in [figure 1](#). The two intervention modalities to be tested may induce modification of the organisation and practices for participating GP offices, with physicians modifying their practices on a daily basis and potentially sharing experience within participating practices. Consequently, cluster randomisation at the GP office level will be used rather than at the patient or individual GP level to avoid contamination bias between control and experimental groups. The unit of randomisation is the GP office, but the unit of analysis for the primary outcome will be the patient, using statistical approaches appropriate for hierarchical data (patients nested within the GP office). Outcomes will be assessed at 6-month and 12-month follow-up. Results will be reported according to Consolidated Standards of Reporting Trials guidelines and the extension for cluster randomised trials.³¹ The trial is registered at ClinicalTrials.gov (NCT02664454).

Participants

In accordance with our main hypothesis, the interventions tested are expected to be effective in older patients

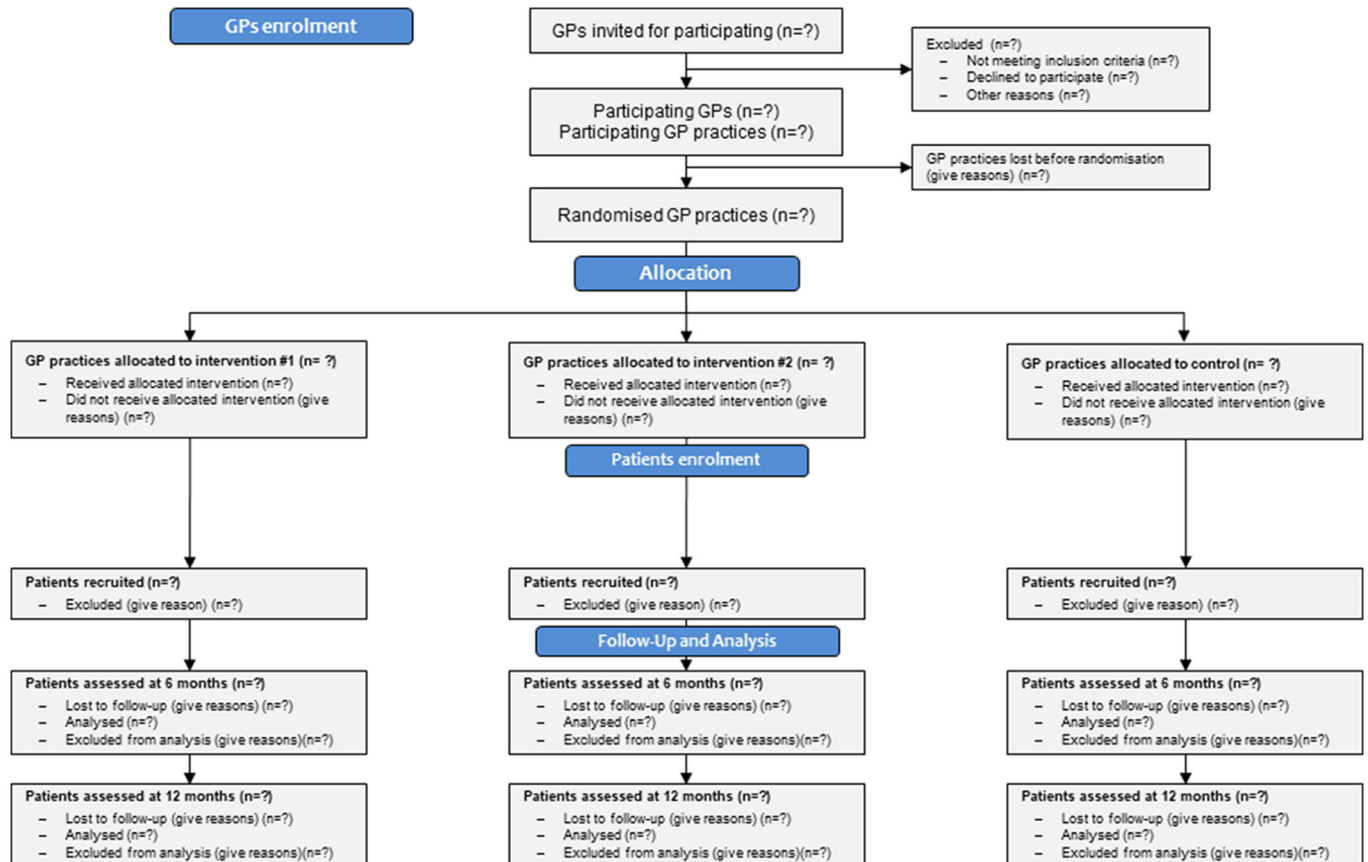


Figure 1 CONSORT flow chart. CONSORT, Consolidated Standards of Reporting Trials; GP, general practitioner.

with mild-to-moderate levels of frailty, including those recently hospitalised and/or with care for chronic disease but still living at home or in a residential home (without nursing care).

Inclusion criteria for patients participating in the study are therefore:

- ▶ aged 70 years and older
- ▶ with a long-term illness as detailed in online supplementary table 1 and/or having an unscheduled hospitalisation in the past 3 months
- ▶ currently cared for by one of the participating GPs
- ▶ informed consent given by the patient or legal representative.

Exclusion criteria include:

- ▶ not speaking or understanding French
- ▶ life expectancy judged by the GP to be <1 year
- ▶ currently institutionalised (ie, nursing home)
- ▶ no health insurance coverage.

Recruitment of health professionals

GPs from three French administrative regions, that is, Ile-de-France, Hauts-de-France, and Champagne-Ardennes, will be invited to participate in the study, by email and/or telephone. All GPs willing to participate will be eligible for the study regardless of the type of practice/offices they work in, including a traditional GP office with one or more GPs, municipal health centres and multidisciplinary practices (*Maisons de Santé Pluri-Professionnelles*).

Patient screening and inclusion

Before randomisation, participating GPs will be invited to screen their patient lists to identify potential eligible patients and facilitate further conduct of the study. Once GP practices will be randomised to one of the three trial arms, patients seen consecutively during consultations or home visits and in compliance with eligibility criteria will be given oral and written information about the trial by the participating GP. Eligible patients will be included after oral informed consent is obtained in conformity with French legislation for the present study.

Randomisation and masking

Randomisation will be computer-generated with an allocation list prepared by an independent statistician not involved in patient enrolment or in the final analysis. Despite randomisation, imbalance of important prognostic factors may still occur in cluster randomised trials that generally rely on a relatively small number of units. To account for this risk, a specific procedure for optimised allocation^{32–34} will be used to achieve optimal balance for the following GP practice characteristics: setting type (rural/urban), proportion of patients ≥ 70 years old during the last year, number of GPs and presence/absence of a nurse in the practice. All units will be enrolled before randomisation, which will allow for collecting this information beforehand. The procedure is based on the calculation of all possible allocations with

estimation of a balanced statistic for each one. A subset of all allocations with the highest degree of balance (ie, 1% lowest measures of imbalance) is then identified, from which the final allocation is randomly selected. At the time of the paper's writing, agreement to participate has been obtained from 40 GP practices, yielding an extremely large total number of possible allocations—more than 1×10^{17} —too computationally intensive to allow for direct calculations. To overcome this limitation, randomisation will thus be performed in three blocks, using block size of 14, 13 and 13 units. Allocation of the greater number of units in each block (ie, 5 units vs 4 and 4 for the other two arms in 13-unit blocks; 5 and 5 units vs 4 for the third arm in the 14-unit block) will be determined following recommendations by Carter *et al* regarding odd block sizes.³⁴ Specifically, the greater number of units will be randomly allocated to one of the three arms for the first block, then randomly allocated to one of the two remaining arms for the second block and finally automatically allocated to the remaining four-unit arm for the last block, thus ensuring equal allocation of GP practices for all three arms.

Because the nature of the intervention precludes blinding the patients and participating GPs, the trial is an open-label study. However, primary and secondary outcomes will be analysed with blinding of the trial statistician, masked to arm allocation.

Study interventions

Interventions deployed in arms 1 and 2 are multifaceted and will comprise three components (figure 2): (1) an interactive and multiprofessional educational seminar

targeted to both GPs and nurses and organised before including patients; (2) a geriatric phone hotline dedicated to helping GPs in case of difficulties encountered with the CGA findings and/or the implementation of corrective actions during the study; and (3) the provision of tools adapted to primary care for the CGA of included patients. Specifically, the CGA will be systematically performed by a trained nurse in arm 1 and the GPs themselves when deemed necessary in arm 2.

Educational seminar

Three 1-day interactive multiprofessional educational seminars are planned for all participating health professionals allocated to one of the two experimental arms. Detailed objectives and the content of the seminar are in box 1. The main objective is to provide participants tools and guidelines to improve the quality of care for patients ≥ 70 years old with chronic conditions. The seminars focus on general principles and reported benefits of CGA, its implementation in primary care using the adapted tool proposed in the study and the actions to plan based on the CGA results and formalised in a PCP. Specific objectives are to train professionals to identify clinical situations requiring a CGA; specify the objectives and features of the CGA for older patients with chronic conditions; adapt and use the tools proposed in the study CGA (see below 'CGA adapted to primary care'); choose realistic strategies taking into account the CGA findings and guidelines and priorities of the patient with a patient-centred approach; create a PCP in concert with other healthcare professionals; formalise aids and/or

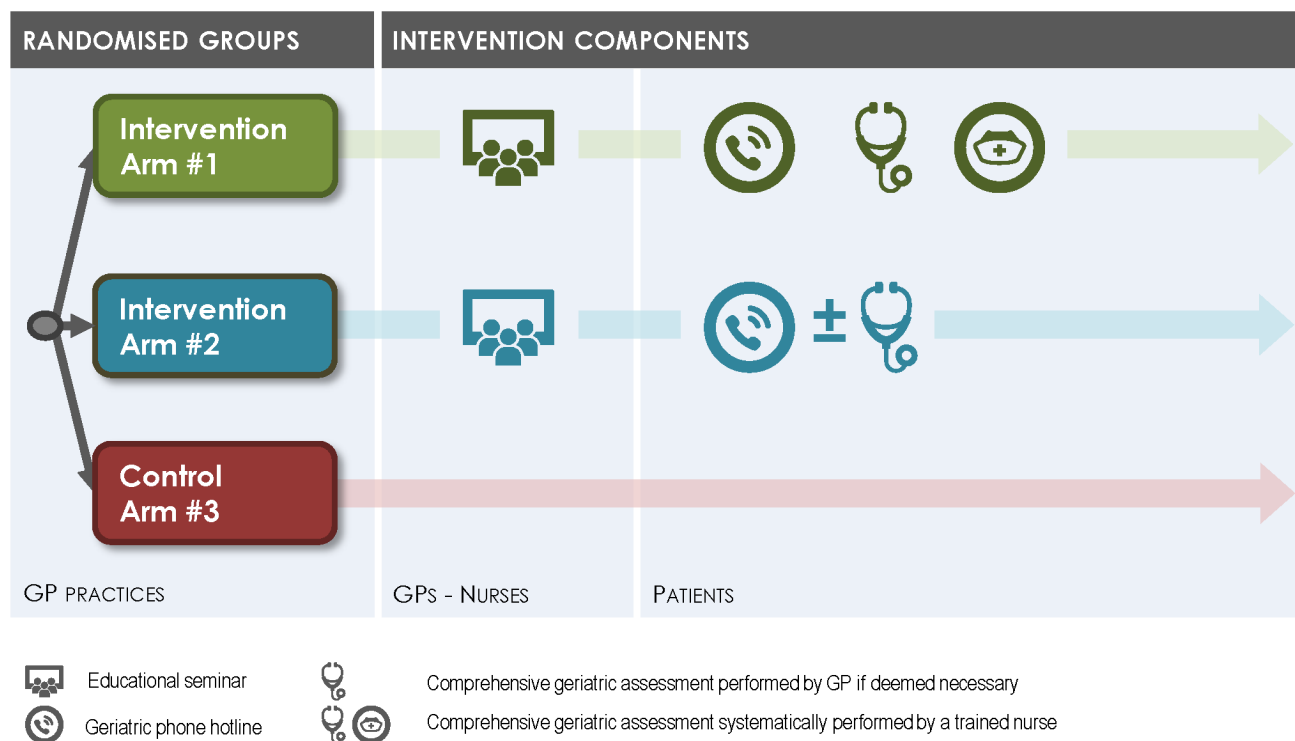


Figure 2 Intervention components. GP, general practitioner.

Box 1 Educational seminar programme

One-day multiprofessional interactive educational seminar

Before seminar: electronic questionnaire completion (demographic, comprehensive geriatric assessment (CGA) tools used in their practice and in what clinical situations). General practitioners (GPs) are asked to bring the assessment tools they usually use.

Main objective: to improve the quality of care for patients ≥ 70 years old with chronic conditions with a CGA adapted to primary care followed by the development of a personalised care plan (PCP).

Specific educational objectives: identify clinical situations requiring a CGA adapted to the primary care setting; specify the objectives and features of the CGA for older patients with chronic conditions; use tools proposed in the CGA; choose realistic strategies taking into account CGA findings, guidelines and priorities of the patient with a patient-centred approach; create a PCP in concert with other healthcare professionals; formalise aids and/or care and/or therapeutic education actions; and coordinate and monitor the patient and reassess the implementation of the PCP.

1st half-day

8:30–9:00 *Welcome to attendees*

9:00–9:15 *Presentation of the seminar*

9:15–10:00 *Small group workshop:* educational method: group discussion on challenges and strategies to assess and monitor old and very old patients with chronic conditions

10:00–10:45 *Small group workshop:* distribution and appropriation of the CGA tool and PCP by the attendees. Collection of questions related to the tools.

10:45–11:00 *Break*

11:00–12:15 *Interactive plenary:* concise report groups; experts present the data on the effect of CGA in older patients, usefulness of CGA, health domains to assess and the Clinical Epidemiology and Ageing tool of the study (CGA+PCP), actions to plan taking into account CGA findings and based on guidelines. Experts answer questions based on the needs of the attendees.

12:15–13:15 *Lunch*

2nd half-day

13:15–14:00 *Presentation of the case report form: inclusion patient procedure and data collection*

14:00–16:00 *Small group workshop: 'From the CGA to the PCP':* educational method: two role-play sessions using two different clinical situations. One of the two participants play the role of an older patient with chronic conditions (case 1) and the other plays the role of the evaluator (GP or nurse). The assessor completes the tool and the PCP. Data from the assessment will be given before the one who plays the role of patient. After the first role play, participants reverse their role and whoever plays the patient uses the case 2.

16:00–16:15 *Break*

16:15–16:45 *Interactive plenary:* groups' feedback and discussion about difficulties related to the use of the tool and PCP especially when the evaluation was conducted by the nurse. Experts answer questions based on the needs of the attendees. Expert also present the importance of patient-centred approach and shared decision making.

16:45–17:30 *Small group workshop: 'Follow-up of the patient with a PCP':* educational method: one role-play session using the same situations with follow-up visit at 2 months (one workshop takes the case 1 and the other workshop case 2). One participant plays the role of the patient and the other the role of the GP. The instruction given to the one who plays the patient is that planned objectives were not or partially achieved. What actions to take?

17:30–18:30 *Interactive plenary+summary and evaluation of the day+study setting-up*

care and/or therapeutic education actions; and coordinate and monitor the patient and reassess the implementation of the PCP.

The seminar will be delivered by three physicians of the study steering committee (ie, two GPs with expertise in the geriatric field (EF and CA) and one geriatric expert for each seminar (EP or SH or SK)). Small-group workshops will alternate with plenary sessions. Educational methods used during workshops will be group discussion and role-play sessions. Printed and emailed material showing guidelines, references and expert presentations will be provided to the attendees at the end of the seminar.

Geriatric phone hotline

After the educational seminars are given and until the end of inclusion and follow-up of patients, a geriatric phone hotline will be available to offer GPs allocated to experimental arms geriatric advice on CGA findings and/or the implementation of corrective actions when creating the PCP. The hotline is not intended to advise GPs on using the CGA tool, and therefore no advice is given before any CGA has been performed. This hotline will be available 5 days a week (Monday to Friday) from 09:00 to 16:30. The medical secretary of the geriatric ward of the University Henri Mondor Hospital, France, will receive calls and will transfer them to the expert geriatricians of the study. Depending on the urgency of the request, the geriatrician will answer immediately or later the same day.

CGA adapted to primary care and PCP based on CGA findings

As showcased during the seminar, a specific instrument will be used by participating GPs and nurses to conduct a CGA adapted to primary care for non-geriatricians healthcare professionals and then build a PCP of actions. A description of the adapted CGA and a PCP template are shown in [table 1](#) and [table 2](#), respectively.

The CGA tool was developed by two GPs trained in the geriatric field, two epidemiologists and three geriatricians by using French guidelines for assessing frail older patients in primary care.³⁵ Domains assessed by the instrument cover chronic diseases and polypharmacy and social, nutritional, functional independence and mobility, sensorial, mood and cognitive functions. Potential deficiencies detected in each domain are then evaluated for concerns or demands from the patient; proposals for actions are finally made by a shared-decision process between patient and the professional.³⁶ The PCP includes the main identified problems prioritised after negotiation between the GP and patient, short-term (<3 months) and medium-term (<6 months) shared objectives, actions to plan, required professionals to achieve actions, indicators related to objectives and assessment of objectives achieved. The GP will give a copy of the PCP to the patient. Information on the level of achievement of PCP objectives will be collected in the case report form (CRF) at M6 and M12 (fully/partially/no).

Table 1 Content of geriatric assessment tool adapted to primary care

Health domain to assess	Tests used and cut-off	Management strategies proposed by the GP, the patients and from the shared decision-making process (<i>non-exhaustive list</i>)
Comorbidity* polypharmacy	<ul style="list-style-type: none"> ▶ Statements of a list of comorbidities and current state (compensated/stable or not). ▶ Search for urinary incontinence (leakage? protections?). ▶ Reassessment of treatments and prescriptions (polypharmacy, interactions, redundancies). ▶ Do you think the patient has a problem of recurring omissions of taking his medication? ▶ Does the patient complain about sleep disorders in the last 3 months? 	<ul style="list-style-type: none"> ▶ strengthening the treatment of chronic diseases (dose increase or addition of one or more drugs) or decrease the treatment (dose decrease or removal of one or more drugs) ▶ prescription of laboratory tests, imagery tests ▶ ensure a secure drug taken by a third Person/set up a pillbox ▶ specialist medical advice/request for geriatric advice ▶ proposition of therapeutic education actions ▶ strengthening the treatment of pain ▶ other
Nutritional status*	<ul style="list-style-type: none"> ▶ Search dry mouth, mastication difficulties? ▶ Does the patient have a loss of appetite? Has he or she eaten less these last 3 months because of lack of appetite, digestive problems, chewing or swallowing difficulties (anorexia)? ▶ Percentage of weight loss in the past month and 6 months (malnutrition if weight loss $\geq 5\%$ in 1 month, or $\geq 10\%$ in 6 months). ▶ BMI (malnutrition if BMI $< 21 \text{ kg} / \text{m}^2$). ▶ Does the patient have dental problems that affect daily life? 	<ul style="list-style-type: none"> ▶ prescription of nutritional supplements ▶ dietary counselling provided by the GP ▶ request for dietitian advice ▶ oral/dental-care prescription ▶ aetiological treatment of malnutrition if appropriate ▶ request for geriatric advice ▶ other
Social status*	<ul style="list-style-type: none"> ▶ Does the patient live alone? ▶ Does the patient live in: house, apartment or retirement home? ▶ Presence of children, primary caregivers/entourage, home aids? ▶ Is the financial position ok? ▶ Does the patient benefit from an adequate healthcare coverage? ▶ Are housing conditions ok? (heating, access, safety, isolated habitat, dwelling in an area at risk) ▶ Does the patient have legal protection? ▶ Does the patient's social environment seem favourable to the patient's situation? 	<ul style="list-style-type: none"> ▶ implementation and/or increase of human aids ▶ implementation and/or increase of material aids ▶ improving access to care and rights ▶ social audit request ▶ request the personalised allocation of autonomy ▶ proposition of change of living place ▶ home furnishing ▶ legal protection measures ▶ other
Cognitive functions*	<ul style="list-style-type: none"> ▶ 5-word test of Dubois (abnormal if $< 10/10$) ▶ Clock-drawing test (abnormal if $< 7/7$) 	<ul style="list-style-type: none"> ▶ planning of a Mini Mental State Examination by the GP ▶ request for a specialised memory visit ▶ implementation and/or increase of human aids ▶ implementation and/or increase of material aids ▶ 6-month reassessment by the GP ▶ proposition of change of living place ▶ prescription of laboratory tests, imagery tests ▶ request for geriatric advice ▶ other
Mood*	<ul style="list-style-type: none"> ▶ Criteria for depression using the DSM-IV-TR (depression if at least five of the list of symptoms for at least 2 weeks and at least symptom 1 or two present) 	<ul style="list-style-type: none"> ▶ prescription of antidepressant drug ▶ prescription of another psychotropic drug ▶ dose increase ▶ reassessment and psychotherapeutic follow-up by the GP ▶ request for psychiatric advice and/or psychologist advice ▶ other
Sensorial functions*	<ul style="list-style-type: none"> ▶ Is the reading impaired? ▶ Does the patient complain of hearing decline that hinders the daily life? 	<ul style="list-style-type: none"> ▶ request for otorhinolaryngology advice ▶ request for ophthalmologist advice ▶ removing earwax by GP ▶ other

Continued

Table 1 Continued

Health domain to assess	Tests used and cut-off	Management strategies proposed by the GP, the patients and from the shared decision-making process (<i>non-exhaustive list</i>)
Functional independence* mobility	<ul style="list-style-type: none"> ▶ Activity of daily living of KATZ (abnormal if ≤5/6) ▶ Has the patient fallen in the last 6 months? ▶ Timed Up and Go Test (abnormal if >20s) 	<ul style="list-style-type: none"> ▶ prescription of motor physiotherapy ▶ prescription of physical activity tailored to the patient's possibilities ▶ implementation and/or increase of human aids ▶ implementation and/or increase of material aids ▶ home furnishing ▶ provide a remote alarm system ▶ prescription of pedicure care ▶ correction of fall trigger factors ▶ request for geriatric advice ▶ other

*For all domains (instruction).

The problems identified in the field of the domain assessed are they subject to request and/or concern (s) specific(s) of the patient ? (yes/no).

What actions seem necessary to implement?

A non-exhaustive list of care actions if proposed with the need to mention such actions is a priority for the professional, for the patient or is the result of the shared decision making (cf. right column).

In arm 1, the CGA will be systematically carried out by a local nurse trained in the CGA during the seminar, preferably at the patient's home but possibly in the office. Findings from the CGA will be communicated and discussed with the GP (onsite, mail, phone or visit) for developing the PCP together. The expected duration of CGA is about

40 min with an additional 10 min on average needed for the GP to create the PCP. In arm 2, the CGA and PCP will be left to the discretion of GP, performed at the office or during a home visit but without the help of a dedicated nurse. The expected duration of the GP-led CGA followed by PCP development is about 40–50 min.

Table 2 Personalised care plan template used in the CEpiA study

Personalised care plan			
N°...			
Problems identified and prioritised after negotiations between the professionals and the patient	Medium-term shared objectives (<3 months) and long-term (<6 months)	Title for care/aids actions (including therapeutic education actions)	Involved professionals
–	–	<ul style="list-style-type: none"> ▶ Modification of usual treatment <input type="checkbox"/> No <input type="checkbox"/> Recommended <input type="checkbox"/> Planned Please specify:..... 	<p>Indicators that define objectives completion</p> <p>Assessment of objectives achievement</p> <p>Completion status and comments</p> <p>Date : .../.../.....</p> <p>Have the results been achieved?</p> <p><input type="checkbox"/> Yes, fully</p> <p><input type="checkbox"/> Yes, partially</p> <p><input type="checkbox"/> No</p> <p>Comments:</p>
–	–	<ul style="list-style-type: none"> ▶ Social care <input type="checkbox"/> No <input type="checkbox"/> Recommended <input type="checkbox"/> Planned Please specify:..... 	
–	–	<ul style="list-style-type: none"> ▶ Nursing care <input type="checkbox"/> No <input type="checkbox"/> Recommended <input type="checkbox"/> Planned Please specify:..... 	
–	–	<ul style="list-style-type: none"> ▶ Motor physiotherapy <input type="checkbox"/> No <input type="checkbox"/> Recommended <input type="checkbox"/> Planned Please specify:..... 	
–	–	<ul style="list-style-type: none"> ▶ Dietary management <input type="checkbox"/> No <input type="checkbox"/> Recommended <input type="checkbox"/> Planned Please specify:..... 	
–	–	<ul style="list-style-type: none"> ▶ Psychological management <input type="checkbox"/> No <input type="checkbox"/> Recommended <input type="checkbox"/> Planned Please specify:..... 	

CEpiA, Clinical Epidemiology and Ageing.

In both arms, the CGA will be performed within the month following the inclusion of the patient. In arm 3 (usual care), GPs will follow their patients as usual, with no specific intervention or access to the geriatric phone hotline.

Information will be collected on the involvement of other health professionals—including physiotherapists, dietitians, psychologists and social workers—but modalities of such multidisciplinary collaborations for implementing the PCP will not be formalised in the protocol and left to the GP's discretion.

Measures

Patients will be followed up at 6 months and 12 months after the baseline assessment. Because the study population is focused on older subjects with a moderate level of frailty, that is, excluding those with a life expectancy less than a year and/or currently institutionalised, beneficial effects on morbimortality are expected from the intervention thanks to the initiation of new treatments guided by CGA findings. The primary endpoint is therefore a composite of any of the following events at 12 months: all-cause mortality, unscheduled hospitalisation, emergency admission and/or permanent admission to institutional care (eg, nursing home).

Secondary endpoints include each component of the composite primary endpoint at 12-month follow-up, as well as change from baseline to month 12 in health-related quality of life, assessed by the validated French version of the Duke questionnaire³⁷; functional independence assessed by the activity of daily living score³⁸; and number of prescribed drugs recorded from medical records. Feasibility, appropriation and satisfaction from the intervention will be assessed for descriptive purpose in GPs (arms 1 and 2) and nurses (arm 1) through an ad hoc self-reported questionnaire collected at end of study. This questionnaire was developed by the study steering committee and comprises 34 multiple-choice items addressing usual practices in management and follow-up of older patients, feasibility aspects, appropriation and satisfaction from the intervention, including the perceived utility of the proposed CGA and PCP, and comprising a free comment section. Comprehension and time for completion was tested beforehand in one nurse and three GPs not participating to the study.

A series of process indicators will also be recorded to measure intervention coverage in the two experimental arms, including number (%) of CGAs and PCPs performed, number (%) of care actions planned and number of (%) and reasons for calls to the geriatric hotline along with the corresponding geriatric advice given. Self-reported overall satisfaction with the intervention tested will be recorded from the participating GPs in the experimental arms at 12 months, by use of a questionnaire. The following data will be collected for patients for descriptive analyses, comparisons of baseline characteristics across groups and/or verifying eligibility criteria: demographic data, marital status, type and date

of onset of comorbidities (ie, cardiovascular risk factors, history of cancer and/or cardiovascular, metabolic, respiratory, kidney, liver, musculoskeletal and neuropsychological chronic diseases), current treatment, referral motive, history of hospitalisation and/or emergency admissions before inclusion and type and date of first qualification for the long-term illness. Information on comorbidities will be further used in subgroup analyses to identify potentially modified effects depending on levels of comorbidity. No specific instrument will be used for identifying frailty in the control group to limit the organised collection of data directly relating to frailty, which could induce modifications of practices in GPs by training or Hawthorne effect. The following data will be collected for GPs: age, gender, rural/urban practice and practice type among office/municipal health centre/multiprofessional health centre.

Data collection and follow-up

Three study visits with the GP are planned for participants: at month 0 (M0; inclusion visit), M6 (6 months after inclusion) and M12 (12 months after inclusion). Printed CRFs will be completed by GPs based on consultation findings and medical records. CRFs will be collected and monitored for consistency and missing data by clinical research technicians at M6 and M12 based on available hospital stay reports. Vital status will be determined from public records office. A summary of the main measures at the patient level and corresponding timetable is shown in table 3.

Table 3 Summary of measures and timetable

Measures	Inclusion	6-month visit	12-month visit
Primary endpoint components			
Vital status		•	•
Unscheduled hospitalisations		•	•
Emergency admissions		•	•
Permanent admission to institutional care		•	•
Secondary endpoints	•		•
Duke health-related quality of life questionnaire	•		•
Activity of daily living	•		•
Number of prescribed drugs	•	•	•
Demographics and marital status	•		
Past and current chronic diseases	•	•	•
Current treatment	•	•	•

Sample size and statistical analysis

Sample size calculation is based on the primary endpoint, the proportion of patients dead or who experienced an unscheduled hospitalisation, emergency admission or institutionalisation at 12 months. On the basis of available data from French social security databases,^{20 39} a basal rate of 35% is expected for the primary outcome with usual care (control group). The highest intervention effect is expected in arm 1, which fully deploys the multifaceted intervention, including performance of the adapted CGA by a dedicated nurse, whereas arm 2 relies only on the GP for completing this task.

At a two-sided type 1 error level of 5%, a total sample size of 510 patients (170 per group) would be required for 80% power for an individually randomised trial to detect a clinically relevant between-group difference of 15% between arm 1 and the control group. To account for test multiplicity, a fixed sequence test procedure will be used for subsequent pairwise comparisons between the three groups, following a prespecified order in accordance with our hypotheses, starting with the comparison of arm 1 with the control, followed by—if step-by-step comparisons are statistically significant—comparison of arm 1 to arm 2, and finally by comparison of arm 2 with the control. Because of the fixed sequence test procedure, no type 1 error adjustment is necessary, so all pairwise tests of the fixed sequence procedure can be performed bilateral at the 5% alpha level.

Assuming an intraclass correlation coefficient of 0.01 to account for the clustering of patients within GP practices^{40 41} and to compensate for inactive GPs and/or patients lost to follow-up (estimated at a maximum of 25%), a sample size of 40 clusters with a mean cluster size of 19 is required, yielding a total of 750 patients.

A detailed statistical analysis plan will be prepared and approved before the database is locked and final analysis by the trial statistician. Analyses for the primary and secondary outcomes will be based on the intention-to-treat (ITT) population at the level of the individual patient while accounting for clustering at the GP practice level by using mixed-effects models, introducing the practice as a random effect to account for intracluster correlation. Analysis of the primary endpoint and secondary endpoints of a binary nature (including the components of the primary endpoint at 1 year) will involve logistic mixed-effects regression models, assessing calibration and discrimination Area under curve receiver operating characteristic (ROC-AUC).⁴² Mixed-effects linear regression models will be used for quantitative criteria, taking into account the intracluster correlation and the repeated nature of data (M0, M6 and M12). Analyses of time to events (death, institutionalisation and hospitalisation) will be estimated by Kaplan-Meier curves, log rank univariate tests and multivariate Cox models, taking into account the intracluster correlation for the SE calculation (cluster effect), with Fine-Gray regression models for survival analysis by specific type of event (ie, hospitalisation, emergency admission and institutionalisation) to

account for competing risk of death. Supportive analyses in the per-protocol (PP) population will be performed to document the patients excluded from the PP, investigate the impact on ITT analysis and check whether similar results are obtained for a robust interpretation. Multiple imputation approaches will be considered to replace missing outcome data for the primary outcome analysis, and other imputation strategies (worst-case assumption, last observation carried forward) will be performed as sensitivity analyses to test the robustness of the main results.⁴³ All tests will be two sided, and $P < 0.05$ will be considered statistically significant. All analyses will involve use of Stata V.14.2 and R V.3.4.0 (R Foundation, Austria).

DISCUSSION AND DISSEMINATION

This cluster randomised trial in three parallel groups will provide robust evidence about the benefits on morbimortality of a pragmatic intervention to improve the management of older patients with chronic conditions. Through the use of a patient-centred approach, it will test strategies that aim to address difficulties encountered by GPs and, hopefully, improve outcomes that matter to patients. To account for previously reported findings on the inefficiency of interventions targeting institutionalised and/or extreme old patients,^{26 27} we will include patients ≥ 70 years old and living at home. Conducting pluriprofessional seminars with GPs, nurses and geriatrician experts might foster collaborations between professionals and therefore improve the coordination of care for the benefit of the patient. In addition, learning material will focus on the shared decision making in the CGA and PCP to promote a patient-centred approach, which has demonstrated significant benefits for health behaviours and satisfaction as well as consultation processes.^{44 45} Other strengths include the thorough adaptation of the CGA to the primary care setting, in line with current French guidelines for primary care CGA. This trial aims to facilitate sustainable collaborations between the primary care setting and hospital professionals. In contrast to approaches based on frailty screening and referral to a geriatrician, the proposed CGA directly mobilises physicians' resources in group practice ('GP empowerment'). The CEpiA study will finally provide new knowledge on the impact of the stakeholder conducting the CGA and whether trained nurses may be a key advantage for efficient CGA implementation.

The CEpiA trial has some limitations. Although the CGA has been adapted to the primary care setting for non-geriatricians healthcare professionals, preliminary tests suggest that it remains time-consuming (about 40–50 min to complete) and its actual usability in real-life setting still needs to be confirmed. Nevertheless, GPs can perform the CGA and PCP once or twice. The intervention comprises educational seminars targeted to professionals with busy schedules and whose attendance will be crucial to the efficacy of the procedure. Consequently, we plan to have several

reminders and organise additional training dates to train all GPs and nurses randomised to interventional arms. Second, GPs who choose to participate to the study may be more interested in and aware of frailty screening and management in older people than GPs who do not participate. Therefore, enrolled patients might be better followed up before and during the study in all arms, so detecting any potential intervention effect might be difficult. Finally, information on the outcomes will be collected by GPs who will be unblinded to the intervention. The potential resulting classification bias will however be limited, considering the objective nature of the endpoints analysed (mortality, hospitalisations and institutionalisation), the thorough verification of the CRF by clinical research technicians based on available hospital stay reports and the direct use of public records office for determining vital status.

Dissemination

The CEpiA study will determine whether a complex intervention based on an adaptation of CGA to primary care is feasible and efficient in terms of 1-year morbimortality. Findings will inform modifying or establishing new guidelines for managing older patients in primary care.

We will seek to publish in leading international geriatric and primary healthcare journals, present at major conferences and disseminate our findings widely through GPs and geriatrician networks.

Trial status

A total of 88 GPs from 40 practices agreed to participate in the study and were randomised to one of the three study arms on 21 December 2015. Educational seminars took place on 21 May 2016 and 2 and 3 June 2016 and involved 70 participants: 58 GPs from arms 1 and 2 and 12 nurses from arm 1. The first patient was included on 24 May 2016. The study is ongoing.

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