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Geriatric CO-mAnagement for Cardiology patients in the Hospital (G-COACH): study protocol of a prospective before-after study

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ABSTRACT

Introduction: Although the majority of older patients admitted to a cardiology unit present with at least one geriatric syndrome, guidelines on managing heart disease often do not consider the complex needs of frail older patients. Geriatric co-management has demonstrated potential to improve functional status, and reduce complications and length of stay, but evidence on the effectiveness in cardiology patients is lacking. This study aims to determine if geriatric co-management is superior to usual care in preventing functional decline, complications, mortality, readmission rates, reducing length of stay and improving quality of life in older patients admitted for acute heart disease or for Transcatheter Aortic Valve Implantation, and to identify determinants of success for geriatric co-management in this population.

Methods and analysis: This prospective quasi-experimental before-and-after study will be performed on two cardiology units of the University Hospitals Leuven in Belgium in patients aged ≥75 years. In the pre-cohort (n = 227), usual care will be documented. A multitude of implementation strategies will be applied to allow for successful implementation of the model. Patients in the after-cohort (n = 227) will undergo a comprehensive geriatric assessment within 24 hours of admission to stratify them into one of three groups based on their baseline risk for developing functional decline: low-risk patients receive proactive consultation, high-risk patients will be co-managed by the geriatric nurse to prevent complications, and patients with acute geriatric problems will receive an additional medication review and co-management by the geriatrician.

Ethics and dissemination: The study protocol was approved by the Medical Ethics Committee UZ Leuven/ KU Leuven (S58296). Written voluntary (proxy-)informed consent will be obtained from all participants at the start of the study. Dissemination of results will be through articles in scientific and professional journals both in English and Dutch and by conference presentations.

Trial registration: Clinicaltrials.gov: NCT02890927

Key words: Activities of Daily Living, Co-management, Frail Elderly, Geriatric Assessment, Geriatric Medicine, Heart failure

Strengths and limitations of this study

- A geriatric co-management intervention theory was developed to increase the a priori probability for a clinically meaningful effect.
- Stakeholder involvement in the development, feasibility and evaluation phase facilitates the implementation of a care programme that fits the local context and is deemed acceptable and feasible by all stakeholders.
- Exploration of components that contributed to the successful implementation using a mixed methods approach will inform scaling up and out of the care model.
- Because of the inability to randomise individual patients in this single-center study, there is a risk of residual confounding.

INTRODUCTION

Longevity is the result of improved population health, but at the same time leads to an absolute increase of people suffering from multiple chronic health problems and disability.[1] The complex care for these patients is hampered by the high prevalence of frailty, cognitive impairment and functional dependency, which has been associated with functional decline, increased mortality, hospital readmission, and need for new social support.[2-4] Concurringly, the majority of healthcare staff is not adequately trained to manage the complex geriatric needs of these older patients.[5] Inappropriate medication use, delirium, cognitive impairment, and depression are often not recognized in older patients, emphasizing the need for better geriatric care.[6-10]

Cardiovascular disease is the leading cause of death and hospitalisation in the Western world.[11] Notably, the majority of older patients admitted to a cardiology unit present with at least one geriatric syndrome.[2] Current evidence-based guidelines on the management of heart disease often do not consider the complex needs of frail older patients, and may even incur harm.[12] This has prompted researchers and clinicians to advocate for a closer collaboration between cardiology and geriatric medicine as the "management of cardiac issues is fundamentally linked to the frailties and multi-morbidities associated with advanced age".[12 13]

Comprehensive geriatric assessment (CGA) has previously been identified as the gold standard for managing geriatric patients, but has not yet been evaluated in older cardiology patients.[14] CGA refers to a "multidimensional, interdisciplinary diagnostic process to determine the medical, psychological and functional capabilities of an older person with frailty, followed by implementation of a coordinated and integrated plan for treatment and follow-up".[15] A model of care that embeds the principles of CGA is the geriatric consultation team model. Geriatric consultation teams are multidisciplinary mobile teams that assess older patients admitted to non-geriatric units and recommend a plan of treatment. However, a meta-analysis detected no significant effect on functional status, length of stay and readmission and only found a moderate beneficial effect on mortality at six and eight months after hospitalization.[16] Subsequently, geriatric co-management programmes have emerged as a new model of CGA-based care for non-geriatric units.

Geriatric co-management is defined as a shared responsibility and decision making between at least a primary treating physician (e.g., cardiologist) and a geriatrician or geriatric team who provides complementary medical care in the prevention and management of geriatric problems.[17] A recent meta-analysis observed a better functional status, a decrease in complications and a reduced length of stay in favour of co-managed patients.[18] These results confirm the potential value of geriatric co-management, but also indicate a need to further evaluate the concept due to the low-quality of evidence. Furthermore, only four studies with inconsistent results assessed functional status as outcome and the majority of studies were performed in orthopedic patients.[18] There is currently no evidence on the effectiveness of geriatric co-management in older cardiology patients.

This protocol is part of the G-COACH project, which aims to develop and evaluate an in-hospital cardio-geriatric co-management model using a mixed-methods multi-phase methodology. The aim of this paper is to present a

detailed overview of the methodology of the G-COACH feasibility and effectiveness study, based on the SPIRIT statement.[19]

METHODOLOGY

Methodological framework

The G-COACH project is based upon the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (see Figure 1).[20] As part of the development phase of the MRC framework and in preparation of the feasibility and evaluation studies, we first developed an intervention theory for geriatric co-management that details how the G-COACH intervention will affect the desired change in outcomes. This theory was developed by integrating evidence from 1) a systematic review and meta-analysis on the effectiveness of geriatric co-management programmes,[18] 2) an international Delphi study that aimed to find consensus on appropriate and feasible structure, process and outcome indicators for the evaluation of in-hospital geriatric co-management programmes [21] and 3) an exploratory prospective cohort study in hospitalized patients with cardiac conditions to determine the incidence of in-hospital functional decline, the associated risk factors, and the link with care processes. [22]. Additionally, we developed a clinical prediction model that identifies patients who are at risk for developing functional decline during hospitalisation. This risk prediction model was built based on data from the pre-cohort of this intervention study, and will be used to identify patients in need for geriatric co-management, i.e. patients with an increased risk for functional decline (data not yet published).

The G-COACH feasibility and effectiveness study described in this paper concerns phase 2 and phase 3 of the MRC framework. However, to substantially increase the likelihood that the evaluated geriatric co-management programme moves from trial to real world, we use a hybrid 1 effectiveness-implementation design. [23] This means that in parallel with evaluating the effectiveness of the geriatric co-management model, we will gather information to inform future implementation strategies for scaling up and scaling out the geriatric co-management model. Hence, while trying to get an in-depth understanding of which intervention components are effective and which are not, we aim to provide a comprehensive overview of barriers and facilitators for large-scale implementation of the care model following its evaluation. The latter will be done by considering contextual factors that may influence the success of the implementation and the variation in outcomes from the very beginning of the project and by actively involving stakeholders in each project phase [23].

Study aims

The overall aim of the feasibility study is to 1) assess reach, fidelity and dose of the intervention; 2) investigate the perceived acceptability of the intervention by healthcare professionals and patients participating in the intervention and 3) determine facilitators and barriers for the implementation of the intervention.

The overall aim of the effectiveness study is twofold. The *outcome* evaluation will determine if geriatric co-management is superior in preventing in-hospital functional decline (primary outcome) and complications, reducing length of stay, decreasing mortality and readmission rates and improving quality of life in older patients admitted for acute heart disease or for Transcatheter Aortic Valve Implantation (TAVI) compared to usual care. The *process* evaluation will determine the quality of the implementation by investigating how well the fidelity and dose is maintained during the study period and how the geriatric co-management programme is adapted over time due to interaction with the local context [24].

Design and setting

This single-center, prospective, quasi-experimental before-and-after study will be performed on two cardiology units of the University Hospitals Leuven in Belgium. The University Hospitals Leuven is one of the seven university and tertiary hospitals in Belgium, and has 1995 beds. The two general cardiology units consist of 44 hospitalisation beds. Between recruiting patients in the before and after-cohort, the geriatric co-management intervention will be implemented and piloted to assess its feasibility.

Study population

Dutch-speaking patients aged 75 years or over are included if they are admitted through the emergency department or cardiology outpatient services for non-surgical treatment of acute heart disease or TAVI, have an expected length of stay of ≥ 3 days and give (proxy) informed consent. Patients are excluded if they are admitted from another hospital or hospital unit (no baseline data for functional status), if they stay in the intensive care unit for three days or longer (health care professionals on these wards are not involved in the development of the geriatric co-management intervention and/or impossibility to execute core components of the intervention, e.g. mobility protocols) or if they receive palliative treatment on hospital admission.

Usual care

The control group receives usual care on the cardiology units. Team members include a cardiology or internal medicine resident supervised by a consultant cardiologist, ward nurses, a physiotherapist, a social worker and a dietician, who meet weekly at a multidisciplinary team meeting. A geriatric support team, consisting of seven geriatric nurses (3.8 FTE including one master-trained nurse), a master-trained head nurse (1 FTE), four occupational therapists (2 FTE) and two geriatricians (0.2 FTE), is available for consultation services upon request of all non-geriatric wards in the study hospital, including the cardiology wards. If consulted, the geriatric support team performs a CGA and gives written and oral recommendations about detected geriatric problems [25].

Geriatric co-management intervention

Every weekday a geriatric nurse is responsible for the geriatric co-management patients and conducts a CGA within 24 hours of admission in eligible patients newly admitted to the cardiology unit (See Figure 2). Subsequently, patients are stratified into one of three groups based on their baseline risk for developing functional decline. This risk prediction considers cognitive impairment (Mini-cog score), mobility impairment (use of ambulatory aid), nutritional risk status (Mini Nutritional Assessment score), depressive symptoms (Geriatric Depression Scale score) and the presence of physical restraint use or an indwelling urinary catheter (data not yet published).

Low risk patients are patients who are at low risk for developing functional decline during hospitalisation. The geriatric nurse provides a proactive consultation without systematic follow-up.

High risk patients are at risk for developing functional decline and other geriatric complications during hospitalisation. The geriatric nurse will work collaboratively with the cardiology team to prevent complications. Interventions include care coordination and bedside education by the geriatric nurse, early rehabilitation by a physical therapist, early discharge planning by a social worker, and availability of evidence-based protocols for the prevention and/or management of functional decline, falls, delirium, cognitive impairment, agitation, malnutrition, urinary incontinence, urinary retention, urinary tract infection, obstipation, pressure sores and pain. All intervention components selected from the protocols are tailored to the specific needs of an individual patient as detected with the CGA on admission. The geriatric nurse provides daily follow-up and coordinates the implementation of the protocols.

Patients with acute geriatric problems have developed one of the following geriatric syndromes: agitation, delirium, urinary retention, urinary incontinence or malnutrition (MNA < 8/14) and are subsequently considered to be at high risk of developing functional decline. These patients receive the same care as the high risk patients. Additionally, the geriatrician will perform a medication review based on clinical expertise and will co-manage the delirium, urinary retention, urinary incontinence and/or malnourishment with the cardiologist.

Implementation strategies

Changing the organisation and daily activities of a geriatric support team that has been working as a consultation team since 2005 is challenging. Both the geriatric support team and the healthcare professionals of the cardiology units need to take up a new role with new responsibilities and competencies. Since the aim is to change behaviour in both the geriatric support team and the cardiology teams, we use the Intervention Mapping taxonomy of behaviour change methods to ensure that our applied implementation strategies were targeting determinants that predict behaviour and were able to actually change that determinant [26]. Table 1 gives a detailed overview of the targeted determinants and practical strategies to change behaviour in the geriatric support and cardiology team.

Table 1. Implementation strategies and related behaviour change methods

Process	Determinant and Aim	Strategy	Taxonomy of behaviour change [26]
Orientation	Knowledge: Stakeholders are aware of the co-management programme	Listing all relevant stakeholders in the organisation	Participation
		Stakeholder meetings in initiation phase to propose programme with head of departments of geriatrics, cardiology, nursing, physiotherapy, nutritional therapy, social work and with head nurses of cardiology and geriatric support team, care programme managers and ICT	Consciousness raising Discussion Participation Systems change
		Use of G-COACH acronym in all communication	Chunking Repeated exposure
	Attitude: Stakeholders are interested and seek involvement in the co-management programme	Inclusion of stakeholders in consensus-development meetings for developing programme, focusing on definition, scope and goals of programme, intervention components and expected benefits	Motivational interviewing Participation
Insight	Knowledge: Stakeholders understand the goals, concepts and intervention components of the co-management programme	Educational presentations focusing on describing the care processes and outcomes of the current standard of care and new intervention components that are expected to improve processes and outcomes. Presentation included case discussion of geriatric needs and how the programme is expected to improve outcomes	Active learning Advance organizers Consciousness raising Discussion Persuasive communication
		Inclusion of stakeholders in consensus-development meetings for developing intervention protocols	Participation
		Intervention manual is available online and in hardcopy to stakeholders	Facilitation
		Publication of poster on participating units detailing the programme components and interventions	Cultural similarity Repeated exposure
	Knowledge: Stakeholders understand the geriatric needs of patients admitted to their unit and know the prevalence of geriatric syndromes on hospital admission and the incidence of geriatric complications during hospitalisation	Situational analysis to document geriatric care needs and the current standard of care by project team	Consciousness raising Organisational diagnosis and feedback
		Fact sheets are disseminated and short educational sessions are repeated in the feasibility and evaluation phase with the purpose of disseminating knowledge about geriatric needs to stakeholders based on the situational analysis	Consciousness raising Providing cues Repeated exposure
		Adaptations to the electronic patient file: risk stratification level and type of follow up visible for all eligible patients	Facilitation Providing cues Technical assistance
Acceptance	Positive attitude: Healthcare professionals are motivated to work with each other and collaborate as one interdisciplinary team	Contracting: an expert in group dynamics and leadership organises two sessions between stakeholders	Elaboration Nudging Shifting perspective
	Self-confidence: Stakeholders feel confident that participating in the co-management programme is feasible and that any problems arising will be solved	Inclusion of stakeholders in consensus-development meetings for developing programme, focusing on definition, scope and goals of programme, intervention components and expected benefits	Nudging Participation Systems change
		The intervention is tailored to match the local context by engaging stakeholders to ensure feasibility of the programme	Elaboration Systems change Tailoring
	Attitude: Stakeholders are convinced that the co-management programme is useful and effective to improve care outcomes for geriatric patients on their units	Programme support by head of department and head nurses	Participation
		Fact sheets and short educational sessions are repeated in the feasibility and evaluation phase with focus on impact and positive feedback on achieved goals	Active learning Advance organizers Consciousness raising Repeated exposure
	Attitude: Stakeholders have decided to change their standard of care and try-out the geriatric co-management programme	Official start of programme announced by head of department	Early commitment Persuasive communication
Systems change	Skills and organization of new care structures and processes: Stakeholders can try the co-	Phased implementation with evaluation of feasibility allowing the programme to adjust if necessary	Active learning Direct experience Feedback

	management programme on a small scale and gain experience and skills necessary for the programme		Guided practice Individualisation Tailoring
		Audit and feedback on implementation based on feasibility study	Discussion Feedback Participatory problem solving
	Skills, habits: Stakeholders have integrated the co-management programme in their daily care and routines	Working group: audit and feedback with key stakeholders from every discipline to discuss the adaptations that are needed to the programme based on audit and future needs	Feedback Participation Participatory problem solving Tailoring
	Qualified staff, self-confidence: Stakeholders are adequately staffed and skilled to try out the co-management programme	Coaching of geriatric nurses and geriatricians responsible for implementing the programme	Active learning Direct experience Feedback Guided practice Individualisation
Maintenance	Skills, habits: Stakeholders have integrated the co-management programme in their daily care and routines	Working group: audit and feedback with key stakeholders from every discipline to discuss the adaptations that are needed to the programme based on audit and future needs	Feedback Participation Participatory problem solving Tailoring
	Leadership, financial resources, opinion of leaders and key figures: University Hospitals Leuven has formally recognized ownership of the co-management programme	Dissemination of programme results to UZ Leuven staff and management	Agenda setting Feedback

The study coordinator (BVG) and research assistant (AJ) take up the role of external facilitators to allow for successful implementation of the G-COACH intervention. One month before the pilot implementation, they organised information sessions for all stakeholders: nurses, physicians, physiotherapists, occupational therapists, social workers, nutritional therapists and management from both the cardiology and geriatric department. Participants were informed on the current standard of care and the prevalence of geriatric problems. A sense of urgency of why change is needed was created. They were further informed on what will change, how it will change and what the intended benefits will be. Instructional materials, such as an electronic project manual including all intervention protocols, intervention pocket cards and posters, were distributed and training sessions were organised for the geriatric support team to explain and practice the intervention protocols. Finally, a meeting was organised with the external facilitators and geriatric support team to discuss how the team perceives the G-COACH intervention, their specific role, and to determine their needs for support towards the external facilitators. This meeting was led by a highly experienced external moderator of the Department of Leadership Development of the University Hospitals Leuven.

At the start of the implementation, an e-mail was sent by the medical head of the departments detailing both the study and instructional materials. The head nurses of the participating units supervised the start of the intervention. A working group was formed consisting of the head nurses of the cardiology units and the geriatric support team, two champion nurses of the cardiology ward, a geriatric expert nurse, cardiologist, geriatrician, physiotherapist, social worker and study coordinator. The purpose of this group that meets monthly, is to discuss the implementation of the intervention, e.g.: Are all intervention components implemented?; What are the reasons for non-implementation?; What are barriers for implementation; and Are adaptations to the

intervention needed?. Based on a consensus decision, the working group will propose changes to the intervention or formulate additional implementation strategies.

During the implementation phase, process data will be systematically collected from the electronic patient record and summarized by the study coordinator and research assistant to inform the working group. The study coordinator will organize short informational sessions throughout the study period to inform all stakeholders on the progression and success of the intervention. Weekly updates about the project are sent by mail to the geriatric support team and regular individual feedback sessions with the members of the geriatric support team are organised to emphasize which parts of the implementation of the intervention went well or were challenging.

Patient and public involvement

Patients and public were not involved in the development of the research questions and outcome measures, the design, recruitment of conduct of the study. Feedback of patients regarding the acceptability of the intervention is actively explore in the feasibility phase of the study using structured patient interviews.

Feasibility evaluation

The feasibility of the intervention will be assessed in a single intervention group before proceeding to the inclusion of patients in the after-cohort. The reach, fidelity (see table 2) and dose (see table 3) will be evaluated by trained researchers using a multi-methods approach.

Table 2. *Fidelity indicators*

Fidelity indicators	Adherence	Timing	Source
The intervention group assignment of a patient is documented in GER contact	Yes No	Within 24 hours of admission to c CAR	Electronic patient record
The intervention group assignment of a patient is documented in CAR contact	Yes No	Within 24 hours of admission to CAR	Electronic patient record
The intervention group assignment of a patient is documented in the patient file	Yes No	Within 24 hours of admission to CAR	Electronic patient record
The number of geriatric risks that are documented in the GER contact compared with the number of geriatric risks that are present	Proportion	Within 24 hours of admission to CAR	Electronic patient record
The number of geriatric complications that are documented in the GER contact compared to the number of geriatric complications that are present	Proportion	Within 24 hours of admission to CAR	Electronic patient record
A follow-up note summarizing the identified risks/complications and interventions is documented in the CAR contact	Yes No	Within 24 hours of admission to CAR	Electronic patient record
If a patient is at risk for functional decline or has experienced acute functional decline, the patient receives physiotherapy *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is at risk for functional decline or has experienced acute functional decline, the patient completes an individual exercise programme *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is at risk for delirium or has developed delirium, the patient receives physiotherapy	Yes No	Within 24 hours of detection	Electronic patient record
If a patient is at risk for delirium or has developed delirium, the patient completes an individual exercise programme	Yes No	Within 24 hours of detection	Electronic patient record
If a patients is at risk for malnutrition or is malnourished, the patient receives a nutritional intervention by a dietician *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is in need for discharge planning, the patient is seen by a social worker	Yes No	Within 48 hours of admission to CAR	Electronic patient record

If a patient developed acute functional decline at hospital admission, the patients receives ADL-training by an occupational therapist.	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is demonstrating agitation, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient is demonstrating agitation, the precipitating factors for the agitation are document in de patients' record	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient is delirious, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient is delirious, the precipitating factors for the delirium are document in de patients' record	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient has a swallowing disorder and is placed on a 'nothing by mouth' order, the patient receives parenteral or intravenous nutritional support	Yes No	Within 2 days	Electronic patient record
If a patient has not passed stool for 3 days, the patient is prescribed oral laxatives *	Yes No	Before day 4 without stool	Electronic patient record
If a patient has not passed stool for 5 days, the patient receives an enema *	Yes No	Before day 6 without stool	Electronic patient record
If a patient reports acute urinary incontinence, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient reports acute urinary incontinence, the precipitating factors for the incontinence are documented in the patients' record	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient reports acute urinary retention, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a post-void residual volume of ≥ 300ml is observed in a patient, the residual volume is removed using intermittent catheterization	Yes No	Before end of shift after detection of symptoms	Electronic patient record
If a post-void residual volume of ≥ 300ml is observed in a patient, the post-void residual volume is monitored using a bladder scan in the next shift	Yes No	n/a	Electronic patient record
If there is no indication for an indwelling catheter, the patient is free of an indwelling catheter *	Yes No	n/a	Electronic patient record
If a patient reports a pain score of 4 or higher (out of 10), pain medication is given unless refused by the patient	Yes No	Within 1 hour of onset of symptoms	Electronic patient record
If a patient reports a pain score of 4 or higher (out of 10), the pain is re-evaluated	Yes No	Within 1 hour of onset of symptoms	Electronic patient record
If a patient has delirium, agitation, acute urinary retention or incontinence, malnutrition, a medication review is performed by a geriatrician	Yes No	Before hospital discharge	Electronic patient record
If a patient has a Mini-Cog score < 3 on hospital admission, a Mini-Mental Status Examination is performed by an occupational therapist	Yes No	Before hospital discharge	Electronic patient record
If a patient is at risk for functional decline, the patient is co-managed by a geriatric nurse *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient has delirium, agitation or acute urinary retention or incontinence, the patient is co-managed by a geriatric nurse *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record

** Indicator that will used to determine the maintenance of the intervention; CAR = cardiology; GER= geriatrics*

Table 3. *Dose indicators*

Dose indicators	Adherence	Duration	Source
The number of days an at risk patient is seen by a geriatric nurse compared to the number of days a patient is at risk per protocol *	Proportion	Hospitalisation period	Electronic patient record
The number of days a patient with geriatric complications is seen by a geriatric nurse compared against the number of days a patient has geriatric complications per protocol	Proportion	Hospitalisation period	Electronic patient record
If a patient has delirium, agitation or acute urinary incontinence or retention, the patient is seen three times a week by a geriatrician	Yes No	Duration of complication	Electronic patient record
If a patient is at risk for functional decline, the patient completes an individual exercise programme *	No Yes, daily Yes, not daily	Hospitalisation period	Patient interview, self-report
If a patient is in need of an ambulatory device, the ambulatory device is available	No Yes, always Yes, not always	Hospitalisation period	Patient interview, self-report
If a patient is at risk for delirium, the Delirium Observation Scale is documented in the morning and evening shift *	Yes No	Three consecutive days after detection of risk	Electronic patient record

If a patient is delirious, the Delirium Observation Scale is documented during the morning and evening shift *	Yes No	Duration of delirium	Electronic patient record
If a patient is at risk for malnutrition or is malnourished, the daily nutritional intake is documented	Yes No	Hospitalisation period	Electronic patient record
If a post-void residual volume between 200 – 300ml is observed in a patient, the post-void residual volume is monitored every shift until volume < 100ml	Yes No	Until < 100ml	Electronic patient record

** Indicator that will used to determine the maintenance of the intervention.*

The *reach* determines the number of eligible patients that were recruited in the intervention. Successful recruitment is defined as 1) having received CGA and 2) being stratified into a risk group. The number of patients recruited in the intervention will be compared against the number of eligible patients using the electronic patient record. The *fidelity* determines how well the intervention is implemented as defined by the protocol and considers both the implementation of specific intervention components, and the correct timing of the implementation. The *dose* determines how much of the intervention is implemented as defined by the protocol and considers both the duration and frequency of specific intervention components. The fidelity and dose will be observed on a daily basis using patient interviews and the electronic patient record.

The experiences of participating healthcare professionals will be captured using focus group discussions or individual interviews. A total of four to five focus groups, including physicians, nurses from the cardiology department and the geriatric support team, physical and occupational therapists and social workers, will be organised. Healthcare professionals not able to participate in the focus groups will be interviewed individually. The experiences of participating patients will be captured using structured patient interviews. The sampled experiences of healthcare professionals and patients will be used to determine the *acceptability* and to *assess for barriers and facilitators* of both the intervention and implementation strategy.

Effectiveness evaluation

Baseline variables

The baseline evaluation of control and intervention patients serves to assess baseline equivalence between patients in the before-and-after cohort for the outcome evaluation. (See Table 4) *Demographic data* will be collected on age, gender, living situation and use of healthcare services using patient interview or review of the electronic record. *Medical variables* include the medical diagnoses, number and type of medications and comorbidities.[27] The following variables related to *functional status* will be measured: (in)dependence on activities of daily living (ADL),[28 29] instrumental ADL,[30] community mobility,[31] physical performance,[32], handgrip strength,[33] fall history,[34] and physical frailty [35]. Regarding *mental status*, presence of cognitive impairment [36], depression,[37] anxiety,[38] and delirium [39] will be measured. Finally, *nutritional status* will be assessed using the Mini Nutritional Assessment – Short form (MNA-SF).[40]

Table 4. *Overview of baseline variables and care processes measured*

Variable	Instrument	Description	Score	Type of assessment	Admission	In-hospital	Discharge	1/3/6 month follow-up
BASELINE VARIABLES								
Demographic data	n/a	Age, gender, living situation (home alone or together, assisted living, nursing home), use of healthcare resources	n/a	Interview	X			
Medical status								
Medical diagnoses	n/a	n/a	n/a	Record	X			
Comorbidity	Cumulative Illness Rating Scale [27]	Assessment of 14 body systems scored based on severity	Score 0 – 56 Overall severity index Range 0 – 4 = total score divided by number of body systems evaluated	Record	X			
Medication	n/a	Polypharmacy ≥ 5 medications		Record	X		X	
Functional status								
Activities of Daily Living (ADL)	Katz Index [28]	Bathing, dressing, toileting, transferring, continence, feeding	Score 6 – 18	Interview	X		X	X
	Barthel Index [29]	Bowels, bladder, grooming, toilet use, feeding, transfer, mobility, dressing, stairs, bathing	Score 0 – 100	Interview	X		X	X
Instrumental ADL	Lawton and Brody Scale [30]	Telephone use, shopping, food preparation, housekeeping, laundry, mode of transportation, medication use, finances		Interview	X			
Community mobility	Life-Space Assessment [31]	Self-reported mobility in last 4 weeks based on mobility in specific life-space levels, frequency of movement and use of assistance	Score 0 – 120	Interview	X			X
Physical performance	Short Physical Performance Battery [32]	Gait speed, standing balance, chair stand test	Score 0 – 12	Test	X		X	
Grip strength	Hydraulic hand dynamometer (Jamar JA Preston Corporation; Jackson, MI) [33]	At the dominant side with the elbow at 90° of flexion, and the forearm and wrist in a neutral position.	Highest value out of 3 tests	Test	X		X	
Fall history	Fall history in the 6 and 12 months [34]	Fall = "an unexpected event in which the patient comes to rest on the ground, floor or lower level" [41]	Yes / No	Interview	X		X	X
Physical frailty	Adjusted Fried criteria [35]	1) self-reported unintentional weight loss of ≥ 4.5 kg in the last year; grip strength in the lowest 20% adjusted for gender and BMI; 2) self-reported poor endurance and energy (question from GDS: "Do you feel full of energy?"); 3) reduced walking speed (≥ 6 sec. to cover 5m); 4) low physical activity (< 30min./day of self-reported physical activity of moderate intensity) [42 43]	Frail = score ≥ 3	Test/ Interview	X		X	
Mental status								

Cognition	Mini-Cog [44]	three-item word memory and clock drawing	Score 0 – 5 Impairment = score < 4	Interview	X		X	
Depressive symptoms	10-item Geriatric Depression Scale [45]		Score 0 – 10 Risk for depression = score ≥ 4	Interview	X			
Anxiety symptoms	Hospital Anxiety and Depression Scale [38]	7-item subscale for anxiety	Score 0 – 21 Anxiety = score ≥ 8	Interview	X			
Delirium	3D Confusion Assessment Method [39]		Delirium = (acute onset OR fluctuating course) AND inattention AND (disorganised thinking OR altered level of consciousness)	Interview	X	X	X	
Nutritional status	Mini Nutritional Assessment [40]	6 screening questions	Score 0 – 14 Malnutrition = score 0 – 7 Risk of malnutrition = score 8 - 11	Interview	X			
CARE PROCESSES								
Rehabilitation	n/a	Number of patients receiving rehabilitation Number of days until start of rehabilitation Number of interventions and contacts by a physiotherapist		Record		X		
Discharge planning	n/a	Number of patients receiving discharge planning Number of days until start of discharge planning Number of social interventions and contacts by a social worker		Record		X		
Dietary advice	n/a	Number of patients receiving dietary advice, the number of days until start of dietary advice, and the number of dietary interventions and contacts by a dietician.		Record		X		
Geriatric consultation	n/a	Number of patients receiving consultation by a member of the geriatric team Number of days until start of the geriatric consultation Number of interventions and contacts by the geriatric consultation team		Record		X		
Physical restraints	n/a	Number of patients being restrained Duration of the use of restraints Type of restraints used		Record		X		
Indwelling catheters	n/a	Number of patients with an indwelling catheter Duration of catheterization Reason for catheterization		Record		X		
Medication reconciliation	n/a	Number of patients discharged with a change in medications, and type of change. Change will be assessed for 1) number of drugs and drug intakes at admission and discharge, 2) potentially inappropriate medications at admission and discharge, and 3) vitamin D at admission and discharge		Record		X		
Detection of impairments and complications	n/a	Related to dementia/cognitive impairment, delirium (risk), depression (risk), anxiety (risk), fall risk, incontinence, malnutrition (risk) and frailty. This will be compared with standardized observations/assessments made by the research team to infer underdiagnoses.		Record		X		
Referral to outpatient care at hospital discharge	n/a	Number of patients referred to the falls clinic, the memory clinic, primary home care, and primary nursing care		Record			X	

Legend: n/a = not applicable, * underscored number indicates the best possible score for all instruments

Outcome variables

Functional decline is the primary outcome of interest measured by comparing the Katz ADL score on hospital admission, hospital discharge, and at 1, 3 and 6 months follow-up.(24,25) An increase of 1 point on the Katz Index will be considered clinically relevant to define functional decline. Secondary outcomes are community mobility assessed at 1, 3 and 6 months follow-up measured with Life-Space Assessment and physical performance at hospital discharge measured with the Short Physical Performance Battery.[31 32]

Incident in-hospital geriatric syndromes include delirium, cognitive decline, falls, and obstipation. *Delirium* will be operationalized using the 3D-CAM after a trained researcher assessed cognitive functioning using the CAM questionnaire on day 1 (day of admission), 3, 5, 7 and 9 (or daily in delirious patients).[46 47] Patients are considered delirious based on the sensitive CAM algorithm criteria. The duration of delirium will be determined as the number of days from the first positive CAM score until the day before a negative CAM score was obtained. [36] *In-hospital cognitive decline* will be determined by a decline on the Mini-Cog score between hospital admission and discharge. [44] *Symptomatic infections* will be assessed by reviewing the patient record for antibiotic treatment for a clinical infection (e.g. lower respiratory tract infection, urinary tract infection, skin and soft tissue infection, infection of unknown origin, and sepsis without primary focus).

Obstipation defined as 'not having passed stool in five days or more', will be assessed by reviewing the patient record for nurses recorded observations (which are assessed every shift). *In-hospital falls and fall related injuries* will be monitored using the patient record, while post-discharge falls and fall related injuries will be monitored at 1, 3 and 6 months follow-up by telephone.

Length of hospital stay will be measured in days and hours for admission on the cardiology unit and non-cardiology unit. *Unplanned readmission rate* will be assessed at 1, 3 and 6 month follow-up by telephone and by checking the electronic patient file. To be considered unplanned, patients should be admitted through the emergency department or outpatient clinic. *Mortality* will be assessed in-hospital using the electronic patient record, and at 1, 3 and 6 months follow-up by telephone. *Institutionalisation,* defined as a new admission to a long-term care facility compared to baseline, will be assessed at discharge and on 1, 3 and 6 months follow-up by telephone. *Quality of life* will be assessed using the EQ-5D-5L on hospital admission, hospital discharge and at 1, 3 and 6 months follow-up.[48 49]

Process evaluation

A process evaluation will be embedded in the after-cohort of the evaluation study to determine how the process of care was changed as a result of the implementation of the intervention and how the intervention was maintained and adapted over time and how this related to the interaction between context factors and the implementation of the intervention. The change in process of care will be observed using the electronic patient record and include the use, time to start and frequency of geriatric support services, physical therapy, discharge planning and nutritional advice, the use and duration of physical restraints and indwelling catheters, the

detection of geriatric syndromes, medication reconciliation and referral to outpatient services. The maintenance of the intervention relates to how well the reach, fidelity and dose of the intervention is maintained over time, which will be monitored using the electronic patient record (see selection of indicators in tables 2 and 3). Adaptations to the intervention will be monitored by the study coordinator during the monthly working group meetings with stakeholders. Focus groups and interviews will be organised to sample the experiences of all healthcare professionals participating in the intervention. The experiences will focus on how contextual factors influenced the maintenance and adaptations of the intervention and how this relates to the sustainability of the intervention.

Sample size

Feasibility evaluation

A total of 30 consecutive patients receiving the intervention will be recruited for the feasibility study. Approximately 30 healthcare professionals will be recruited for the focus groups and interviews. The total sample will be based on the willingness to participate and data saturation.

Effectiveness evaluation

A sample size has been calculated for in-hospital functional decline, the primary outcome of the evaluation study. We assumed a minimal important difference of 1 mean point on the Katz ADL and a standard deviation of 3 points on the Katz ADL with equal groups, based on observations in a pilot study.[22] This equals a standardized effect size of 0.33 (Cohen's d) and indicates a low to moderate effect size. Therefore, a total of 159 patients are needed per group (alfa = 0.05, power = 0.8, two sided test), accounting for 10% missing data. However, we hypothesized that not all patients will benefit from the intervention as several studies have identified larger effects sizes in patients with premorbid impairments but sufficient capacity to participate in in-hospital interventions. [50-54] Based on these studies, we expect that 30% of the patients will be at low risk, 50% at high risk, and that 20% will have an acute problem. This means that 227 patients need to be assessed to be able to evaluate the geriatric co-management intervention in 159 patients in the high risk (n = 114) or acute problem group (n = 45).

Process evaluation

The process evaluation is embedded in the sample of patients recruited for the effectiveness evaluation. A comprehensive sample of all healthcare professionals with at least four weeks of exposure to the intervention will be recruited, with the total sample depending on the willingness to participate and data saturation.

Data collection procedure

Feasibility evaluation

Researchers will recruit patients on hospital admission after written (proxy-)informed consent has been obtained and will monitor the feasibility indicators using the electronic patient record daily and by bedside

assessment every other day. Patients are interviewed upon hospital discharge by a researcher using a structured patient questionnaire. At the end of the feasibility phase, focus group discussions will be organised. One researcher will coordinate the group discussions and a second researcher will take notes. Healthcare professionals not able to participate in group discussions will be interviewed individually. An interview guide will be composed based on a literature search for existing barriers and facilitators and the role of contextual factors. All discussions will be tape recorded and written out verbatim. The audio recordings will be deleted and only the verbatim text will be saved.

Effectiveness evaluation

In the before and after cohorts, patients are recruited on hospital admission by the researchers, who screen the patient records for eligibility criteria and obtain written (proxy-) informed consent in a face-to-face interview. A research assistant will monitor the incidence of complications using patient assessment and by monitoring the patient record throughout hospitalisation, and will assess the outcomes on hospital discharge using patient interview. Patients will receive a letter by post with instructions and an assessment questionnaire for follow-up assessment at 1, 3 and 6 months post discharge. Researchers will contact the patient by telephone to complete the assessment. Due to the nature of the intervention and study design, health professionals and patients cannot be blinded. Blinding of outcome assessors is not considered feasible due to limited resources.

Process evaluation

The data collection procedure for the process evaluation is equal to the one of the feasibility evaluation, but only a selection of fidelity and dose indicators will be measured for all patients in the after cohort.

Data management and monitoring

Standardized data collection forms will be drafted and piloted by all researchers. Databases will be drafted in Excel and SPSS and all researchers will have access to a codebook. The study coordinator will assess the integrity of all completed informed consents and will monitor the assessment documents for missing data. Written assessments will be recorded in an Excel and SPSS database on a password protected computer, and will be analyzed for d data, wild codes and extreme values. All data will be coded and analysed anonymously. A formal data monitoring committee is not considered necessary as the study duration is relatively short and the risks for patients are considered minimal. Interim analyses and stopping rules have not been defined. Researchers will be trained to monitor for and record adverse events during assessments and tests, which will always be performed in proximity of a licensed health professional.

Statistical methods, qualitative analysis and data integration

Variables will be explored using visual and descriptive statistics and analysed for missing data. Categorical data will be expressed as number of cases and percentages. Continuous data will be expressed as means with

standard deviations. All primary analyses will be conducted on the patients who were at high risk for functional decline or patients experiencing an acute problem. For evaluating the primary outcome, we will first explore the baseline equivalence between the control and intervention group. If equivalent, we will test the absolute difference in ADL scores on hospital discharge between the two groups. If not equivalent, we will test the mean decline in ADL between hospital admission and discharge in both group. The analysis of covariance (ANCOVA) model will be used to adjust for confounders. For secondary outcomes, logistic regression will be used for dichotomous outcomes, survival analyses for time to event variables and ANCOVA for mean differences between groups. We will explore several moderating variables. We hypothesize that the effect of the intervention will be dependent on 1) the baseline risk of patients for developing functional decline, 2) the fidelity and dose of the implementation and intervention, and 3) the presence of heart failure. Results will not be corrected for multiple testing. Statistical inference will be based on 95% confidence intervals.

Focus group discussions and individual interviews will be analyzed using a thematic analysis to understand how experiences influenced the implementation and feasibility of the intervention. Two researchers will independently code the data using Word-documents. Transcripts and results will not be returned to participants for feedback. The following strategies will be used to support the methodological quality: peer review, triangulation, audit trial, methodological and reflective notes and thick description.

Integration of quantitative and qualitative data will be done through embedding.[55] Data collection and analysis will be recurrently linked at multiple points: in the development phase to clarify outcome measures, in the evaluation phase to understand contextual factors that influence the study findings, and in the post-evaluation phase to explain outliers or develop hypotheses about necessary changes for large-scale implementation. Quantitative and qualitative data will be integrated in a narrative way using a contiguous approach, meaning that findings will be presented in a single report in different sections. In case qualitative and quantitative findings are inconsistent, contradict or conflict, we will reanalyze the existing databases to resolve differences, seek explanations from theory, or further analyse discordance in follow-up studies.[55]

Ethics and dissemination

The study protocol was approved by the Medical Ethics Committee of UZ/KU Leuven (S58296). Written voluntary (proxy-) informed consent will be obtained from all participants at the start of the study. Upon each assessment, the research assistant will obtain oral informed consent for the assessment. Patients will be considered the owners of their data, and data will be removed or changed upon the request of the patient. No financial compensation is rewarded for participation, and patients are not charged any costs as a result of any action in this study. Dissemination of the results will be through articles in scientific and professional journals both in English and Dutch and by conference presentations. A G-COACH publication policy has been developed and was approved on the first consortium meeting.

DISCUSSION

This paper presents the study design and methods of the G-COACH intervention study, which is to our knowledge the first study evaluating the feasibility and effectiveness of a geriatric co-management intervention in older cardiology patients. In view of the rapidly increasing number of hospitalized older patients and the continuous efforts to further improve quality of care for these frail and complex patients, this study is timely and needed.

We hypothesize that our framework of geriatric co-management will be beneficial in this population, because of the applied methodological framework. First, a theoretical geriatric co-management model was developed by integrating evidence from a meta-analysis, quality indicators, and a prospective cohort study.[18 21 22] Such a theoretical model not only details how the intervention will impact the desired outcomes, but also increases the a priori probability for a clinically meaningful effect.[56] Second, important stakeholders will be involved in translating the theoretical care model in an operational geriatric co-management programme.[57]. Therefore, not only physicians, nurses and allied healthcare workers, but also nursing, medical and administrative management, are involved in the development, feasibility and evaluation phase of the project. This will allow us to implement and evaluate a care programme that fits the local context of the hospital and the participating units, hence, a programme that is deemed beneficial, acceptable and feasible by all stakeholders involved. Third, we will formally test the feasibility of a geriatric co-management programme. By first testing the feasibility, the intervention can be adjusted and optimised before investing in a large-scale evaluation.[20 58] This approach contrasts with the majority of studies in which feasibility problems are detected in evaluation studies leading to inconclusive results. Finally, because information is currently missing on what components make geriatric co-management effective in order to replicate the observed effects in daily practice, we will evaluate geriatric co-management using a mixed-methods design. By incorporating quantitative and qualitative information in both the outcome and process evaluation, we can move beyond effect outcomes and understand how intervention components interact with context and system factors to derive an effect on patient outcomes.[55] This will help us understand why geriatric co-management worked or - in case the intervention would not be successful - why it did not work.(15) The study will therefore in any case add to the evidence-base regarding the development, evaluation and implementation of geriatric co-management programmes.

Despite the absence of strong evidence regarding the impact of geriatric co-management in a recent meta-analysis,[18] we have deliberately chosen to use a hybrid 1 effectiveness-implementation design. This is one of the three hybrid designs described by Curran et al. who mapped different implementation research designs.[23] By systematically addressing the healthcare needs, preferences and values at different levels (i.e. patient, provider, system, and policy level) and by engaging relevant stakeholders, implementation research effectively brings evidence-based models into practice in a context-sensitive way leading to sustainable change. While large-scale implementation is outside the scope of the G-COACH project we will actively explore components that will facilitate future implementation of the care model if it proves to be successful by: 1) defining core intervention

components that are essential for all co-management programmes and defining peripheral components that can be adapted to the local context; 2) describing how context factors influenced the processes of geriatric co-management; 3) describing how participants experienced geriatric co-management and how this influenced adopting the programme locally; 4) evaluating how well geriatric co-management was implemented on the participating units.[59] Addressing these knowledge gaps is essential before considering scaling up and scaling out the geriatric co-management model of care.

In conclusion, the G-COACH intervention study will be the first to evaluate the impact of cardio-geriatric co-management and has the potential to change the current clinical practice of frail older hospitalized patients.

Trial status

Data for the 227 patients in the before cohort was collected between 20 September 2016 and 27 June 2017. The feasibility study was conducted between 28 June and 31 December 2017. Data for the 227 patients in the after-cohort commenced on 01 January 2018 and is expected to continue until October 2018.

Contributors

All authors made significant contribution to the conception and design of the study protocol. MD and BVG designed the original concept and wrote the study protocol and manuscript. The protocol and manuscript was critically reviewed by AJ, ED, BDC, CD, KF, MCH, MH, BM, SR, JT, KM and JF. BVG wrote the statistical analysis plan. MD is the principal investigator and BVG is the study coordinator of the G-COACH project. All authors gave approval for the publication.

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Competing interests

None to declare.

Data sharing

Anonymous data can be requested by sending a letter of intent (including a short background, research question, analysis plan, data requirements and a list of collaborators/authors) to the corresponding author, who will review the letter of intent together with the G-COACH co-investigators. The principal investigator will provide feedback concerning required adaptations or acceptance within one month.

Figure legends

Figure 1: Overview of the G-COACH project

Figure 2: Overview of the G-COACH intervention

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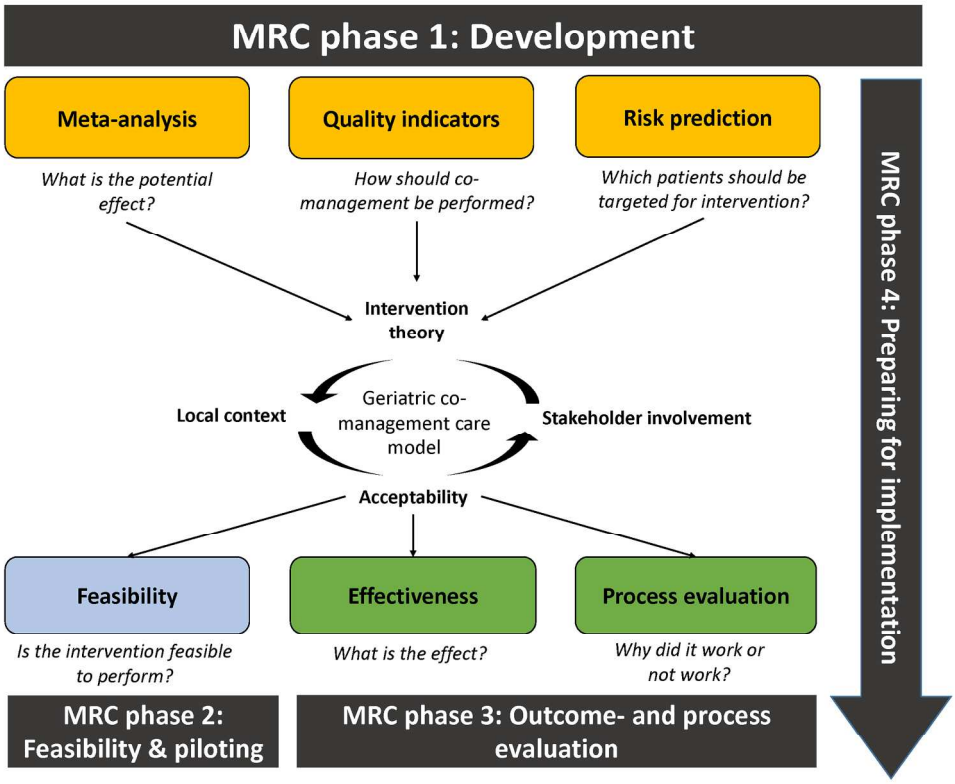

Figure 1: Overview of the G-COACH project

199x199mm (300 x 300 DPI)

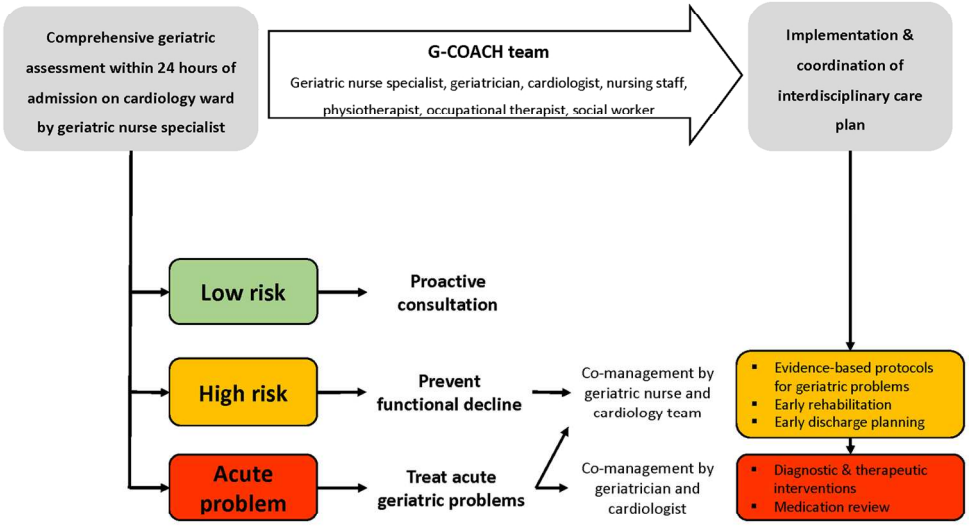

Figure 2: Overview of the G-COACH intervention

150x150mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

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Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	20
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1; 20
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	20

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	20
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	5,6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	9
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6, 15
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	16
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	n/a

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6,17
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	17
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16,17
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	1,18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	18
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Data access	#29	Statement of who will have access to the final trial dataset,	n/a

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	18
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Geriatric CO-mAnagement for Cardiology patients in the Hospital (G-COACH): study protocol of a prospective before-after effectiveness-implementation study

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Geriatric CO-mAnagement for Cardiology patients in the Hospital (G-COACH): study protocol of a prospective before-after effectiveness-implementation study

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ABSTRACT

Introduction: Although the majority of older patients admitted to a cardiology unit present with at least one geriatric syndrome, guidelines on managing heart disease often do not consider the complex needs of frail older patients. Geriatric co-management has demonstrated potential to improve functional status, and reduce complications and length of stay, but evidence on the effectiveness in cardiology patients is lacking. This study aims to determine if geriatric co-management is superior to usual care in preventing functional decline, complications, mortality, readmission rates, reducing length of stay and improving quality of life in older patients admitted for acute heart disease or for Transcatheter Aortic Valve Implantation, and to identify determinants of success for geriatric co-management in this population.

Methods and analysis: This prospective quasi-experimental before-and-after study will be performed on two cardiology units of the University Hospitals Leuven in Belgium in patients aged ≥75 years. In the pre-cohort (n = 227), usual care will be documented. A multitude of implementation strategies will be applied to allow for successful implementation of the model. Patients in the after-cohort (n = 227) will undergo a comprehensive geriatric assessment within 24 hours of admission to stratify them into one of three groups based on their baseline risk for developing functional decline: low-risk patients receive proactive consultation, high-risk patients will be co-managed by the geriatric nurse to prevent complications, and patients with acute geriatric problems will receive an additional medication review and co-management by the geriatrician.

Ethics and dissemination: The study protocol was approved by the Medical Ethics Committee UZ Leuven/ KU Leuven (S58296). Written voluntary (proxy-)informed consent will be obtained from all participants at the start of the study. Dissemination of results will be through articles in scientific and professional journals both in English and Dutch and by conference presentations.

Trial registration: Clinicaltrials.gov: NCT02890927

Key words: Activities of Daily Living, Co-management, Frail Elderly, Geriatric Assessment, Geriatric Medicine, Heart failure

Strengths and limitations of this study

- A geriatric co-management intervention theory was developed to increase the a priori probability for a clinically meaningful effect.
- Stakeholder involvement in the development, feasibility and evaluation phase facilitates the implementation of a care programme that fits the local context and is deemed acceptable and feasible by all stakeholders.
- Exploration of components that contributed to the successful implementation using a mixed methods approach will inform scaling up and out of the care model.
- Because of the inability to randomise individual patients in this single-center study, there is a risk of residual confounding.

INTRODUCTION

Longevity is the result of improved population health, but at the same time leads to an absolute increase of people suffering from multiple chronic health problems and disability.[1] The complex care for these patients is hampered by the high prevalence of frailty, cognitive impairment and functional dependency, which has been associated with functional decline, increased mortality, hospital readmission, and need for new social support.[2-4] Concurringly, the majority of healthcare staff is not adequately trained to manage the complex geriatric needs of these older patients.[5] Inappropriate medication use, delirium, cognitive impairment, and depression are often not recognized in older patients, emphasizing the need for better geriatric care.[6-10]

Cardiovascular disease is the leading cause of death and hospitalisation in the Western world.[11] Notably, the majority of older patients admitted to a cardiology unit present with at least one geriatric syndrome.[2] Current evidence-based guidelines on the management of heart disease often do not consider the complex needs of frail older patients, and may even incur harm.[12] This has prompted researchers and clinicians to advocate for a closer collaboration between cardiology and geriatric medicine as the "management of cardiac issues is fundamentally linked to the frailties and multi-morbidities associated with advanced age".[12 13]

Comprehensive geriatric assessment (CGA) has previously been identified as the gold standard for managing geriatric patients, but has not yet been evaluated in older cardiology patients.[14] CGA refers to a "multidimensional, interdisciplinary diagnostic process to determine the medical, psychological and functional capabilities of an older person with frailty, followed by implementation of a coordinated and integrated plan for treatment and follow-up".[15] A model of care that embeds the principles of CGA is the geriatric consultation team model. Geriatric consultation teams are multidisciplinary mobile teams that assess older patients admitted to non-geriatric units and recommend a plan of treatment. However, a meta-analysis detected no significant effect on functional status, length of stay and readmission and only found a moderate beneficial effect on mortality at six and eight months after hospitalization.[16] Subsequently, geriatric co-management programmes have emerged as a new model of CGA-based care for non-geriatric units.

Geriatric co-management is defined as a shared responsibility and decision making between at least a primary treating physician (e.g., cardiologist) and a geriatrician or geriatric team who provides complementary medical care in the prevention and management of geriatric problems.[17] A recent meta-analysis observed a better functional status, a decrease in complications and a reduced length of stay in favour of co-managed patients.[18] These results confirm the potential value of geriatric co-management, but also indicate a need to further evaluate the concept due to the low-quality of evidence. Furthermore, only four studies with inconsistent results assessed functional status as outcome and the majority of studies were performed in orthopedic patients.[18] There is currently no evidence on the effectiveness of geriatric co-management in older cardiology patients.

This protocol is part of the G-COACH project, which aims to develop and evaluate an in-hospital cardio-geriatric co-management model using a mixed-methods multi-phase methodology. The aim of this paper is to present a

detailed overview of the methodology of the G-COACH feasibility and effectiveness study, based on the SPIRIT statement.[19]

METHODOLOGY

Methodological framework

The G-COACH project is based upon the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (see Figure 1).[20] As part of the development phase of the MRC framework and in preparation of the feasibility and evaluation studies, we first developed an intervention theory for geriatric co-management that details how the G-COACH intervention will affect the desired change in outcomes. This theory was developed by integrating evidence from 1) a systematic review and meta-analysis on the effectiveness of geriatric co-management programmes,[18] 2) an international Delphi study that aimed to find consensus on appropriate and feasible structure, process and outcome indicators for the evaluation of in-hospital geriatric co-management programmes [21] and 3) an exploratory prospective cohort study in hospitalized patients with cardiac conditions to determine the incidence of in-hospital functional decline, the associated risk factors, and the link with care processes.[22] Additionally, we developed a clinical prediction model that identifies patients who are at risk for developing functional decline during hospitalisation. This risk prediction model was built based on data from the pre-cohort of this intervention study, and will be used to identify patients in need for geriatric co-management, i.e. patients with an increased risk for functional decline (submitted manuscript). To the best of our knowledge, no such model is available for older patients admitted to an acute cardiac care unit. The model will be validated in a cohort of 189 patients aged 75 year or older who are admitted to an acute cardiac care unit. Nonparametric bootstrapping will be used for internal validation.

The G-COACH feasibility and effectiveness study described in this paper concerns phase 2 and phase 3 of the MRC framework. However, to substantially increase the likelihood that the evaluated geriatric co-management programme moves from trial to real world, we use a hybrid 1 effectiveness-implementation design. [23] This means that in parallel with evaluating the effectiveness of the geriatric co-management model, we will gather information to inform future implementation strategies for scaling up and scaling out the geriatric co-management model. Hence, while trying to get an in-depth understanding of which intervention components are effective and which are not, we aim to provide a comprehensive overview of barriers and facilitators for large-scale implementation of the care model following its evaluation. The latter will be done by considering contextual factors that may influence the success of the implementation and the variation in outcomes from the very beginning of the project and by actively involving stakeholders in each project phase [23].

Study aims

The overall aim of the feasibility study is to 1) assess reach, fidelity and dose of the intervention; 2) investigate the perceived acceptability of the intervention by healthcare professionals and patients participating in the intervention and 3) determine facilitators and barriers for the implementation of the intervention.

The overall aim of the effectiveness study is twofold. The *outcome* evaluation will determine if geriatric co-management is superior in preventing in-hospital functional decline (primary outcome) and complications, reducing length of stay, decreasing mortality and readmission rates and improving quality of life in older patients admitted for acute heart disease or for Transcatheter Aortic Valve Implantation (TAVI) compared to usual care. The *process* evaluation will determine the quality of the implementation by investigating how well the fidelity and dose is maintained during the study period and how the geriatric co-management programme is adapted over time due to interaction with the local context [24].

Design and setting

This single-center, prospective, quasi-experimental before-and-after study will be performed on two cardiology units of the University Hospitals Leuven in Belgium. The University Hospitals Leuven is one of the seven university and tertiary hospitals in Belgium, and has 1995 beds. The two general cardiology units consist of 44 hospitalisation beds. Between recruiting patients in the before and after-cohort, the geriatric co-management intervention will be implemented and piloted to assess its feasibility.

Study population

Dutch-speaking patients aged 75 years or over are included if they are admitted through the emergency department or cardiology outpatient services for non-surgical treatment of acute heart disease or TAVI, have an expected length of stay of ≥ 3 days and give (proxy) informed consent. Patients are excluded if they are admitted from another hospital or hospital unit (no baseline data for functional status), if they stay in the intensive care unit for three days or longer (health care professionals on these wards are not involved in the development of the geriatric co-management intervention and/or impossibility to execute core components of the intervention, e.g. mobility protocols) or if they receive palliative treatment on hospital admission.

Usual care

The control group receives usual care on the cardiology units. Team members include a cardiology or internal medicine resident supervised by a consultant cardiologist, ward nurses, a physiotherapist, a social worker and a dietician, who meet weekly at a multidisciplinary team meeting. A geriatric support team, consisting of seven geriatric nurses (3.8 FTE including one master-trained nurse), a master-trained head nurse (1 FTE), four occupational therapists (2 FTE) and two geriatricians (0.2 FTE), is available for consultation services upon request of all non-geriatric wards in the study hospital, including the cardiology wards. If consulted, the geriatric

support team performs a CGA and gives written and oral recommendations about detected geriatric problems [25].

Geriatric co-management intervention

Every weekday a geriatric nurse is responsible for the geriatric co-management patients and conducts a CGA within 24 hours of admission in eligible patients newly admitted to the cardiology unit (See Figure 2). Subsequently, patients are stratified into one of three groups based on their baseline risk for developing functional decline. This risk prediction considers cognitive impairment (Mini-cog score), mobility impairment (use of ambulatory aid), nutritional risk status (Mini Nutritional Assessment score), depressive symptoms (Geriatric Depression Scale score) and the presence of physical restraint use or an indwelling urinary catheter (data not yet published).

Low risk patients are patients who are at low risk for developing functional decline during hospitalisation. The geriatric nurse provides a proactive consultation without systematic follow-up.

High risk patients are at risk for developing functional decline and other geriatric complications during hospitalisation. The geriatric nurse will work collaboratively with the cardiology team to prevent complications. Interventions include care coordination and bedside education by the geriatric nurse, early rehabilitation by a physical therapist, early discharge planning by a social worker, and availability of evidence-based protocols for the prevention and/or management of functional decline, falls, delirium, cognitive impairment, agitation, malnutrition, urinary incontinence, urinary retention, urinary tract infection, obstipation, pressure sores and pain. All intervention components selected from the protocols are tailored to the specific needs of an individual patient as detected with the CGA on admission. The geriatric nurse provides daily follow-up and coordinates the implementation of the protocols.

Patients with acute geriatric problems have developed one of the following geriatric syndromes: agitation, delirium, urinary retention, urinary incontinence or malnutrition (MNA < 8/14) and are subsequently considered to be at high risk of developing functional decline. These patients receive the same care as the high risk patients. Additionally, the geriatrician will perform a medication review based on clinical expertise and will co-manage the delirium, urinary retention, urinary incontinence and/or malnourishment with the cardiologist.

Implementation strategies

Changing the organisation and daily activities of a geriatric support team that has been working as a consultation team since 2005 is challenging. Both the geriatric support team and the healthcare professionals of the cardiology units need to take up a new role with new responsibilities and competencies. Since the aim is to change behaviour in both the geriatric support team and the cardiology teams, we use the Intervention Mapping taxonomy of behaviour change methods to ensure that our applied implementation strategies were targeting determinants that predict behaviour and were able to actually change that determinant [26]. Table 1

gives a detailed overview of the targeted determinants and practical strategies to change behaviour in the geriatric support and cardiology team.

Table 1. Implementation strategies and related behaviour change methods

Process	Determinant and Aim	Strategy	Taxonomy of behaviour change [26]
Orientation	Knowledge: Stakeholders are aware of the co-management programme	Listing all relevant stakeholders in the organisation	Participation
		Stakeholder meetings in initiation phase to propose programme with head of departments of geriatrics, cardiology, nursing, physiotherapy, nutritional therapy, social work and with head nurses of cardiology and geriatric support team, care programme managers and ICT	Consciousness raising Discussion Participation Systems change
		Use of G-COACH acronym in all communication	Chunking Repeated exposure
	Attitude: Stakeholders are interested and seek involvement in the co-management programme	Inclusion of stakeholders in consensus-development meetings for developing programme, focusing on definition, scope and goals of programme, intervention components and expected benefits	Motivational interviewing Participation
Insight	Knowledge: Stakeholders understand the goals, concepts and intervention components of the co-management programme	Educational presentations focusing on describing the care processes and outcomes of the current standard of care and new intervention components that are expected to improve processes and outcomes. Presentation included case discussion of geriatric needs and how the programme is expected to improve outcomes	Active learning Advance organizers Consciousness raising Discussion Persuasive communication
		Inclusion of stakeholders in consensus-development meetings for developing intervention protocols	Participation
		Intervention manual is available online and in hardcopy to stakeholders	Facilitation
		Publication of poster on participating units detailing the programme components and interventions	Cultural similarity Repeated exposure
	Knowledge: Stakeholders understand the geriatric needs of patients admitted to their unit and know the prevalence of geriatric syndromes on hospital admission and the incidence of geriatric complications during hospitalisation	Situational analysis to document geriatric care needs and the current standard of care by project team	Consciousness raising Organisational diagnosis and feedback
		Fact sheets are disseminated and short educational sessions are repeated in the feasibility and evaluation phase with the purpose of disseminating knowledge about geriatric needs to stakeholders based on the situational analysis	Consciousness raising Providing cues Repeated exposure
		Adaptations to the electronic patient file: risk stratification level and type of follow up visible for all eligible patients	Facilitation Providing cues Technical assistance
Acceptance	Positive attitude: Healthcare professionals are motivated to work with each other and collaborate as one interdisciplinary team	Contracting: an expert in group dynamics and leadership organises two sessions between stakeholders	Elaboration Nudging Shifting perspective
	Self-confidence: Stakeholders feel confident that participating in the co-management programme is feasible and that any problems arising will be solved	Inclusion of stakeholders in consensus-development meetings for developing programme, focusing on definition, scope and goals of programme, intervention components and expected benefits	Nudging Participation Systems change
		The intervention is tailored to match the local context by engaging stakeholders to ensure feasibility of the programme	Elaboration Systems change Tailoring
	Attitude: Stakeholders are convinced that the co-management programme is useful and effective to improve care outcomes for geriatric patients on	Programme support by head of department and head nurses	Participation
		Fact sheets and short educational sessions are repeated in the feasibility and evaluation phase with focus on impact and positive feedback on achieved goals	Active learning Advance organizers Consciousness raising

	their units		Repeated exposure
	Attitude: Stakeholders have decided to change their standard of care and try-out the geriatric co-management programme	Official start of programme announced by head of department	Early commitment Persuasive communication
Systems change	Skills and organization of new care structures and processes: Stakeholders can try the co-management programme on a small scale and gain experience and skills necessary for the programme	Phased implementation with evaluation of feasibility allowing the programme to adjust if necessary	Active learning Direct experience Feedback Guided practice Individualisation Tailoring
		Audit and feedback on implementation based on feasibility study	Discussion Feedback Participatory problem solving
	Skills, habits: Stakeholders have integrated the co-management programme in their daily care and routines	Working group: audit and feedback with key stakeholders from every discipline to discuss the adaptations that are needed to the programme based on audit and future needs	Feedback Participation Participatory problem solving Tailoring
	Qualified staff, self-confidence: Stakeholders are adequately staffed and skilled to try out the co-management programme	Coaching of geriatric nurses and geriatricians responsible for implementing the programme	Active learning Direct experience Feedback Guided practice Individualisation
Maintenance	Skills, habits: Stakeholders have integrated the co-management programme in their daily care and routines	Working group: audit and feedback with key stakeholders from every discipline to discuss the adaptations that are needed to the programme based on audit and future needs	Feedback Participation Participatory problem solving Tailoring
	Leadership, financial resources, opinion of leaders and key figures: University Hospitals Leuven has formally recognized ownership of the co-management programme	Dissemination of programme results to UZ Leuven staff and management	Agenda setting Feedback

The study coordinator (BVG) and research assistant (AJ) take up the role of external facilitators to allow for successful implementation of the G-COACH intervention. One month before the pilot implementation, they organised information sessions for all stakeholders: nurses, physicians, physiotherapists, occupational therapists, social workers, nutritional therapists and management from both the cardiology and geriatric department. Participants were informed on the current standard of care and the prevalence of geriatric problems. A sense of urgency of why change is needed was created. They were further informed on what will change, how it will change and what the intended benefits will be. Instructional materials, such as an electronic project manual including all intervention protocols, intervention pocket cards and posters, were distributed and training sessions were organised for the geriatric support team to explain and practice the intervention protocols. Finally, a meeting was organised with the external facilitators and geriatric support team to discuss how the team perceives the G-COACH intervention, their specific role, and to determine their needs for support towards the external facilitators. This meeting was led by a highly experienced external moderator of the Department of Leadership Development of the University Hospitals Leuven.

At the start of the implementation, an e-mail was sent by the medical head of the departments detailing both the study and instructional materials. The head nurses of the participating units supervised the start of the

intervention. A working group was formed consisting of the head nurses of the cardiology units and the geriatric support team, two champion nurses of the cardiology ward, a geriatric expert nurse, cardiologist, geriatrician, physiotherapist, social worker and study coordinator. The purpose of this group that meets monthly, is to discuss the implementation of the intervention, e.g.: Are all intervention components implemented?; What are the reasons for non-implementation?; What are barriers for implementation; and Are adaptations to the intervention needed?. Based on a consensus decision, the working group will propose changes to the intervention or formulate additional implementation strategies.

During the implementation phase, process data will be systematically collected from the electronic patient record and summarized by the study coordinator and research assistant to inform the working group. The study coordinator will organize short informational sessions throughout the study period to inform all stakeholders on the progression and success of the intervention. Weekly updates about the project are sent by mail to the geriatric support team and regular individual feedback sessions with the members of the geriatric support team are organised to emphasize which parts of the implementation of the intervention went well or were challenging.

Patient and public involvement

Patients and public were not involved in the development of the research questions and outcome measures, the design, recruitment of conduct of the study. Feedback of patients regarding the acceptability of the intervention is actively explored in the feasibility phase of the study using structured patient interviews.

Feasibility evaluation

The feasibility of the intervention will be assessed in a single intervention group before proceeding to the inclusion of patients in the after-cohort. The reach, fidelity (see table 2) and dose (see table 3) will be evaluated by trained researchers using a multi-methods approach.

Table 2. *Fidelity indicators*

Fidelity indicators	Adherence	Timing	Source
The intervention group assignment of a patient is documented in GER contact	Yes No	Within 24 hours of admission to c CAR	Electronic patient record
The intervention group assignment of a patient is documented in CAR contact	Yes No	Within 24 hours of admission to CAR	Electronic patient record
The intervention group assignment of a patient is documented in the patient file	Yes No	Within 24 hours of admission to CAR	Electronic patient record
The number of geriatric risks that are documented in the GER contact compared with the number of geriatric risks that are present	Proportion	Within 24 hours of admission to CAR	Electronic patient record
The number of geriatric complications that are documented in the GER contact compared to the number of geriatric complications that are present	Proportion	Within 24 hours of admission to CAR	Electronic patient record
A follow-up note summarizing the identified risks/complications and interventions is documented in the CAR contact	Yes No	Within 24 hours of admission to CAR	Electronic patient record
If a patient is at risk for functional decline or has experienced acute functional decline, the patient receives physiotherapy *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is at risk for functional decline or has experienced acute functional	Yes	Within 48 hours of	Electronic

decline, the patient completes an individual exercise programme *	No	admission to CAR	patient record
If a patient is at risk for functional decline or has experienced acute functional decline, the patient receives physiotherapy	Yes No	Within 24 hours of detection	Electronic patient record
If a patient is at risk for delirium or has developed delirium, the patient completes an individual exercise programme	Yes No	Within 24 hours of detection	Electronic patient record
If a patients is at risk for malnutrition or is malnourished, the patient receives a nutritional intervention by a dietician *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is in need for discharge planning, the patient is seen by a social worker	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient developed acute functional decline at hospital admission, the patients receives ADL-training by an occupational therapist.	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient is demonstrating agitation, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient is demonstrating agitation, the precipitating factors for the agitation are document in de patients' record	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient is delirious, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient is delirious, the precipitating factors for the delirium are document in de patients' record	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient has a swallowing disorder and is placed on a 'nothing by mouth' order, the patient receives parenteral or intravenous nutritional support	Yes No	Within 2 days	Electronic patient record
If a patient has not passed stool for 3 days, the patient is prescribed oral laxatives *	Yes No	Before day 4 without stool	Electronic patient record
If a patient has not passed stool for 5 days, the patient receives an enema *	Yes No	Before day 6 without stool	Electronic patient record
If a patient reports acute urinary incontinence, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient reports acute urinary incontinence, the precipitating factors for the incontinence are documented in the patients' record	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a patient reports acute urinary retention, the patient is co-managed by a geriatrician *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record
If a post-void residual volume of ≥ 300ml is observed in a patient, the residual volume is removed using intermittent catheterization	Yes No	Before end of shift after detection of symptoms	Electronic patient record
If a post-void residual volume of ≥ 300ml is observed in a patient, the post-void residual volume is monitored using a bladder scan in the next shift	Yes No	n/a	Electronic patient record
If there is no indication for an indwelling catheter, the patient is free of an indwelling catheter *	Yes No	n/a	Electronic patient record
If a patient reports a pain score of 4 or higher (out of 10), pain medication is given unless refused by the patient	Yes No	Within 1 hour of onset of symptoms	Electronic patient record
If a patient reports a pain score of 4 or higher (out of 10), the pain is re-evaluated	Yes No	Within 1 hour of onset of symptoms	Electronic patient record
If a patient has delirium, agitation, acute urinary retention or incontinence, malnutrition, a medication review is performed by a geriatrician	Yes No	Before hospital discharge	Electronic patient record
If a patient has a Mini-Cog score < 3 on hospital admission, a Mini-Mental Status Examination is performed by an occupational therapist	Yes No	Before hospital discharge	Electronic patient record
If a patient is at risk for functional decline, the patient is co-managed by a geriatric nurse *	Yes No	Within 48 hours of admission to CAR	Electronic patient record
If a patient has delirium, agitation or acute urinary retention or incontinence, the patient is co-managed by a geriatric nurse *	Yes No	Within 48 hours of onset of symptoms	Electronic patient record

** Indicator that will used to determine the maintenance of the intervention; CAR = cardiology; GER= geriatrics*

Table 3. *Dose indicators*

Dose indicators	Adherence	Duration	Source
The number of days an at risk patient is seen by a geriatric nurse compared to the number of days a patient is at risk per protocol *	Proportion	Hospitalisation period	Electronic patient record
The number of days a patient with geriatric complications is seen by a geriatric nurse compared against the number of days a patient has geriatric complications per protocol	Proportion	Hospitalisation period	Electronic patient record
If a patient has delirium, agitation or acute urinary incontinence or retention,	Yes	Duration of	Electronic patient

the patient is seen three times a week by a geriatrician	No	complication	record
If a patient is at risk for functional decline, the patient completes an individual exercise programme *	No Yes, daily Yes, not daily	Hospitalisation period	Patient interview, self-report
If a patient is in need of an ambulatory device, the ambulatory device is available	No Yes, always Yes, not always	Hospitalisation period	Patient interview, self-report
If a patient is at risk for delirium, the Delirium Observation Scale is documented in the morning and evening shift *	Yes No	Three consecutive days after detection of risk	Electronic patient record
If a patient is delirious, the Delirium Observation Scale is documented during the morning and evening shift *	Yes No	Duration of delirium	Electronic patient record
If a patient is at risk for malnutrition or is malnourished, the daily nutritional intake is documented	Yes No	Hospitalisation period	Electronic patient record
If a post-void residual volume between 200 – 300ml is observed in a patient, the post-void residual volume is monitored every shift until volume < 100ml	Yes No	Until < 100ml	Electronic patient record

** Indicator that will used to determine the maintenance of the intervention.*

The *reach* determines the number of eligible patients that were recruited in the intervention. Successful recruitment is defined as 1) having received CGA and 2) being stratified into a risk group. The number of patients recruited in the intervention will be compared against the number of eligible patients using the electronic patient record. The *fidelity* determines how well the intervention is implemented as defined by the protocol and considers both the implementation of specific intervention components, and the correct timing of the implementation. The *dose* determines how much of the intervention is implemented as defined by the protocol and considers both the duration and frequency of specific intervention components. The fidelity and dose will be observed on a daily basis using patient interviews and the electronic patient record.

The experiences of participating healthcare professionals will be captured using focus group discussions or individual interviews. A total of four to five focus groups, including physicians, nurses from the cardiology department and the geriatric support team, physical and occupational therapists and social workers, will be organised. Healthcare professionals not able to participate in the focus groups will be interviewed individually. The experiences of participating patients will be captured using structured patient interviews. The sampled experiences of healthcare professionals and patients will be used to determine the *acceptability* and to *assess for barriers and facilitators* of both the intervention and implementation strategy.

Effectiveness evaluation

Baseline variables

The baseline evaluation of control and intervention patients serves to assess baseline equivalence between patients in the before-and-after cohort for the outcome evaluation. (See Table 4) *Demographic data* will be collected on age, gender, living situation and use of healthcare services using patient interview or review of the electronic record. *Medical variables* include the medical diagnoses, number and type of medications and comorbidities.[27] The following variables related to *functional status* will be measured: (in)dependence on activities of daily living (ADL),[28 29] instrumental ADL,[30] community mobility,[31] physical performance,[32], handgrip

strength,[33] fall history,[34] and physical frailty [35]. Regarding *mental status*, presence of cognitive impairment [36], depression,[37] anxiety,[38] and delirium [39] will be measured. Finally, *nutritional status* will be assessed using the Mini Nutritional Assessment – Short form (MNA-SF).[40]

Table 4. *Overview of baseline variables and care processes measured*

Variable	Instrument	Description	Score	Type of assessment	Admission	In-hospital	Discharge	1/3/6 month follow-up
BASELINE VARIABLES								
Demographic data	n/a	Age, gender, living situation (home alone or together, assisted living, nursing home), use of healthcare resources	n/a	Interview	X			
Medical status								
Medical diagnoses	n/a	n/a	n/a	Record	X			
Comorbidity	Cumulative Illness Rating Scale [27]	Assessment of 14 body systems scored based on severity	Score 0 – 56 Overall severity index Range 0 – 4 = total score divided by number of body systems evaluated	Record	X			
Medication	n/a	Polypharmacy ≥ 5 medications		Record	X		X	
Functional status								
Activities of Daily Living (ADL)	Katz Index [28]	Bathing, dressing, toileting, transferring, continence, feeding	Score 6 – 18	Interview	X		X	X
	Barthel Index [29]	Bowels, bladder, grooming, toilet use, feeding, transfer, mobility, dressing, stairs, bathing	Score 0 – 100	Interview	X		X	X
Instrumental ADL	Lawton and Brody Scale [30]	Telephone use, shopping, food preparation, housekeeping, laundry, mode of transportation, medication use, finances		Interview	X			
Community mobility	Life-Space Assessment [31]	Self-reported mobility in last 4 weeks based on mobility in specific life-space levels, frequency of movement and use of assistance	Score 0 – 120	Interview	X			X
Physical performance	Short Physical Performance Battery [32]	Gait speed, standing balance, chair stand test	Score 0 – 12	Test	X		X	
Grip strength	Hydraulic hand dynamometer (Jamar JA Preston Corporation; Jackson, MI) [33]	At the dominant side with the elbow at 90° of flexion, and the forearm and wrist in a neutral position.	Highest value out of 3 tests	Test	X		X	
Fall history	Fall history in the past 6 and 12 months [34]	Fall = "an unexpected event in which the patient comes to rest on the ground, floor or lower level" [41]	Yes / No	Interview	X		X	X
Physical frailty	Adjusted Fried criteria [35]	1) self-reported unintentional weight loss of ≥ 4.5 kg in the last year; grip strength in the lowest 20% adjusted for gender and BMI; 2) self-reported poor endurance and energy (question from GDS: "Do you feel full of energy?"); 3) reduced walking speed (≥ 6 sec. to cover 5m); 4) low physical activity (< 30min./day of self-reported physical activity of moderate intensity) [42 43]	Frail = score ≥ 3	Test/ Interview	X		X	

Mental status								
Cognition	Mini-Cog [44]	three-item word memory and clock drawing	Score 0 – 5 Impairment = score < 4	Interview	X		X	
Depressive symptoms	10-item Geriatric Depression Scale [45]		Score 0 – 10 Risk for depression = score ≥ 4	Interview	X			
Anxiety symptoms	Hospital Anxiety and Depression Scale [38]	7-item subscale for anxiety	Score 0 – 21 Anxiety = score ≥ 8	Interview	X			
Delirium	3D Confusion Assessment Method [39]		Delirium = (acute onset OR fluctuating course) AND inattention AND (disorganised thinking OR altered level of consciousness)	Interview	X	X	X	
Nutritional status	Mini Nutritional Assessment [40]	6 screening questions	Score 0 – 14 Malnutrition = score 0 – 7 Risk of malnutrition = score 8 - 11	Interview	X			
CARE PROCESSES								
Rehabilitation	n/a	Number of patients receiving rehabilitation Number of days until start of rehabilitation Number of interventions and contacts by a physiotherapist		Record		X		
Discharge planning	n/a	Number of patients receiving discharge planning Number of days until start of discharge planning Number of social interventions and contacts by a social worker		Record		X		
Dietary advice	n/a	Number of patients receiving dietary advice, the number of days until start of dietary advice, and the number of dietary interventions and contacts by a dietician.		Record		X		
Geriatric consultation	n/a	Number of patients receiving consultation by a member of the geriatric team Number of days until start of the geriatric consultation Number of interventions and contacts by the geriatric consultation team		Record		X		
Physical restraints	n/a	Number of patients being restrained Duration of the use of restraints Type of restraints used		Record		X		
Indwelling catheters	n/a	Number of patients with an indwelling catheter Duration of catheterization Reason for catheterization		Record		X		
Medication reconciliation	n/a	Number of patients discharged with a change in medications, and type of change. Change will be assessed for 1) number of drugs and drug intakes at admission and discharge, 2) potentially inappropriate medications at admission and discharge, and 3) vitamin D at admission and discharge		Record		X		
Detection of impairments and complications	n/a	Related to dementia/cognitive impairment, delirium (risk), depression (risk), anxiety (risk), fall risk, incontinence, malnutrition (risk) and frailty. This will be compared with standardized observations/assessments made by the research team to infer underdiagnoses.		Record		X		
Referral to outpatient care at hospital discharge	n/a	Number of patients referred to the falls clinic, the memory clinic, primary home care, and primary nursing care		Record			X	

Legend: n/a = not applicable, * underscored number indicates the best possible score for all instruments

Outcome variables

Functional decline is the primary outcome of interest measured by comparing the Katz ADL score on hospital admission, hospital discharge, and at 1, 3 and 6 months follow-up.(24,25) An increase of 1 point on the Katz Index will be considered clinically relevant to define functional decline. Secondary outcomes are community mobility assessed at 1, 3 and 6 months follow-up measured with Life-Space Assessment and physical performance at hospital discharge measured with the Short Physical Performance Battery.[31 32]

Incident in-hospital geriatric syndromes include delirium, cognitive decline, falls, and obstipation. *Delirium* will be operationalized using the 3D-CAM after a trained researcher assessed cognitive functioning using the CAM questionnaire on day 1 (day of admission), 3, 5, 7 and 9 (or daily in delirious patients).[46 47] Patients are considered delirious based on the sensitive CAM algorithm criteria. The duration of delirium will be determined as the number of days from the first positive CAM score until the day before a negative CAM score was obtained. [36] *In-hospital cognitive decline* will be determined by a decline on the Mini-Cog score between hospital admission and discharge. [44] *Symptomatic infections* will be assessed by reviewing the patient record for antibiotic treatment for a clinical infection (e.g. lower respiratory tract infection, urinary tract infection, skin and soft tissue infection, infection of unknown origin, and sepsis without primary focus).

Obstipation defined as 'not having passed stool in five days or more', will be assessed by reviewing the patient record for nurses recorded observations (which are assessed every shift). *In-hospital falls and fall related injuries* will be monitored using the patient record, while post-discharge falls and fall related injuries will be monitored at 1, 3 and 6 months follow-up by telephone.

Length of hospital stay will be measured in days and hours for admission on the cardiology unit and non-cardiology unit. *Unplanned readmission rate* will be assessed at 1, 3 and 6 month follow-up by telephone and by checking the electronic patient file. To be considered unplanned, patients should be admitted through the emergency department or outpatient clinic. *Mortality* will be assessed in-hospital using the electronic patient record, and at 1, 3 and 6 months follow-up by telephone. *Institutionalisation,* defined as a new admission to a long-term care facility compared to baseline, will be assessed at discharge and on 1, 3 and 6 months follow-up by telephone. *Quality of life* will be assessed using the EQ-5D-5L on hospital admission, hospital discharge and at 1, 3 and 6 months follow-up.[48 49]

Process evaluation

A process evaluation will be embedded in the after-cohort of the evaluation study to determine how the process of care was changed as a result of the implementation of the intervention and how the intervention was maintained and adapted over time and how this related to the interaction between context factors and the implementation of the intervention. The change in process of care will be observed using the electronic patient record and include the use, time to start and frequency of geriatric support services, physical therapy, discharge planning and nutritional advice, the use and duration of physical restraints and indwelling catheters, the

detection of geriatric syndromes, medication reconciliation and referral to outpatient services. The maintenance of the intervention relates to how well the reach, fidelity and dose of the intervention is maintained over time, which will be monitored using the electronic patient record (see selection of indicators in tables 2 and 3). Adaptations to the intervention will be monitored by the study coordinator during the monthly working group meetings with stakeholders. Focus groups and interviews will be organised to sample the experiences of all healthcare professionals participating in the intervention. The experiences will focus on how contextual factors influenced the maintenance and adaptations of the intervention and how this relates to the sustainability of the intervention.

Sample size

Feasibility evaluation

A total of 30 consecutive patients receiving the intervention will be recruited for the feasibility study. Approximately 30 healthcare professionals will be recruited for the focus groups and interviews. The total sample will be based on the willingness to participate and data saturation.

Effectiveness evaluation

A sample size has been calculated for in-hospital functional decline, the primary outcome of the evaluation study. We assumed a minimal important difference of 1 mean point on the Katz ADL and a standard deviation of 3 points on the Katz ADL with equal groups, based on observations in a pilot study.[22] This equals a standardized effect size of 0.33 (Cohen's d) and indicates a low to moderate effect size. Therefore, a total of 159 patients are needed per group (alfa = 0.05, power = 0.8, two sided test), accounting for 10% missing data. However, we hypothesized that not all patients will benefit from the intervention as several studies have identified larger effects sizes in patients with premorbid impairments but sufficient capacity to participate in in-hospital interventions. [50-54] Based on these studies, we expect that 30% of the patients will be at low risk, 50% at high risk, and that 20% will have an acute problem. This means that 227 patients need to be assessed to be able to evaluate the geriatric co-management intervention in 159 patients in the high risk (n = 114) or acute problem group (n = 45).

Process evaluation

The process evaluation is embedded in the sample of patients recruited for the effectiveness evaluation. A comprehensive sample of all healthcare professionals with at least four weeks of exposure to the intervention will be recruited, with the total sample depending on the willingness to participate and data saturation.

Data collection procedure

Feasibility evaluation

Researchers will recruit patients on hospital admission after written (proxy-)informed consent has been obtained and will monitor the feasibility indicators using the electronic patient record daily and by bedside

assessment every other day. Patients are interviewed upon hospital discharge by a researcher using a structured patient questionnaire. At the end of the feasibility phase, focus group discussions will be organised. One researcher will coordinate the group discussions and a second researcher will take notes. Healthcare professionals not able to participate in group discussions will be interviewed individually. An interview guide will be composed based on a literature search for existing barriers and facilitators and the role of contextual factors. All discussions will be tape recorded and written out verbatim. The audio recordings will be deleted and only the verbatim text will be saved.

Effectiveness evaluation

In the before and after cohorts, patients are recruited on hospital admission by the researchers, who screen the patient records for eligibility criteria and obtain written (proxy-) informed consent in a face-to-face interview. A research assistant will monitor the incidence of complications using patient assessment and by monitoring the patient record throughout hospitalisation, and will assess the outcomes on hospital discharge using patient interview. Patients will receive a letter by post with instructions and an assessment questionnaire for follow-up assessment at 1, 3 and 6 months post discharge. Researchers will contact the patient by telephone to complete the assessment. Due to the nature of the intervention and study design, health professionals and patients cannot be blinded. Blinding of outcome assessors is not considered feasible due to limited resources.

Process evaluation

The data collection procedure for the process evaluation is equal to the one of the feasibility evaluation, but only a selection of fidelity and dose indicators will be measured for all patients in the after cohort.

Data management and monitoring

Standardized data collection forms will be drafted and piloted by all researchers. Databases will be drafted in Excel and SPSS and all researchers will have access to a codebook. The study coordinator will assess the integrity of all completed informed consents and will monitor the assessment documents for missing data. Written assessments will be recorded in an Excel and SPSS database on a password protected computer, and will be analyzed for d data, wild codes and extreme values. All data will be coded and analysed anonymously. A formal data monitoring committee is not considered necessary as the study duration is relatively short and the risks for patients are considered minimal. Interim analyses and stopping rules have not been defined. Researchers will be trained to monitor for and record adverse events during assessments and tests, which will always be performed in proximity of a licensed health professional.

Statistical methods, qualitative analysis and data integration

Variables will be explored using visual and descriptive statistics and analysed for missing data. Categorical data will be expressed as number of cases and percentages. Continuous data will be expressed as means with

standard deviations. All primary analyses will be conducted on the patients who were at high risk for functional decline or patients experiencing an acute problem. For evaluating the primary outcome, we will first explore the baseline equivalence between the control and intervention group. If equivalent, we will test the absolute difference in ADL scores on hospital discharge between the two groups. If not equivalent, we will test the mean decline in ADL between hospital admission and discharge in both group. The analysis of covariance (ANCOVA) model will be used to adjust for confounders. For secondary outcomes, logistic regression will be used for dichotomous outcomes, survival analyses for time to event variables and ANCOVA for mean differences between groups. We will explore several moderating variables. We hypothesize that the effect of the intervention will be dependent on 1) the baseline risk of patients for developing functional decline, 2) the fidelity and dose of the implementation and intervention, and 3) the presence of heart failure. Results will not be corrected for multiple testing. Statistical inference will be based on 95% confidence intervals.

Focus group discussions and individual interviews will be analyzed using a thematic analysis to understand how experiences influenced the implementation and feasibility of the intervention. Two researchers will independently code the data using Word-documents. Transcripts and results will not be returned to participants for feedback. The following strategies will be used to support the methodological quality: peer review, triangulation, audit trial, methodological and reflective notes and thick description.

Integration of quantitative and qualitative data will be done through embedding.[55] Data collection and analysis will be recurrently linked at multiple points: in the development phase to clarify outcome measures, in the evaluation phase to understand contextual factors that influence the study findings, and in the post-evaluation phase to explain outliers or develop hypotheses about necessary changes for large-scale implementation. Quantitative and qualitative data will be integrated in a narrative way using a contiguous approach, meaning that findings will be presented in a single report in different sections. In case qualitative and quantitative findings are inconsistent, contradict or conflict, we will reanalyze the existing databases to resolve differences, seek explanations from theory, or further analyse discordance in follow-up studies.[55]

Ethics and dissemination

The study protocol was approved by the Medical Ethics Committee of UZ/KU Leuven (S58296). Written voluntary (proxy-) informed consent will be obtained from all participants at the start of the study. Upon each assessment, the research assistant will obtain oral informed consent for the assessment. Patients will be considered the owners of their data, and data will be removed or changed upon the request of the patient. No financial compensation is rewarded for participation, and patients are not charged any costs as a result of any action in this study. Dissemination of the results will be through articles in scientific and professional journals both in English and Dutch and by conference presentations. A G-COACH publication policy has been developed and was approved on the first consortium meeting.

DISCUSSION

This paper presents the study design and methods of the G-COACH intervention study, which is to our knowledge the first study evaluating the feasibility and effectiveness of a geriatric co-management intervention in older cardiology patients. In view of the rapidly increasing number of hospitalized older patients and the continuous efforts to further improve quality of care for these frail and complex patients, this study is timely and needed.

We hypothesize that our framework of geriatric co-management will be beneficial in this population, because of the applied methodological framework. First, a theoretical geriatric co-management model was developed by integrating evidence from a meta-analysis, quality indicators, and a prospective cohort study.[18 21 22] Such a theoretical model not only details how the intervention will impact the desired outcomes, but also increases the a priori probability for a clinically meaningful effect.[56] Second, important stakeholders will be involved in translating the theoretical care model in an operational geriatric co-management programme.[57]. Therefore, not only physicians, nurses and allied healthcare workers, but also nursing, medical and administrative management, are involved in the development, feasibility and evaluation phase of the project. This will allow us to implement and evaluate a care programme that fits the local context of the hospital and the participating units, hence, a programme that is deemed beneficial, acceptable and feasible by all stakeholders involved. Third, we will formally test the feasibility of a geriatric co-management programme. By first testing the feasibility, the intervention can be adjusted and optimised before investing in a large-scale evaluation.[20 58] This approach contrasts with the majority of studies in which feasibility problems are detected in evaluation studies leading to inconclusive results. Finally, because information is currently missing on what components make geriatric co-management effective in order to replicate the observed effects in daily practice, we will evaluate geriatric co-management using a mixed-methods design. By incorporating quantitative and qualitative information in both the outcome and process evaluation, we can move beyond effect outcomes and understand how intervention components interact with context and system factors to derive an effect on patient outcomes.[55] This will help us understand why geriatric co-management worked or - in case the intervention would not be successful - why it did not work. The study will therefore in any case add to the evidence-base regarding the development, evaluation and implementation of geriatric co-management programmes.

Despite the absence of strong evidence regarding the impact of geriatric co-management in a recent meta-analysis,[18] we have deliberately chosen to use a hybrid 1 effectiveness-implementation design. This is one of the three hybrid designs described by Curran et al. who mapped different implementation research designs.[23] By systematically addressing the healthcare needs, preferences and values at different levels (i.e. patient, provider, system, and policy level) and by engaging relevant stakeholders, implementation research effectively brings evidence-based models into practice in a context-sensitive way leading to sustainable change. While large-scale implementation is outside the scope of the G-COACH project we will actively explore components that will facilitate future implementation of the care model if it proves to be successful by: 1) defining core intervention

components that are essential for all co-management programmes and defining peripheral components that can be adapted to the local context; 2) describing how context factors influenced the processes of geriatric co-management; 3) describing how participants experienced geriatric co-management and how this influenced adopting the programme locally; 4) evaluating how well geriatric co-management was implemented on the participating units.[59] Addressing these knowledge gaps is essential before considering scaling up and scaling out the geriatric co-management model of care.

In conclusion, the G-COACH intervention study will be the first to evaluate the impact of cardio-geriatric co-management and has the potential to change the current clinical practice of frail older hospitalized patients.

Trial status

Data for the 227 patients in the before cohort was collected between 20 September 2016 and 27 June 2017. The feasibility study was conducted between 28 June and 31 December 2017. Data for the 227 patients in the after-cohort commenced on 01 January 2018 and is expected to continue until October 2018.

Contributors

All authors made significant contribution to the conception and design of the study protocol. MD and BVG designed the original concept and wrote the study protocol and manuscript. The protocol and manuscript was critically reviewed by AJ, ED, BDC, CD, KF, MCH, MH, BM, SR, JT, KM and JF. BVG wrote the statistical analysis plan. MD is the principal investigator and BVG is the study coordinator of the G-COACH project. All authors gave approval for the publication.

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Competing interests

None to declare.

Data sharing

Anonymous data can be requested by sending a letter of intent (including a short background, research question, analysis plan, data requirements and a list of collaborators/authors) to the corresponding author, who will review the letter of intent together with the G-COACH co-investigators. The principal investigator will provide feedback concerning required adaptations or acceptance within one month.

Figure legends

Figure 1: Overview of the G-COACH project

Figure 2: Overview of the G-COACH intervention

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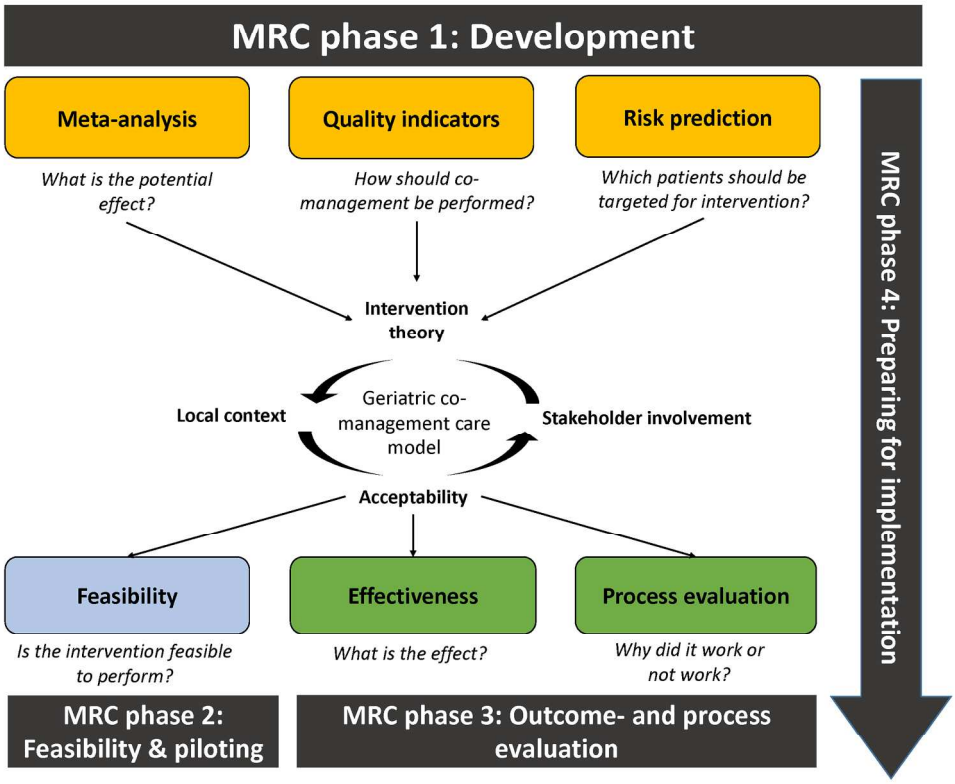

Figure 1: Overview of the G-COACH project

199x199mm (300 x 300 DPI)

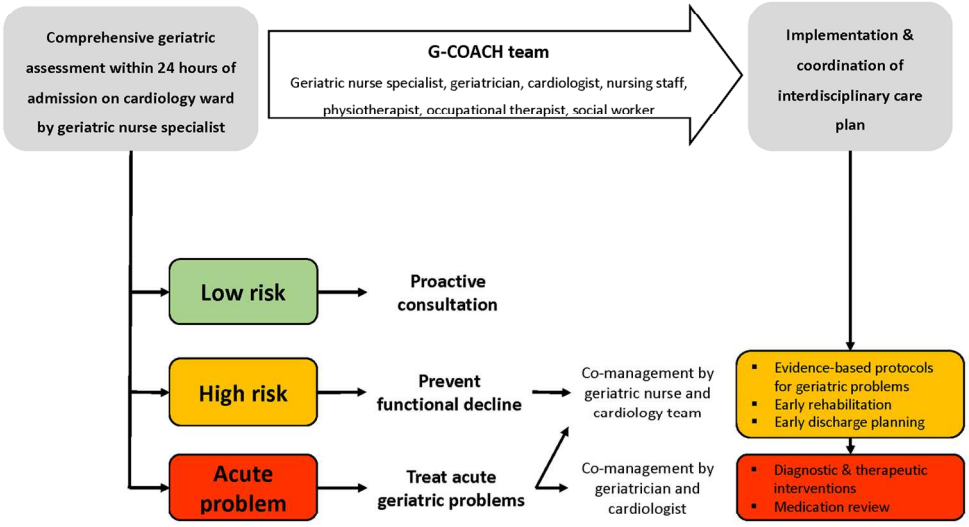

Figure 2: Overview of the G-COACH intervention

150x150mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	20
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1; 20
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	20

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	20
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	5,6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	9
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6, 15
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	16
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	n/a

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6,17
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	17
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16,17
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	1,18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	18
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Data access	#29	Statement of who will have access to the final trial dataset,	n/a

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	18
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a