G-COACH: Feasibility of the geriatric comanagement for cardiology patients in the hospital programme

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/05/2020		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/05/2020	Completed	[X] Results		
Last Edited 26/10/2022	Condition category Circulatory System	[] Individual participant data		
20/10/2022	Circulatory System			

Plain English summary of protocol

Background and study aims

Older patients admitted to an cardiac care unit often experience functional decline and sustained disability. Geriatric co-management has demonstrated significant improvements on outcomes in older patients with a hip fracture, but has never been evaluated in the cardiac care setting.

This study introduced a new geriatric co-management programme on the cardiac care units of the University Hospitals Leuven. The aim was to evaluate whether this programme was acceptable and feasible to perform.

Who can participate?

Patients aged 75 years or older admitted for acute cadiovascular disease or transcatheter aortic valve implentation to the cardiac care units of the University Hospitals Leuven and healthcare professionals working on the acute cardiac care units of the University Hospitals Leuven.

What does the study involve?

On admission to the hospital, a comprehensive geriatric assessment was performed, care needs were determined, and an interdisciplinary care plan was drafted. A nurse from the geriatrics department provided daily follow-up until hospital discharge.

What are the possible benefits and risks of participating?

The programme was developed to benefit patients, including a better functional status and less complications. There are no direct risks.

Where is the study run from? University Hospitals Leuven (Belgium)

When is the study starting and how long is it expected to run for? January 2015 to May 2018

Who is funding the study?
Onderzoeksraad, KU Leuven (Research Council, KU Leuven), Belgium

Who is the main contact?

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Study website

https://gbiomed.kuleuven.be/english/research/50000625/50000630/researchprojects/gcoach

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

REF 22/15/028

Study information

Scientific Title

Implementation of the Geriatric CO-mAnagement for Cardiology patients in the Hospital (G-COACH) programme: a feasibility study

Acronym

G-COACH

Study objectives

Is a geriatric co-management programme implemented on the acute cardiac care units of the University Hospitals Leuven considered acceptable and feasible to perform?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/08/2017, The Medical Ethics Committee of the University Hospitals Leuven (Ethische commissie onderzoek UZ Leuven, Herestraat 49, 3000 Leuven, Belgium; +32 16 34 86 00; ec@uzleuven.be), ref: s59543

Study design

One-group experimental single centre feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Older patients with geriatric profile admitted to cardiac care units

Interventions

Nurse-led geriatric co-management programme, including a comprehensive geriatric assessment on hospital admission, risk stratification, daily follow-up by geriatrics team until hospital discharge, implementation of standardised and evidence-based protocols for geriatric syndromes, early rehabilitation, individual exercise programme, and early discharge planning.

Informed consent is obtained within three days of admission to the cardiac care unit (15 minutes). A nurse enrols the patient in the geriatric co-management programme (30 minutes). A researcher performs an interview and asks about the experiences with the programme (15 minutes). A researcher observes daily health status and whether there are any complications (10 minutes) until discharge from the cardiac care unit. The participation ends when discharged from the hospital.

Intervention Type

Other

Primary outcome measure

Experiences with the programme, including self-perceived acceptability and self-perceived feasibility, measured using structured interviews with questionnaires during hospitalisation.

Secondary outcome measures

Measured during hospitalisation on the cardiac care unit. This is case dependent (some patients have a long length of stay, others short) and there is no one fixed timepoint:

- 1. Reach of the programme, measured using registrations in the electronic patient record
- 2. Fidelity, measured suing registrations in the electronic patient record
- 3. Dose, measured suing registrations in the electronic patient record
- 4. Determinants for implementation, measured using a questionnaire and interviews

Overall study start date

28/01/2015

Completion date

Eligibility

Key inclusion criteria

- 1. Patients aged 75 years or older admitted for acute cadiovascular disease or transcatheter aortic valve implentation to the cardiac care units of the University Hospitals Leuven
- 2. Healthcare professionals working on the acute cardiac care units of the University Hospitals Leuven

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

3 sequential cohorts of 30 patients with follow-up in the geriatric co-management programme; All healthcare professionals with at least 4 weeks of exposure to the geriatric co-management programme

Total final enrolment

199

Key exclusion criteria

- 1. Length of stay < 3 days
- 2. No baseline assessment (included transfers from other units or hospitals)
- 3. Unable to complete assessment
- 4. No inform consent
- 5. Receiving palliative care

Date of first enrolment

07/11/2017

Date of final enrolment

02/05/2018

Locations

Countries of recruitment

Belgium

Study participating centre University Hospitals Leuven

Herestraat 49

Sponsor information

Organisation

KU Leuven

Sponsor details

Oude markt 13 Leuven Belgium 3000 +32 16 3 24010 onderzoek@kuleuven.be

Sponsor type

University/education

Website

https://www.kuleuven.be/english/

ROR

https://ror.org/05f950310

Funder(s)

Funder type

Research council

Funder Name

Onderzoeksraad, KU Leuven

Alternative Name(s)

Research Council, KU Leuven

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Results and Publications

Publication and dissemination plan

Presented at a conference (2019 Wintermeeting, Oostende, Belgium) and submitted for publication in a high-impact peer-reviewed journal.

Intention to publish date

30/06/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Koen Milisen (koen.milisen@kuleuven.be). Each request will be considered on a case basis. Reasonable requests include use of baseline data for epidemiological purposes.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/10/2018	22/05/2020	Yes	No
Results article		02/05/2022	26/10/2022	Yes	No