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Is care based on Comprehensive Geriatric Assessment with Mobile Teams better than usual care? – a study protocol article of a randomized controlled trial (The GerMoT-study)"

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Title page:

"Is care based on Comprehensive Geriatric Assessment with Mobile Teams better than usual care? – a study protocol article of a randomized controlled trial (The GerMoT-study)"

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Keywords

Comprehensive Geriatric Assessment, Frailty, Geriatric Medicine, Randomised Controlled Trial, Out-Patient Care

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Abstract

Introduction Comprehensive geriatric assessment (CGA) is a multidimensional, interdisciplinary diagnostic process used to determine the medical, psychological and functional capabilities of frail older people. Evidence suggests that CGA-based care is superior to usual care. However, so far, most CGA-based studies have been performed on hospitalized patients and only a few in out-patient care settings.

The primary aim of our current study is to confirm whether CGA-based out-patient care is superior to usual care in terms of days in hospital during the study period. As secondary aims, we will assess possible differences in health-related outcomes, resource use and costs.

Methods and analysis The GerMoT-trial is designed as a singelcentre randomised, controlled, assessor blinded (at baseline) trial. All participants will be identified via local health care registers with the following inclusion criteria: age ≥ 75 years, ≥ 3 different diagnoses and ≥ 3 visits to the emergency care unit (with or without admittance to hospital care) during the past 18 months. Nursing home residency will be an exclusion criterion. Baseline assessments will be done before the 1:1 randomisation. Follow up assessments will be performed 12 and 24 months after inclusion. Both descriptive and analytic statistics will be used, in order to compare groups and for analyses of outcomes over time including changes therein.

Ethics and dissemination The care of old people with multimorbidity and high Health Care consumption is characterised of being fragmented and expensive to the society. We add CGA-based care to this population in order to coordinate and improve care. In case of success the study will promote the implementation of CGA in out-patient care settings and thereby contribute to an improved care of older people with multimorbidity through dissemination of the results through scientific articles, information to politicians and to the public.

The trial is registered in ClinicalTrials.Gov: NCT02923843.

Strengths and limitations of this study:

Strengths:

- The randomized design in a well-defined population
- The urgent need of better care models for old people with high health care utilisation

Limitations:

- A limitation is the highly personalised care (the intervention) which cannot be fully standardized
- The single centre design limits generalisation

Introduction

Background

With the ageing of populations worldwide, increasing numbers of people are living with multiple chronic conditions and frailty (1). However, our health care system is not optimally designed to meet the complex needs of older people with multimorbidity. Instead, it has been subdivided into an ever-increasing number of entities and specialities over the last decades. Thus, the development has led care providers to focus on the treatment of single diseases instead of addressing multimorbidity. As a consequence, the care of old people has become more fragmented leading to increased risks, such as medication errors (1). In addition, the current health system is associated with high costs because of repeated visits to emergency care units and hospitalization of older people (2).

Comprehensive geriatric assessment (CGA) is a multidimensional, interdisciplinary diagnostic process used to determine the medical, psychological and functional capabilities of frail older people (3). Evidence suggests that CGA-based care is superior to usual care in terms of improving functional capacity and reducing the risk of institutionalisation (3, 4).

Older people with multimorbidity often require hospital care to optimise the treatment of chronic diseases or to diagnose and treat newly arisen conditions (2). At the same time, hospitalisation may serve as a marker of unmet health care needs and should, if possible, be avoided due to the associated risks of fractures, medication errors, delirium, iatrogenic infections and further disabilities (5).

There have been several studies and meta-analyses on CGA-based care compared to usual care in the acute inpatient care setting (3, 4, 6-8), but only a few randomised controlled trials on the effect of CGA-based outpatient care (9, 10). Boult et al. (9) showed better functionality but no difference in mortality with CGA-based care. Our own previous study, the Age-FIT trial, showed superior results of CGA-based care compared to usual care with respect to days in hospital, feeling of security and mortality (11). In addition, unpublished results from the same study indicated a reduction of progression in frailty.

We have selected in-hospital days as the primary study outcome because of the risk for delirium, falls, infections and other iatrogenic complications associated with hospitalization of older people (12).

In this study, we have chosen to exclude persons living in nursing homes as they receive health care by designated primary care physicians who make weekly rounds at the respective accommodations. Moreover, we decided to only include subjects residing in municipalities located in the vicinity of the hospital (as one of our inclusion criteria is based on the frequency of the subjects having attended the emergency care unit). Importantly, we do not exclude participants with cognitive decline as we know that these individuals often seek care and that their cognitive decline are frequently not properly addressed (13).

Despite the evidence behind CGA-based care, health care providers have been reluctant to adopt this method, probably due to the anticipation of increased costs and the need for substantial shifts in practice towards interprofessional teamwork - including gerontological

and geriatric competences. The study will therefore include health economic data from both in- and outpatient's health care and care given by the municipality, which makes it possible to evaluate the cost-effectiveness of the study.

In the present study, we seek to confirm our earlier results with a slightly modified recruitment scheme (≥ 3 visits to the emergency care unit, with or without subsequent admittance).

We used the SPIRIT checklist when writing our report (14).

The first protocol version 1.6 was launched 14th of October, 2016. This article is based on protocol version 1.7. launched 24th of April 2017. Changes can be followed in ClinicalTrials.Gov and the main change between version 1.6 and 1.7 was that we lowered the age to ≥ 75 years as in our previous study instead of ≥ 78 years as it showed up to be too few eligible participants otherwise.

The funder of the clinical part of this trial is Region Skane, Sweden. For the scientific part the Primary Sponsor is the first author and PI Anne W. Ekdahl, anneekdahl@gmail.com, cell 046 70 787 4250

The status of this trial is still recruiting with the first patient enrolled 26th of October 2016 and the last is expected to be enrolled in June 2018. After the recruitment of the last patient the trial will go on for further 24 months and thus expected to end in the summer 2020.

All items asked for in the WHO Organization Trial Registration Data Set is found in the ClinicalTrials.Gov: NCT02923843 together with information on this page.

Methods and analyses

Trial design

The study is designed as a randomised, controlled, assessor blinded, single centre trial. Participants are randomised to one of two groups; an intervention group (IG) receiving care of the CGA-based team in addition to usual health care and a control group (CG), with access to usual health care only. The study will be conducted at a medium sized non-academic hospital in the south of Sweden. The hospital have approximately 140 000 inhabitants to serve. The care will be described through reviews of registries as well as the case report form.

Patient and Public Involvement

The base for the interventions was founded through several meetings with the Swedish Retirements organizations and three medical Societies (General Practitioners, Specialists in Internal Medicine and Geriatricians). The meetings resulted in a statement on how to take care of old people with multimorbidity the best way: "Around every frail old person there should be a multiprofessional team adapted to the specific needs of that person. The team should coordinate the care around the frail old person".

This project aims to fulfill that goal – to provide with a multiprofessional team adapted to each patients' needs. The patients were, however, not involved in the study-design, the recruitment or the choice of outcomes. The burden of the intervention was not assessed by the patients before the start of the study, but it was explained in detail in the study information before any agreement of participation.

The results of the study will be expressed in a reader-friendly version and mailed out to all study participants.

Setting

The hospital have a 24-hour admittance for surgical and medical emergencies. The Geriatric Mobile Team (GerMoT) are situated at a geriatric clinic and several team-members work both

in the mobile team and in other parts of the clinic. Apart from the GerMoT there is no general geriatric outpatient clinic and no private geriatric practitioners in the municipality.

Eligibility

Eligible participants will

1) have had ≥ 3 visits to the emergency care unit within the past 18 months
2) have ≥ 3 different diagnoses according to the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10)
3) be living in, or close to, the municipality in which the hospitals are situated
4) be ≥75 years old
5) not be living in a nursing home

Outcomes

Primary outcome

- Days of in-hospital care during 24 months (obtained from the registers of care in Region Skåne).

Secondary outcomes

- Mortality after 12 months (security data) and after 24 months (obtained from the Swedish National Population Register)
- Quality of life, as measured by the EQ-5D-5L (15) after 12 and 24 months (secondary outcome).
- Health care use (obtained from the local care register, where contacts in primary and secondary care - including visits to nurses, paramedics, physicians etc. - are registered, together with data from the Registry of social care from the

National Board of Health and Welfare, which describes the social service interventions during the study period).

- Physical functional level (obtained by SPPB) (16) after 12 and 24 months.
- Frailty, as measured according to the Fried (phenotype) and Rockwood 's deficit index of frailty after 24 months (17, 18)
- Dependence measured with Katz' Activities of Daily Living (19)
- Cognition, as measured with Montreal Cognitive Assessment at baseline and after 24 months (20)

Background variables will be the following sociodemographic factors: age, sex, marital status, living alone/in relationship and education – as they are all known to be associated with the health status.

Data will be collected by means of structured interviews at baseline, and after 12, and 24 months as well as by collection of registry data. Registry data will be collected for the period four years before inclusion in the study to 24 months after inclusion. Mortality data will be analysed for the first 12 month after inclusion for security reasons.

Participant timeline

For the timeline, please see Figure.

Sample size

A power calculation was made based on the primary outcome variable, i.e. mean number of days in hospital. Based on a former similar study there will be an assumed difference between the intervention group and the control group of 4.1 days in hospital during the 24 months study period (11.1 days in the intervention group and 15.2 in the control group) with a standard deviation of 15 days in both groups. To be able to detect a difference between the

intervention and the control groups with a two-sided test and with a significance level of α=0.05 and 80% power, at least 211 participants in each group will be needed. There will be almost no loss to follow-up of the primary outcome based on previous research of this patient-group and intervention (10). Thus, a total of 450 persons will be included.

Recruitment

Lists of eligible participants will be obtained from the Health Care Administrative System in Region Skåne. To ensure as many participants as possible all eligible individuals will receive a letter with an explanation of the aim and procedure of the study about a week before they are contacted via phone by an experienced study nurse (the head researcher nurse). If requested, further information can be given at this point. In case of a preliminary consent, the participants' address and phone numbers are given to the data-collecting nurses who will make an appointment for a home visit, during which the written consent will be obtained before the baseline-data collection. If a person due to cognitive decline is unable to answer the study questions or give informed consent, a proxy will be contacted.

Unreachable eligible participants will be contacted at least three times before we give up contacting them.

Allocation

Prior to inclusion of the first patient a randomisation master list with 450 numbers (the number needed according to the power calculation) was created by the project coordinator via a computer-package (IBM SPSS Statistics version 23.0). The participants were randomized 1:1 to either the IG or the CG.

The list is kept by a study administrator who is not involved in the recruitment of participants.

When informed consent and baseline measures have been collected, the protocol will be delivered to the study administrator who randomizes the participants consecutively as the protocols becomes available to her. After randomization, the participants will receive an information letter, describing the study conditions for that group. In addition, a nurse from GerMoT will get in contact with each participant allocated to the IG to arrange for the further procedures as described in the intervention. Similarly, the participants in the CG will receive a letter explaining the study conditions and that they will be contacted again after 12 and 24 months, respectively.

Only the project coordinator and the study administrator have access to the randomisation list during the study.

Blinding

All pre-randomisation baseline data are collected by blinded assessors/interviewers, who will not take part in the patient care before or after randomisation. The participants in this study cannot be blinded to their assigned groups at 12 and 24 months, as only participants in the intervention group are assessed and cared for by the GerMoT. All register data will be extracted by blinded administrative personnel not involved in the study.

Data collection

All instruments in the questionnaires are validated (see references in the Outcomes section (15, 17-21)). All data collectors are registered nurses who have been trained in Good Clinical Practice (GCP). There will be regular meetings between the data collectors, the head researcher nurse and the project leader. Such meetings will be held primarily to provide training for all instruments and later also to address all upcoming questions. All paper protocols will be kept safely and when data are transferred to a computerized data base the

questionnaires will be controlled for errors and missing data by research staff. Data entry are double checked against the paper questionnaires, and in case of inconsistencies in data entries, corrections will be made by referring back to the paper questionnaires.

Through the ten-digit unique personal identification number provided to all people in Sweden it will be possible to extract register data on all participants who have provided informed consent, even in the case they have died.

The intervention

The key component of the intervention is a CGA, including a plan for future care and follow up contacts. All care is personalized and adapted to each individual's needs. The following scheme will be used for most of the participants (exceptions can be made, e.g. if it is difficult for the participant to visit the hospital):

1) Home visit by a nurse: An interview regarding the participant's conception of his or her health and health problems. The interview is conducted by a nurse in the participant's home environment as it gives us a better opportunity to further deepen our understanding of the participant's living conditions. The interview has a holistic character and follows a template that covers areas closely related to the patient's quality of life. In addition, a venous blood sample is drawn and the following parameters will be analysed: haemoglobin, white blood cell and platelet count, proB-type natriuretic protein, blood glucose, creatinine, sodium, potassium, and c-reactive protein.
2) Drug review by a clinical pharmacist: A thorough drug review is performed together with the participants and their relatives as well as via the pharmacies' national registries and the participants' medical records. Potentially harmful drugs or doses are being revised. Finally, this information is assembled into the medical record.

3) Physician´s visit at the hospital: Prior to the visit, the physician performs a thorough review of the medical records. This information is assembled into one comprehensive medical history entry. To the visit to the physician the participant is asked to bring a relative or a close friend. At this time, the medical history is confirmed, current health symptoms are listed and a physical examination, including neurological assessment and an electrocardiogram, is performed. The participant receives information on the outcome of the blood analyses. The visit ends with a summary of all assessments, adjustment of the current medication list and a plan for the next contact, which will usually take place via telephone by a nurse or another team-member some weeks after the interdisciplinary meeting conference. The patient is handed a printout of his or her current medication list (or one will be sent by mail within the following days).
4) Interdisciplinary meeting conference: Such conferences are held twice a week by the CGA team. The team includes nurses, physicians, a physiotherapist, an occupational therapist and a pharmacist. In addition, social workers from the municipality will attend. The team summarizes the participants' physical, psychological, social and functional situation, with a focus on actions to improve quality of life. A plan for further actions is taken if possible and necessary. Examples of such actions include home visits by occupational therapists or physiotherapists as well as further pharmaceutical adjustments or new contacts with the municipal liaison for reassessment of service needs. Decisions are also made on the type and frequency of the follow-up contacts. Importantly, the plan can vary widely between participants and range from a short period of daily contacts with the nurse and extra doctor's visits, to scheduled six months' phone calls or visits after one year by a nurse (in cases where no earlier contact is deemed necessary).

Accessibility

The GerMoT office is open for telephone calls during office hours (weekdays 08-16.30) and typically one of the nurses will answer the participants' calls. If the nurses are unable to answer, the participant has the opportunity to leave a recorded message, upon which the nurse will return the call on the same day. The GerMoT instructs the participants to contact the regular emergency health care services whenever there is a need outside office hours. In cases of uncertainty whether to contact emergency services during office hours, patients are encouraged to call the GerMoT first. In case of an urgent health related problem, the GerMoT can guide the participant to the appropriate caregiver. The GerMoT will have no formal right to admit a patient directly to a particular department of the hospital but will, whenever needed, consult with appropriate specialist colleagues to make the best possible arrangements.

Collaboration and coordination

The GerMoT must cooperate extensively with other health care providers, as it is regarded as an adjunct to the existing health care system. If patients have contacts with several physicians in parallel, especially in primary care, these are contacted in order to minimize the risk of an uncoordinated care. The primary care-based management of certain diagnoses will be available also to the participants in the intervention group. For example, health services for diabetes, chronic obstructive pulmonary disease and skin ulcers will be continually provided by specialized nurses at the primary care centres. The physicians and coordinator nurses at the GerMoT have regular contact with these nurses as deemed appropriate. For organ specific consultations, the physicians and nurses of the GerMoT contact consultant physicians at relevant hospital departments.

Usual care

Participants allocated to the CG receive health care either from their primary care physician, the community services or the in- and outpatient hospital care. Normally, most primary care is provided at the request of the patients - and only more seldom in the form of pre-scheduled proactive health visits. Both the IG and the CG have access to the primary care centres, the hospital and various ambulatory units on equal conditions. The GerMoT concept is not a part of the regular health care system, where the patients instead are seeking one professional at a time – e.g. either a physician, a nurse or a physiotherapist.

Criteria for discontinuing or modifying the allocated interventions

A participant may at any time leave the trial, without having to explain the decision. If a patient moves to a nursing home, the intervention given by the GerMoT will be ended at the same time as the physician in the nursing home takes over the responsibility for coordination of the medical care. The intervention will also be stopped if a patient moves out of the area within the near range of the hospital.

Strategies to improve adherence to the intervention

Adherence to the intervention is promoted by pro-active calls by the GerMoT nurse, especially if there are reasons to believe that the participant does not seek appropriate care on his or her own initiative.

In addition to the service provided by the GerMoT, care is permitted without restrictions.

Statistical methods

Both descriptive and analytic statistics will be used, in order to compare groups and for analyses of outcomes over time including changes therein.

Continuous outcomes, e.g. days in hospital, will be analysed using analysis of variance (ANOVA), using in-transformed values if needed to achieve normal distribution of the residuals. Dichotomous outcomes will be evaluated using relative risks (RRs) estimated by generalized linear models (GLMs) with a Poisson distribution, log link function and robust covariance matrix estimator. Outcomes described by ordinal data will be investigated using non-parametric statistical methods, such as Pearson's chi-squared test[2].

A two-sided p-value ≤ 0.05 will be considered statistically significant. Analyses will be made on the basis of the intention-to-treat principle. Given the old age of the participants, a relatively high drop-out rate is expected and missing data will not be at random. Simply analysing complete cases is not relevant and might lead to bias. Therefore, the approach of data imputation will be the replacement of missing values with a value based on the median change of deterioration. A worst case change will be applied for those who have died before follow-up.

Ethics and dissemination

The study results will be disseminated in national and international scientific peer-reviewed journals and on appropriate congresses. The results will also be disseminated to leaders of health care and health care stakeholders.

Ethical approval has already been obtained by the Regional Ethical Committee in Lund Dnr: 2016/630.

Protocol amendments will be published in ClinicalTrials.gov as amendments to the initial registration NCT02923843.

An interim analysis will be made on mortality after one year. This will be done by an independent researcher and the study will be stopped in case of a statistically significant increase or decrease in mortality. The independent researcher must in that case inform the project leader who will then terminate the trial.

There are no specific data monitoring committee beside the above-mentioned mortality analysis as we are using no new methods in the control or interventions group which could be considered to harm the patient.

Data management and monitoring

All participants are given a code number between 1 and 450. The master randomization list is safely stored by the study administrator. All case-report forms (CRF) with code numbers are safely locked in and stored in a locked cabinet in the head research nurse's office. The initial entry of data will be made in a computerized data base constructed by an experienced statistician able to promote data quality by allowing data-entry within certain ranges. The study conducted at the centre in Region Skåne will be monitored by **Clinical Studies Sweden - Forum South** after baseline, 12 and 24 months. This organisation has no connection to the study beside quality assurance of clinical trials conducted by Lund University and in Region Skåne.

The GCP-trained head researcher nurse will first obtain a verbal consent and later the data-collecting nurses will obtain written consent during the home visits to each participant. In case of language problems or cognitive decline a next of kin can sign the written informed consent – preferably together with the participant.

All CRFs will be kept in a locked cabinet at the head research nurse's office during the trial. However, at the 12 months and the 24 months monitoring independent staff will be allowed to access all the CRF, randomization list and medical records.

The principal investigator (PI) and the authors of relevant articles will have access to the dataset. Further dissemination of the dataset can be decided by the PI.

Consent to publish

This manuscript does not include details, images, or videos relating to an individual person why a consent form to publish is not applicable.

Later all results will be disseminated on a group level and no personal information will be revealed. In order to ensure that single individuals cannot be identified, only results for groups comprising at least five persons will be presented.

Author contributions

AE designed the study and wrote this manuscript. AA and KSC participated in designing the study, with a focus on statistics and health-economy, respectively. All authors have scrutinized, improved and approved the final manuscript.

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Competing interest

All authors claim no conflict of interest.

Availability of data and materials

The study-protocol is registered in ClinicalTrials.gov and available at https://clinicaltrials.gov/ct2/show/NCT02923843?term=Ekdahl&cntry1=EU%3ASE&rank=1

The study-protocol in Swedish available at https://www.researchgate.net/project/Geriatric-Outpatient-Care-versus-usual-care-a-Randomsed-Controlled-trial

and patient information letter in Swedish available at

https://www.researchgate.net/project/Geriatric-Outpatient-Care-versus-usual-care-a-Randomsed-Controlled-trial

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Figure. Schedule of enrollment, interventions and assessments in the GerMoT-trial

	STUDY PERIOD			
	Enrollment	**Allocation**	**Post-allocation**	**Close-out**
TIMEPOINT**	$-t_1$	**0**	***12 months***	***24 months***
ENROLLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Intervention			X	X
Control group			X	X
ASSESSMENTS: (after informed consent)				
Frailty	X		X	X
Quality of Life	X		X	X
Dependency	X		X	X
Cognition	X			X
Functional capacity	X			X
Number of days in hospital				X
Mortality			X	X
Care consumption			X	X

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
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	_____3_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____6_____
Protocol version	3	Date and version identifier	_____6_____
Funding	4	Sources and types of financial, material, and other support	_____22_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	____1 + 22___
	5b	Name and contact information for the trial sponsor	____22 + 6___
	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	__6 + 22 + 17_
	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)	___16_____

Introduction			
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_____
	6b	Explanation for choice of comparators	__5_____
Objectives	7	Specific objectives or hypotheses	__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, noninferiority, exploratory)	__7_____
Methods: Participants, interventions, and outcomes			
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	__7_____
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)	__7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	__11 - 14_____
	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)	__14_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	__15_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	__14_____
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	___8_____
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)	___9_____

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	__9_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	__8_____
Methods: Assignment of interventions (for controlled trials)			
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	__10 + 23____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	__10_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	__10_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	__10_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	__10_____
Methods: Data collection, management, and analysis			
Data collection methods	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	__11_____
	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	___16_____
Statistical methods	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	___15_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___15_____
	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)	___15_____
Methods: Monitoring			
Data monitoring	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	___16_____
	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	___16_____
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	___16_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___16_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	____16_____
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)	____n/a_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	__11_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	__n/a_____
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	__16 + 17____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	__22_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	__17_____
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	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	___16_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	___n/a_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___17 + 18__
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	___18_____
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_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

"Is care based on Comprehensive Geriatric Assessment with Mobile Teams better than usual care? – a study protocol of a randomized controlled trial (The GerMoT-study)"

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Title page:

"Is care based on Comprehensive Geriatric Assessment with Mobile Teams better than usual care? – a study protocol of a randomized controlled trial (The GerMoT-study)"

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Abstract

Introduction Comprehensive geriatric assessment (CGA) is a multidimensional, interdisciplinary diagnostic process used to determine the medical, psychological and functional capabilities of frail older people.

The primary aim of our current study is to confirm whether CGA-based out-patient care is superior than usual care in terms of health-related outcomes, resource use and costs.

Methods and analysis The GerMoT-trial is designed as a single-centre randomised, controlled, assessor blinded (at baseline) trial. All participants will be identified via local healthcare registries with the following inclusion criteria: age ≥ 75 years, ≥ 3 different diagnoses and ≥ 3 visits to the emergency care unit (with or without admittance to hospital) during the past 18 months. Nursing home residency will be an exclusion criterion. Baseline assessments will be done before the 1:1 randomisation. Participants in the intervention group will, after an initial CGA, have access to care given by a geriatric team in addition to usual care. The control group receives usual care only. The primary outcome is the total number of inpatient days during the follow-up period. Assessments of the outcomes: mortality, quality of life, health care use, physical functional level, frailty, dependence and cognition will be performed 12 and 24 months after inclusion.

Both descriptive and analytical statistics will be used, in order to compare groups and for analyses of outcomes over time including changes therein. The primary outcome will be analysed using analysis of variance (ANOVA), including in-transformed values if needed to achieve normal distribution of the residuals.

Ethics and dissemination

Ethical approval has been obtained and the results will be disseminated in national and international journals and to health care leaders and stakeholders.

Protocol amendments will be published in ClinicalTrials.gov as amendments to the initial registration NCT02923843.

In case of success the study will promote the implementation of CGA in out-patient care settings and thereby contribute to an improved care of older people with multimorbidity through dissemination of the results through scientific articles, information to politicians and to the public.

The trial is registered in ClinicalTrials.Gov: NCT02923843.

Strengths and limitations of this study:

Strengths:

- Uses randomized design in a well-defined population
- Addresses the urgent need of better care models for older people with high health care utilisation

Limitations:

- Uses highly personalised care (the intervention) which cannot be fully standardized
- The single centre design limits generalisation

Introduction

Background

With the ageing of populations worldwide, increasing numbers of people are living with multiple chronic conditions and frailty (1). However, our health care system is not optimally designed to meet the complex needs of older people with multimorbidity. Instead, it has been subdivided into an ever-increasing number of entities and specialities over the last decades. Thus, the development of health care has led care providers to focus on the treatment of single diseases instead of addressing multimorbidity. As a consequence, the care of old people has become more fragmented leading to increased risks, such as medication errors (1). In addition, the current health system is associated with high costs because of repeated visits to emergency care units and hospitalization of older people (2).

Comprehensive geriatric assessment (CGA) is a multidimensional, interdisciplinary diagnostic process used to determine the medical, psychological and functional capabilities of frail older people (3) and includes further planning and follow-up of the patients (3). Evidence suggests that CGA-based care is superior to usual care in terms of improving functional capacity and reducing the risk of institutionalisation (3, 4).

Older people with multimorbidity often require hospital care to optimise the treatment of chronic diseases or to diagnose and treat newly diagnosed conditions (2). At the same time, hospitalisation may serve as a marker of unmet health care needs and should, if possible, be avoided due to the associated risks of fractures, falls, medication errors, delirium, iatrogenic infections and further disabilities (5).

There have been several studies and meta-analyses on CGA-based care compared to usual care in the acute inpatient care setting (3, 4, 6-8), but only a few randomised controlled trials on the effect of CGA-based outpatient care (9, 10). Boult et al. (9) showed better functionality but no difference in mortality with CGA-based care. Our own previous study, the Age-FIT trial, showed superior results of CGA-based care compared to usual care with respect to days in hospital, feeling of security and mortality (11). In addition, results from the same study indicated a reduction of progression in frailty (12).

Despite the evidence behind CGA-based care, health care providers have been reluctant to adopt this method, probably due to the anticipation of increased costs and the need for substantial shifts in practice towards interprofessional teamwork - including gerontological and geriatric competences. The study will therefore include health economic data from both in- and outpatient's health care and care given by the municipality, which makes it possible to evaluate the cost-effectiveness of the study.

By giving patients in the intervention group easy access to care given by a team who knows them well we hope, as in our former study, we will be able to diminish the need of inpatient days in hospital which is an important outcome because of the risk for delirium, falls, infections and other iatrogenic complications associated with hospitalization of older people (13) beside high health care costs.

We used the SPIRIT checklist when writing our report (14)

Methods and analyses

Trial design

The study is designed as a randomised, controlled, assessor blinded, single centre trial. Participants are randomised to one of two groups; an intervention group (IG) receiving care of the CGA-based team in addition to usual health care and a control group (CG), with access to usual health care only. The study will be conducted at a medium sized non-academic hospital in the south of Sweden. The hospital has approximately 140 000 inhabitants to serve. The care will be described through reviews of registries as well as the case report form. The care registries are: "The Patient Administrative System in Skane" (PASIS) (15), which is a population based, administrative database run by the County Council of Skane together with the database of decisions according to the Social Care Act in Sweden run by the Swedish National Board of Health and Welfare(16). PASIS gives the base for all funding and follow up of care in Skane. Both registries use the specific person-identification number which all inhabitants in Sweden have.

Patient and Public Involvement

The base for the interventions was founded through several meetings with the Swedish Retirements organizations and three medical Societies (General Practitioners, Specialists in Internal Medicine and Geriatricians). The meetings resulted in a statement outlining best way to take care of older people with multimorbidity : "Around every frail older person there should be a multiprofessional team adapted to the specific needs of that person. The team should coordinate the care around the frail older person".

This project aims to fulfill that goal – to provide with a multiprofessional team adapted to each patients' needs. The patients were, however, not involved in the study-design, the recruitment or the choice of outcomes. The burden of the intervention was not assessed by the patients before the start of the study, but it was explained in detail in the study information before any agreement of participation.

The results of the study will be expressed in a reader-friendly version and mailed out to all study participants.

Setting

The hospital admits surgical and medical emergencies 24 hours a day. The Geriatric Mobile Team (GerMoT) is located in a geriatric department and several team-members work both in the mobile team and in other parts of the department. Apart from the GerMoT there is no general geriatric outpatient clinic and no private geriatric practitioners in the municipality.

Eligibility

Eligible participants will

1) have had ≥ 3 visits to the emergency care unit within the past 18 months
2) have ≥ 3 different diagnoses according to the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10)
3) be living in, or close to, the municipality in which the hospitals are situated
4) be ≥75 years old
5) not be living in a nursing home

In this study, we have chosen to exclude persons living in nursing homes as they receive health care by designated primary care physicians who make weekly rounds at the respective accommodations. Moreover, we decided to only include subjects residing in municipalities

located in the vicinity of the hospital (as one of our inclusion criteria is based on the frequency of the subjects having attended the emergency care unit).

Importantly, we did not exclude participants with cognitive decline as we know that these individuals often seek care and that their cognitive decline is frequently not addressed properly. (17).

In the present study, we seek to confirm our earlier results with a slightly modified recruitment scheme (≥ 3 visits to the emergency care unit, with or without subsequent admittance).

Outcomes

Primary outcome

- Total number of days of inpatient care days during 24 months obtained from the registers of care in Region Skåne, PASIS). This registry will capture all kinds of care in the Region of Skane given by both private and public care in the Region – not only care given in the hospital in which the intervention is placed. The number of inpatient days are strictly defined as more than 24 hours of inpatient care.

Secondary outcomes

- Mortality after 12 months (security data) and after 24 months (obtained from the Swedish National Population Register)
- Quality of life, as measured by the EQ-5D-5L (18) at baseline, after 12 and 24 months
- Health care use (obtained from the local care register, PASIS, where contacts with primary and secondary care - including visits to nurses, paramedics,

physicians etc. - are registered, together with data from the Registry of social care from the National Board of Health and Welfare, which describes the social service interventions during the study period).

- Physical function level (obtained by SPPB) (19) at baseline, after 12 and 24 months.
- Frailty, as measured according to the Fried (phenotype) and Rockwood 's deficit index of frailty at baseline, after 12 and after 24 months (20, 21)
- Dependence measured with Katz' Activities of Daily Living at baseline, after 12 and 24 months (22)
- Cognition, as measured with Montreal Cognitive Assessment at baseline and after 24 months (23)

Background variables will be the following sociodemographic factors: age, sex, marital status, living alone/in relationship and education – as they are all known to be associated with health status.

Data will be collected by means of structured interviews at baseline, after 12 and 24 months as well as by collection of registry data. Registry data will be collected for the period four years before inclusion in the study to 24 months after inclusion. Mortality data will be analysed for the first 12 month after inclusion for security reasons.

Participant timeline

For the timeline, please see research-checklist..

Sample size

A power calculation was made based on the primary outcome variable, i.e. mean number of days in hospital. Based on a former similar study there will be an assumed difference between

the intervention group and the control group of 4.1 days in hospital during the 24 months study period (11.1 days in the intervention group and 15.2 in the control group) with a standard deviation of 15 days in both groups. To be able to detect a difference between the intervention and the control groups with a two-sided test and with a significance level of α=0.05 and 80% power, at least 211 participants in each group will be needed. There will be almost no loss to follow-up of the primary outcome based on previous research of this patient-group and intervention (10). Thus, a total of 450 persons will be included.

Recruitment

Lists of eligible participants will be obtained from the Health Care Administrative System (PASIS) in Region Skane. To ensure as many participants as possible, all eligible individuals will receive a letter with an explanation of the aim and procedure of the study about a week before they are contacted via phone by an experienced study nurse (the head researcher nurse). If requested, further information can be given at this point. In case of a preliminary consent, the participants' address and phone numbers are given to the data-collecting nurses who will make an appointment for a home visit, during which the written consent will be obtained before the baseline-data is collected. If a person due to cognitive decline is unable to answer the study questions or give informed consent, a proxy will be contacted. Unreachable eligible participants will be contacted at least three times before we give up contacting them.

Allocation

Prior to inclusion of the first patient a randomisation master list with 450 numbers (the number needed according to the power calculation) was created by the project coordinator via

a computer-package (IBM SPSS Statistics version 23.0). The participants were randomized 1:1 to either the IG or the CG.

The list is kept by a study administrator who is not involved in the recruitment of participants. When informed consent and baseline measurements have been collected, the protocol will be delivered to the study administrator who randomizes the participants consecutively as the protocols become available to her. After randomization, the participants will receive an information letter describing the study conditions for that group. In addition, a nurse from GerMoT will get in contact with each participant allocated to the IG to arrange for further procedures as described in the intervention. Similarly, the participants in the CG will receive a letter explaining the study conditions and that they will be contacted again after 12 and 24 months respectively.

Only the project coordinator and the study administrator have access to the randomisation list during the study.

Blinding

All pre-randomisation baseline data are collected by blinded assessors/interviewers, who will not take part in the patient's care before or after randomisation. The participants in this study cannot be blinded to their assigned groups at 12 and 24 months, as only participants in the intervention group are assessed and cared for by the GerMoT. All register data will be extracted by blinded administrative personnel not involved in the study.

Data collection

All instruments in the questionnaires are validated (see references in the Outcomes section (18, 21-24). All data collectors are registered nurses who have been trained in Good Clinical Practice (GCP). There will be regular meetings between the data collectors, the head

researcher nurse and the project leader. Such meetings will be held primarily to provide training for all instruments and later also to address all upcoming questions. All paper protocols will be kept safe and when data is transferred to a computerized data-base the questionnaires will be checked for errors and missing data by research staff. Data entry are double checked against the paper questionnaires, and in case of inconsistencies in data entries, corrections will be made by referring back to the paper questionnaires.

Through the ten-digit unique personal identification number provided to all people in Sweden it will be possible to extract register data on all participants who have provided informed consent, even in case they have died.

The intervention

The key component of the intervention is a CGA, including a plan for future care and follow up contacts. All care is personalized and adapted to each individual's needs. The following scheme will be used for most of the participants (exceptions can be made, e.g. if it is difficult for the participant to visit the hospital):

1) Home visit by a nurse: An interview regarding the participant's own view of his or her health and health problems. The interview is conducted by a nurse in the participant's home environment as it gives us a better opportunity to further deepen our understanding of the participant's living conditions. The interview has a holistic character and follows a template that covers areas closely related to the patient's quality of life. In addition, a venous blood sample is drawn and the following parameters will be analysed: haemoglobin, white blood cell and platelet count, proB-type natriuretic protein, blood glucose, creatinine, sodium, potassium, and c-reactive protein.

2) Drug review by a clinical pharmacist: A thorough drug review is performed together with the participants and their relatives as well as via the pharmacies' national registries and the participants' medical records. Potentially harmful drugs or doses are being revised. Finally, this information is assembled into the medical record.
3) Visiting a physician in hospital:: Prior to the visit, the physician performs a thorough review of the medical records. This information is assembled into one comprehensive medical history entry. When visiting the physician the participant is asked to bring a relative or a close friend. At this time, the medical history is confirmed, current health symptoms are listed and a physical examination, including neurological assessment and an electrocardiogram, is performed. The participant receives information about the outcome of the blood analyses. The visit ends with a summary of all assessments, adjustment of the current medication list and a plan for the next contact, which will usually take place via telephone by a nurse or another team-member some weeks after the interdisciplinary meeting conference. The patient is handed a printout of his or her current medication list (or one will be sent by mail within the following days).
4) Interdisciplinary meeting conference: Such conferences are held twice a week by the CGA team. The team includes nurses, physicians, a physiotherapist, an occupational therapist and a pharmacist. In addition, social workers from the municipality will attend. The team summarizes the participants' physical, psychological, social and functional situation, with a focus on actions to improve quality of life. A plan for further actions is taken if possible and necessary. Examples of such actions include home visits by occupational therapists or physiotherapists as well as further pharmaceutical adjustments or new contacts with the municipal liaison for reassessment of service needs. Decisions are also made on the type and frequency of the follow-up contacts. Importantly, the plan can vary widely between participants and

range from a short period of daily contacts with the nurse and extra doctor's visits, to scheduled six monthly phone calls or visits after one year by a nurse (in cases where no earlier contact is deemed necessary).

Accessibility

The GerMoT office is open for telephone calls during office hours (weekdays 08.00-16.30) and typically one of the nurses will answer the participants' calls. If the nurses are unable to answer, the participant has the opportunity to leave a recorded message, upon which the nurse will return the call on the same day. The GerMoT instructs the participants to contact the regular emergency health care services whenever there is a need outside office hours. In cases of uncertainty whether to contact emergency services during office hours, patients are encouraged to call the GerMoT first. In case of an urgent health related problem, the GerMoT can guide the participant to the appropriate caregiver. The GerMoT will have no formal right to admit a patient directly to a particular department of the hospital but will, whenever needed, consult with appropriate specialist colleagues to make the best possible arrangements.

Collaboration and coordination

The GerMoT must cooperate extensively with other health care providers, as it is regarded as an adjunct to the existing health care system. If patients have contacts with several physicians in parallel, especially in primary care, these are contacted in order to minimize the risk of uncoordinated care. The primary care-based management of certain diseases will also be available to the participants in the intervention group. For example, health services for diabetes, chronic obstructive pulmonary disease and skin ulcers will be continually provided by specialized nurses at the primary care centres. The physicians and coordinator nurses at the GerMoT have regular contact with these nurses as deemed appropriate. For organ specific

consultations, the physicians and nurses of the GerMoT contact consultant physicians at relevant hospital departments.

Usual care

Participants allocated to the CG receive health care either from their primary care physician, the community services or the in- and outpatient hospital care. Normally, most primary care is provided at the request of the patients - and only more seldom in the form of pre-scheduled proactive health visits. Both the IG and the CG have access to the primary care centres, the hospital and various ambulatory units on equal conditions. The GerMoT concept is not part of the regular health care system, where the patients instead are seeking one professional at a time – e.g. either a physician, a nurse or a physiotherapist.

Criteria for discontinuing or modifying the allocated interventions

A participant may at any time leave the trial, without having to explain their decision. If a patient moves to a nursing home, the intervention given by the GerMoT will end at the same time as the physician in the nursing home takes over the responsibility for coordination of the medical care. The intervention will also be stopped if a patient moves out of the hospital's catchment area.

Strategies to improve adherence to the intervention

Adherence to the intervention is promoted by pro-active calls by the GerMoT nurse, especially if there are reasons to believe that the participant does not seek appropriate care on his or her own initiative.

In addition to the service provided by the GerMoT, care is permitted without restrictions.

Statistical methods

Both descriptive and analytical statistics will be used in order to compare groups and for analyses of outcomes over time including changes therein.

Continuous outcomes, e.g. days in hospital, will be analysed using analysis of variance (ANOVA), including in-transformed values if needed to achieve normal distribution of the residuals. Dichotomous outcomes will be evaluated using relative risks (RRs) estimated by generalized linear models (GLMs) with a Poisson distribution, log link function and robust covariance matrix estimator. Outcomes described by ordinal data will be investigated using non-parametric statistical methods, such as Pearson's chi-squared test[2].

A two-sided p-value ≤ 0.05 will be considered statistically significant. Analyses will be made on the basis of the intention-to-treat principle. Given the old age of the participants, a relatively high drop-out rate is expected, and missing data will not be at random. Simply analysing complete cases is not relevant and might lead to bias. Therefore, the approach to data imputation will be the replacement of missing values with a value based on the median change of deterioration. A worst case change will be applied for those who have died before follow-up.

The first protocol version 1.6 was launched on the 14th of October, 2016. This article is based on protocol version 1.7. launched on the 24th of April 2017. Changes can be followed in ClinicalTrials.Gov and the main change between version 1.6 and 1.7 was that we lowered the recruitment age to ≥ 75 years as in our previous study instead of ≥ 78 years. This was done to allow recruitment of a sufficient number of eligible participants

The funder of the clinical part of this trial is Region Skane, Sweden. For the scientific part the Primary Sponsor is the first author and PI Anne W. Ekdahl, anneekdahl@gmail.com, cell 046 70 787 4250

Participants are still being recruited to the trial. The first patient was enrolled on the 26th of October 2016 and the last is expected to be enrolled in June 2018. After the recruitment of the last patient the trial will go on for a further 24 months and is therefore expected to end in the summer of 2020.

All items asked for in the WHO Organization Trial Registration Data Set can be found in the ClinicalTrials.Gov: NCT02923843 together with the information on this page.

Ethics and dissemination

The study results will be disseminated in national and international scientific peer-reviewed journals and on appropriate congresses. The results will also be disseminated to health care leaders and stakeholders.

Ethical approval has already been obtained by the Regional Ethical Committee in Lund Dnr: 2016/630.

Protocol amendments will be published in ClinicalTrials.gov as amendments to the initial registration NCT02923843.

An interim analysis will be made on mortality after one year. This will be done by an independent researcher and the study will be stopped in case of a statistically significant increase or decrease in mortality. The independent researcher must in that case inform the project leader who will then terminate the trial.

There is no specific data monitoring committee beside the above-mentioned mortality analysis as we are using no new methods in the control or interventions group which could be considered harmful the patient.

Data management and monitoring

All participants are given a code number between 1 and 450. The master randomization list is safely stored by the study administrator. All case-report forms (CRF) with code numbers are safely locked in and stored in a locked cabinet in the head research nurse's office. The initial entry of data will be made in a computerized data base constructed by an experienced statistician able to promote data quality by allowing data-entry within certain ranges. The study conducted at the centre in Region Skane will be monitored by **Clinical Studies Sweden - Forum South** after baseline, 12 and 24 months. This organisation has no connection to the study beside quality assurance of clinical trials conducted by Lund University and in Region Skane.

The GCP-trained head researcher nurse will first obtain a verbal consent and later the data-collecting nurses will obtain written consent during the home visits to each participant. In case of language problems or cognitive decline a next of kin can sign the written informed consent – preferably together with the participant.

All CRFs will be kept in a locked cabinet at the head research nurse's office during the trial. However, at the 12 months and the 24 months monitoring independent staff will be allowed to access all the CRF, randomization list and medical records.

The principal investigator (PI) and the authors of relevant articles will have access to the dataset. Further dissemination of the dataset can be decided by the PI.

Consent to publish

This manuscript does not include details, images, or videos relating to an individual person why a consent form to publish is not applicable.

Later all results will be disseminated on a group level and no personal information will be revealed. In order to ensure that single individuals cannot be identified, only results for groups comprising at least five persons will be presented.

Author contributions

AE designed the study and wrote this manuscript. AA and KSC participated in designing the study, with a focus on statistics and health-economy, respectively. All authors, AE, AA, KSC and MS, have scrutinized, improved and approved the final manuscript.

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Competing interest

All authors claim no conflict of interest.

Availability of data and materials

The study-protocol is registered in ClinicalTrials.gov and available at https://clinicaltrials.gov/ct2/show/NCT02923843?term=Ekdahl&cntry1=EU%3ASE&rank=1

The study-protocol in Swedish available at https://www.researchgate.net/project/Geriatric-Outpatient-Care-versus-usual-care-a-Randomsed-Controlled-trial

and patient information letter in Swedish available at

https://www.researchgate.net/project/Geriatric-Outpatient-Care-versus-usual-care-a-Randomsed-Controlled-trial

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Research-checklist.. Schedule of enrollment, interventions and assessments in the GerMoT-trial

Research-checklist: Schedule of enrollment, interventions and assessments in the GerMoT-trial

	STUDY PERIOD			
	Enrollment	**Allocation**	**Post-allocation**	**Close-out**
TIMEPOINT**	***-t_1***	**0**	***12 months***	***24 months***
ENROLLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Intervention			X	X
Control group			X	X
ASSESSMENTS: (after informed consent)				
Frailty	X		X	X
Quality of Life	X		X	X
Dependency	X		X	X
Cognition	X			X
Functional capacity	X			X
Number of days in hospital				X
Mortality			X	X
Care consumption			X	X