Comprehensive Geriatric Assessment for Frail Older People in Swedish Acute Care Settings (CGA-Swed): A Randomised Controlled Study

NCT02773914

2024-09-10

Study Protocol with SAP and/or ICF

Aim

The aim of the study was to evaluate the effects of the CGA for frail older people in Swedish acute hospital settings. The study addressed the following research questions:

Can the Comprehensive Geriatric Assessment for frail older people in Swedish acute hospital settings:

1. *Maintain independence in activities of daily living, functional status, health-related quality of life and life satisfaction?*
2. *Increase satisfaction with health care?*
3. *Reduce hospital and primary health care consumption?*

How feasible and acceptable are the study processes and procedures of the CGA from the perspective of care givers and older persons in Swedish settings?

Material and methods

The study was a two-armed randomised controlled trial that started with a pilot study in 2016. Ethical approval was obtained for the study, ref. no: 4,899-15, Regional Ethical Review Board in Gothenburg. Trial Registration: ClinicalTrials.gov, NCT02773914.

Data collection and participants: The study group included 155 older people who sought acute medical care at the emergency department during the period between March 2016 and December 2018. Inclusion criteria were that participants were to be ≥75 years of age, in need of acute in-hospital care and screened as frail according to the FRESH-screening instrument. Exclusion criteria were not being screened as frail according to the FRESH-screening instrument, being admitted through a "fast track" for direct admission to a designated ward (for predefined diagnosis such as stroke, acute myocardial infarction and hip fracture) and having an acute severe condition requiring a higher level of care (e.g., intensive care) than the intervention ward. Baseline measures were collected by a research assistant who gathered data from the frail older patient and/or from the medical records during the hospital stay. Follow-up interviews were performed in the older person's home at 1, 6 and 12 months after hospital discharge. The follow-ups were performed using a structured questionnaire including questions about demographic data and assessments of outcome measures. The interviews lasted for approximately 1.5 h.

Intervention/control group: The intervention was the ward working according to the Comprehensive Geriatric Assessment. Key components of the CGA are multi-disciplinary teamwork, use of a person-centred approach, comprehensive assessments, treatment and rehabilitation, discharge planning and follow-up. The multi-disciplinary team consisted of a physician, registered nurse (RN), assistant nurse (AN), physiotherapist (PT) and occupational therapist (OT) as well as other team members, such as a social worker (SW) and dietician, if needed. The control group received the usual acute hospital care, i.e., care given at an ordinary medical hospital ward without a specialised multi-disciplinary team approach and without the CGA. The assessments and care provided at the control wards were based on the acute problem/symptom that the patients had and did not include the comprehensive and person-centred approach to the health and life situation of the patient inherent in a CGA.

Measurements: Dependence in daily activities was measured using the ADL-staircase assessment by combining both interviews and observations. It includes dependence in nine activities: cleaning, shopping, transportation, cooking, bathing, dressing, going to the toilet, transferring and feeding. Dependence was defined as a state in which another person is involved in the activity by giving personal or directive assistance. The sum of dependence in the nine activities of daily living is calculated, range 0–9, with a clinically significant change of ≥1 unit between baseline and follow-up.

Functional status was measured using the Timed Up and Go (TUG) test, the Berg Balance Scale, Gait Speed four-metre walking test and Grip Strength with North Coast Dynamometer. The TUG test measures the time for a person to rise from a chair, walk 3 m, turn around, walk back,

and sit down again. It measures both static and dynamic balance. In this study, we defined a change of ≥4 s as a clinically significant difference between baseline and follow-up, with 3.6 s considered as the minimal detectable change for TUG test measurements. For details on Berg Balance Scale, Gait Speed and Grip Strength, Cognition was measured using the Mini Mental State Examination.
Self-rated was measured by the question: "In general, would you say your health is", with the response alternatives: excellent, very good, good, fair, and poor. Clinically significant difference was defined as ≥1 step in the response alternatives between baseline and follow-up. In addition, self-reported symptoms were measured using the Göteborg Quality of Life Instrument.

Life satisfaction was measured using the Fugl–Meyer–Lisat-11 Questionnaire which includes 11 items concerning satisfaction with: life as a whole, work, financial situation, leisure, friends and acquaintances, sexual life, functional capacity, family life, partner relationship, physical health and psychological health. Response alternatives included: very dissatisfied, dissatisfied, rather dissatisfied, rather satisfied, satisfied and very satisfied. In the analysis, the responses to each question were dichotomised into satisfied (very satisfied and satisfied) or not satisfied (rather satisfied, rather dissatisfied, dissatisfied and very dissatisfied) as was done in the validation of the questionnaire. The sum of items for which the respondent reported being satisfied were calculated, range 0–11, with a clinically significant change of ≥1 between baseline and follow-up.
Satisfaction with quality of care was measured by the participant's agreement with six statements with a person-centred approach: "I feel that the care given during the hospital stay meets my needs", "I feel that the care planning meeting before discharge was valuable", "I was able to take part in the discussion of my needs in the care planning meeting", "I feel that the actions planned equal my needs", "I feel that the actions delivered equal my needs" and "I am satisfied with the hospital care". The response alternatives were agree completely, agree partly, neither agree nor disagree, disagree, and disagree completely. An answer of agree completely or agree partly were considered as satisfied. These questions were only measured once (at 1 month follow-up) and were used as the difference between intervention and control groups in the proportion of participants being satisfied for each question at follow-up as has been done previously. In this study, we used the following measurements and cut-off levels of frailty indicators: Weakness: Reduced grip strength considered to be below lowest norm range for ages 80–84, 13 kg for women and 21 kg for men for the right hand and below 10 kg for women and 18 kg for men for the left hand, using a North Coast dynamometer.
Fatigue: Question from the Göteborg Quality of Life Instrument, answering "Yes" to the question "Have you suffered any general fatigue/tiredness over the last three months?"
Weight loss: Question from the Göteborg Quality of Life Instrument, answering "Yes" to the question "Have you suffered any weight loss over the last three months?"
Reduced physical activity: Taking 1–2 or less outdoor walks per week.
Impaired balance: The Berg Balance Scale, reduced balance defined as having a value of 47 or less.
Reduced gait speed: Walking four metres with a gait speed of 0.6 metres/second or slower.
Visual impairment: The KM chart (Konstantin Moutakis chart), impaired vision defined as having a visual acuity of 0.5 or less.
Impaired cognition: The MMSE, impaired cognition defined as having a score below 25.

Statistical analysis
A power calculation was done based on the primary outcome variable, dependence in activities of daily living (range 0–9) with an assumed difference between the intervention and control groups of one dependence (i.e., dependent in one or more activities of daily living, a clinically relevant difference of importance to the individual as well as the caregiver) and a standard deviation of 2 in both groups. To detect a difference between the intervention and control groups with a two-sided test and with a significance level of $\alpha = 0.05$ and 80% power, at least 64 participants were needed in each group. To take a potential loss to follow-up into account, a total of 150 persons (75 in the control group and 75 in the intervention group) were initially planned to be included. This was later revised to allow for a higher loss to follow-up (22%) with 78 + 78, equalling a total of 156 participants.

Both descriptive and analytical statistics were used in order to compare groups and to analyse changes over time. Non-parametric statistics were used when ordinal data were analysed. Otherwise, parametric statistics were used. Besides descriptive statistics, the chi^2 and Fisher's two-tailed exact tests to test differences in the proportions among the groups were used. A value of $p \leq 0.05$ (two-tailed) were considered significant. The analysis were made on the basis of the intention-to-treat principle, meaning that participants were analysed on the basis of the group to which they were initially randomised. The approach of data imputation was the replacement of missing values with a value based on the median change of deterioration between baseline and follow-up of all who participated in the follow-up.