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Original Study

Costs and Effects of an Ambulatory Geriatric Unit (the AGe-FIT Study): A Randomized Controlled Trial

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A B S T R A C T

Objectives: To examine costs and effects of care based on comprehensive geriatric assessment (CGA) provided by an ambulatory geriatric care unit (AGU) in addition to usual care.

Design: Assessor-blinded, single-center randomized controlled trial.


Participants: Community-dwelling individuals aged 75 years or older who had received inpatient hospital care 3 or more times in the past 12 months and had 3 or more concomitant medical diagnoses were eligible for study inclusion and randomized to the intervention group (IG; n = 208) or control group (CG; n = 174). Mean age (SD) was 82.5 (4.9) years.

Intervention: Participants in the IG received CGA-based care at the AGU in addition to usual care.

Outcome measures: The primary outcome was number of hospitalizations. Secondary outcomes were days in hospital and nursing home, mortality, cost of public health and social care, participant’s sense of security in care, and health-related quality of life (HRQoL).

Results: Baseline characteristics did not differ between groups. The number of hospitalizations did not differ between the IG (2.1) and CG (2.4), but the number of inpatient days was lower in the IG (11.1 vs 15.2; P = .035). The IG showed trends of reduced mortality (hazard ratio 1.51; 95% confidence interval [CI] 0.988–2.310; P = .057) and an increased sense of security in care interaction. No difference in HRQoL was observed. Costs for the IG and CG were £33,371 (£31,568; P = .432).

Conclusions and relevance: This study of CGA-based care was performed in an ambulatory care setting, in contrast to the greater part of studies of the effects of CGA, which have been conducted in hospital settings. This study confirms the superiority of this type of care to elderly people in terms of days in hospital and sense of security in care interaction and that a shift to more accessible care for older people with multimorbidity is possible without increasing costs. This study can aid the planning of future interventions for older people.

Trial Registration: clinicaltrials.gov identifier: NCT01446757.

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people with multimorbidity require a holistic approach to care that considers the entire spectrum of their life situations, including the sense of security in care.7

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 in terms of improving functional capacity and reducing the risk of institutionalization.8–12 Health care providers, however, have been reluctant to organize this kind of care, probably because of the anticipation of increased costs and the need for substantial shifts in practice toward interprofessional teamwork and gerontological and geriatric competences.

Older people with multimorbidity often require hospital care to optimize the treatment of chronic diseases or to diagnose and treat newly arising conditions. At the same time, avoidance of unnecessary hospitalization is important because of the associated risks of fracture, medication error, patient confusion, and further disability13–16 and the high costs of this type of care. A Cochrane report based on 22 randomized controlled trials (RCTs) found no significant difference in rehospitalization associated with the use of CGA in a hospital care setting.17 Because of differences among trials in the reporting of costs and outcome measures, the authors of this report could make no conclusion concerning resource utilization. These findings were replicated in a recent review on the same subject based on 19 RCTs.18 None of these studies reported on the effects of CGA on patients’ quality of life.

Objectives

Most studies of CGA have examined inpatient hospital care; few have been conducted in ambulatory care settings.18,19 To the authors’ knowledge, no study of CGA has included the outcome measures of quality of life, sense of security, or total cost of social and health care. The aim of this study was thus to compare costs and effects between participants with access to CGA at an ambulatory geriatric unit and a control group receiving usual care only. This article reports the first results after 24 months of follow-up. The study hypothesis was that CGA-based care provided in an ambulatory geriatric unit would reduce hospitalizations (primary outcome) compared with usual care. Analyses also were conducted to compare the number of inpatient days, total cost of health and social care, mortality, care in nursing home, patients’ sense of security in care, and health-related quality of life (HRQoL).

Methods

Trial Design

The Ambulatory Geriatric Assessment—a Frailty Intervention Trial (AGe-FIT) was designed as a randomized, controlled, assessor-blinded, single-center trial with 2 parallel groups. Participants were randomized to the intervention group, which received interdisciplinary care based on CGA at an ambulatory geriatric unit in addition to usual care, or the control group, which received usual care only. Outcomes were assessed at baseline and 12 and 24 months later. The protocol has been described in detail previously.20 The regional ethical review board in Linköping, Sweden, approved the study (Dnr. 2011/41–31) and all participants provided written informed consent.

Study Setting

Data were collected between February 2011 and December 2013 in a municipality in southeastern Sweden, which contains rural and urban areas and had approximately 130,000 inhabitants, 8.3% of whom were 75 years or older.21 The county council and municipality are responsible for the provision of health and social care, funded mainly by income taxes. Most health care is provided at 10 primary centers and 1 hospital, which has approximately 300 beds and 12 specialist departments and offers 24-hour admittance for surgical and medical emergencies. The municipality provides home health and social care, including care provision in nursing homes (ie, special accommodations for elderly patients) when needed. Home care typically includes home help services to support older people in conducting activities of daily living (ADLs) and instrumental ADLs.

Participants

Potential participants were identified using the care data warehouse of Östergötland, a population-based administrative database maintained by the county council.22 Community-dwelling individuals 75 years or older who had received inpatient hospital care 3 or more times in the previous 12 months and had 3 or more concomitant medical diagnoses were considered eligible to participate in this study.

Randomization and Blinding

Eligible participants were assigned randomly to the intervention or control group based on a randomization master list using SPSS software (version 18.0; SPSS Inc., Chicago, IL; Figure 1). Only the project coordinator and the nurse who planned the schedules of physicians working in the ambulatory geriatric unit had access to the randomization protocol.

Procedures

All eligible participants received an invitation letter by post that included information about the purpose and protocol of the study. They were then contacted by telephone and asked to provide verbal informed consent to study participation, and home visits were made to collect further information and obtain written informed consent. The group identities were thus blinded to both the assessors and participants at baseline.

Baseline Assessment and Outcome Measures

For consenting participants at baseline and 12 and 24 months thereafter, registered nurses and a registered occupational therapist (ie, assessors) who were not involved in other aspects of participants’ care conducted assessments in participants’ homes.20 They conducted interviews to collect background data (eg, age, sex, educational level, cohabitation, hearing and vision problems) and to assess independence in ADLs, cognition, sense of security in care, and HRQoL. Independence in ADLs was assessed using the Barthel index,23 which has shown good reliability and validity.24 Cognition was assessed using the Mini Mental State Examination,25 which includes measures of orientation, immediate and short-term memory, attention and calculation, and language and praxis. This instrument has been found to have good construct validity.26

Patients’ sense of security in care was measured by the Sense of Security in Care—Patients’ Evaluation (SEC-P), which has been shown to have good validity and reliability, including in samples of older people. The instrument contains 3 scales: care interaction (8 items), identity (4 items), and mastery (3 items). Responses are structured by a 6-point Likert scale (1 = never, 6 = always).27

HRQoL was measured using the generic preference-based 3-level version of the 5-dimensional (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) EuroQol instrument.
Possible responses to each EQ-5D-3 L item are "no problem," "some problems," and "severe problems." The EQ-5D questionnaire has been shown to be a simple, valid and responsive measure of HRQoL.

**Intervention**

The ambulatory geriatric unit was opened at the time of study initiation with a diverse team of professionals: a nurse, a geriatrician/resident physician, a municipal care manager, an occupational therapist, a physiotherapist, a dietician, and an administrative assistant. Access to other professionals (e.g., dental hygienist, psychologist) was readily available on demand. After baseline assessment by research personnel, participants in the intervention group were invited to receive individually tailored care and attend follow-up visits at the ambulatory geriatric unit during the study period. Initial CGA was performed based on a standardized procedure. Thereafter, all care was personalized according to patients’ situations and preferences, best-known evidence and practice, and team members’ competences. However, nurses clinically reassessed all participants after 1 year and then initialized (home) visits by physicians or other professionals if needed. Ambulatory geriatric unit staff planned participants’ care during team meetings, with the common goal of increasing participants’ quality of life.

During the study period, the team’s social care manager contacted all participants in the intervention group to inform them of available forms of support from the municipality, such as home help services. The intensity of clinical follow-up depended on participants’ needs and demands, ranging from a few contacts per year to daily or weekly contacts by telephone or ambulatory or home visits. Intervention activities (clinical assessments, home or ambulatory visits, telephone calls) were most intensive at the beginning of the intervention period. Many intervention activities had preventive goals (e.g., training programs conducted by a physiotherapist, fall prevention measures performed by a physiotherapist and occupational therapist during home visits, and optimization of pharmacotherapy with the help of clinical pharmacists). Nurses also ensured that patients understood new prescriptions and provided advice and counsel by telephone. Team members from the ambulatory unit visited participants admitted to the hospital to provide further information to patients and staff with the goal of facilitating care, discharge, and/or transfer to other types of care.

**Usual Care**

Participants allocated to the control group received usual health and social care (i.e., health care provided by primary care centers, in- and outpatient hospital care, and social care as usual). They did not
have access to the ambulatory geriatric unit. Participants in the intervention group had the same access to usual care.

**Primary and Secondary Outcomes**

The primary outcome assessed was hospitalization during the 24-month study period. Secondary outcomes were the number of days in hospital, mortality, admittance to a nursing home, total cost of health and social care, and participants’ sense of security in care and HRQoL.

Dates of death were collected from electronic medical records linked to the MASTER Swedish total population register. Costs of health care consumption, including inpatient care, ambulatory visits, and prescribed drugs, were obtained from the care data warehouse of Östergötland and the cost per patient and prescribed drug databases. The Östergötland data warehouse contains administrative information about patients’ characteristics, visits to health care providers, and hospitalizations (including number of inpatient days), with registry of primary and secondary diagnoses for each contact. Data were extracted from the Östergötland data warehouse in June 2014. The cost per patient database is linked to this data warehouse and records costs for each contact. The county council’s prescribed drug database contains local information extracted from national pharmaceutical data on the volumes and costs of prescribed and dispensed drugs. Information on participants’ use hours of home help services, transfer to nursing homes, and days spent at nursing homes was obtained from the social care managers’ records.

**Sample Size**

Sample size calculation was based on a 2-tailed significance level of 5%, power of 80%, and an expected detectable effect over 24 months of a 20% reduction in the mean hospital admission rate from 5 to 4 admissions per year, leading to a minimum requirement of 142 participants per trial arm. Based on previous research conducted in the area, we anticipated approximately 40% attrition over the 24-month study period for reasons such as death, withdrawal from the study, and relocation. The estimated sample size was thus increased by 40%; we aimed to include 200 participants in each group to enable detection of a significant difference in hospitalizations over the 24-month period.

**Statistical Analyses**

Student’s t test was used to compare continuous data between the intervention and control groups, and the χ² test was used to compare categorical data. Mean costs of health and social care were calculated for the 2 groups, and mean differences (Δ) between groups were determined after 24 months. All cost estimates are presented in 2013 British Pounds (GBP). All recruited participants (intention-to-treat sample) were included in mortality and cost of care analyses, and patients following the protocol (ie, those who received care at the ambulatory geriatric unit) were included in an additional mortality analysis.

Mortality rates after 24 months were calculated as percentages of deaths in the total population per group. A Cox proportional-hazard regression model in which the number of months from the time of study inclusion until death served as the follow-up time variable was used to calculate hazard ratios (HRs) for death with 95% confidence intervals (CIs). The number of months to mortality is also presented using a Kaplan-Meier curve.

To assess participants’ sense of security in care, mean SEC-P scale scores were compared between groups. HRQoL was examined using a primary analysis based on participants’ responses at all 3 assessment time points and 3 sensitivity analyses that included patients for whom EQ-5D-3 L scores from 1 or more time points were missing. In the first sensitivity analysis, missing values were preferably replaced with participants’ last available EQ-5D-3 L score (carry forward); when no preceding value was available, the following available value was used (carry backward). In the second sensitivity analysis, a value of 0 was assigned for deceased persons to assessment time points following dates of death. The third sensitivity analysis combined the methods used in the first 2 sensitivity analyses. In all statistical tests, the significance level was set to P less than .05.

**Results**

**Participants and Baseline Characteristics**

Between January and November 2011, 844 eligible patients were randomized to the intervention and control groups. Of these, 382 (45%) individuals consented to participation and were enrolled in the study (mean age, 82.5 years; 48% female). A total of 130 participants were lost during the study period: 87 (23%) of these individuals died (Figure 1). No baseline characteristic differed significantly between groups (Table 1). Participants in both groups were severely affected by diseases, and frequencies of hearing and vision problems and cognitive decline were high. More than 90% of participants had previously been diagnosed with cardiovascular diseases.

**Outcomes**

**Hospitalization**

The mean number of hospitalizations per patient did not differ significantly between groups (intervention, 2.1 [SD 2.6]; control, 2.4 [2.5]; P = .212). The mean number of inpatient days during the 24-month follow-up period was smaller in the intervention group (11.1 [15.9]) than in the control group (15.2 [20.2]; P = .035).

**Table 1** Baseline Characteristics of the Intervention and Control Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>208</td>
<td>174</td>
</tr>
<tr>
<td>Age, y, mean (SD)</td>
<td>82.3 (4.6)</td>
<td>82.7 (5.1)</td>
</tr>
<tr>
<td>Sex, female, n (%)</td>
<td>108 (47)</td>
<td>81 (50)</td>
</tr>
<tr>
<td>Living alone, n (%)</td>
<td>102 (49)</td>
<td>93 (54)</td>
</tr>
<tr>
<td>Primary school only, n (%)</td>
<td>127 (62)</td>
<td>109 (63)</td>
</tr>
<tr>
<td>Hearing impairment with hearing aid, n (%)</td>
<td>75 (36)</td>
<td>59 (34)</td>
</tr>
<tr>
<td>Vision impairment with glasses, n (%)</td>
<td>49 (24)</td>
<td>56 (32)</td>
</tr>
<tr>
<td>Barthel index score, mean (SD)</td>
<td>26.2 (3.3)</td>
<td>26.6 (3.0)</td>
</tr>
<tr>
<td>Previous diagnoses, n (%)</td>
<td>89.6 (14.8)</td>
<td>92.0 (9.9)</td>
</tr>
<tr>
<td>Certain infectious and parasitic diseases (A00–B99)</td>
<td>97 (47)</td>
<td>71 (41)</td>
</tr>
<tr>
<td>Neoplasms (C00–D48)</td>
<td>89 (43)</td>
<td>70 (40)</td>
</tr>
<tr>
<td>Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50–D89)</td>
<td>60 (30)</td>
<td>56 (32)</td>
</tr>
<tr>
<td>Endocrine, nutritional, and metabolic diseases (E00–E90)</td>
<td>102 (49)</td>
<td>87 (50)</td>
</tr>
<tr>
<td>Mental and behavioral disorders (F00–F99)</td>
<td>78 (38)</td>
<td>53 (31)</td>
</tr>
<tr>
<td>Diseases of the nervous system (G00–G99)</td>
<td>78 (38)</td>
<td>53 (30)</td>
</tr>
<tr>
<td>Diseases of the circulatory system (I00–I99)</td>
<td>197 (95)</td>
<td>169 (97)</td>
</tr>
<tr>
<td>Diseases of the respiratory system (J00–J99)</td>
<td>112 (54)</td>
<td>100 (56)</td>
</tr>
<tr>
<td>Diseases of the digestive system (K00–K93)</td>
<td>117 (56)</td>
<td>91 (52)</td>
</tr>
<tr>
<td>Diseases of the musculoskeletal system/ connective tissue (M00–M99)</td>
<td>167 (80)</td>
<td>112 (76)</td>
</tr>
<tr>
<td>Symptoms, signs, and abnormal clinical/laboratory findings, not elsewhere classified</td>
<td>207 (100)</td>
<td>174 (99)</td>
</tr>
</tbody>
</table>

*Codes are taken from the International Classification of Diseases, 10th edition.*
Cost of health and social care

The total cost of health and social care did not differ between groups during the 24-month period after baseline assessment (GBP/patient [SD]: intervention, 33,371 [39,947]; control, 30,490 [31,568]; P = .432). Costs of primary care and in- and outpatient hospital care are presented in Table 2. The intervention resulted in higher costs for ambulatory care, such as for visits to physicians and other staff and operative activities (eg, telephone calls placed by ambulatory unit staff), but lower costs for inpatient hospital care. Participants in the intervention group used 25% more hours of home help services (373 vs 298 hours) during the study period and spent 20% fewer days in nursing homes (29 vs 36 days) than did those in the control group, but these differences were not significant.

Mortality

Mortality rates 24 months after study enrolment were 18.8% (n = 39) in the intervention group and 27.0% (n = 47) in the control group (HR 1.51, 95% CI 0.99–2.31, P = .057). For the Kaplan-Meier survival curve, see Figure 2. Participants in the intervention group lived an average of 30.9 days longer than did those in the control group (HR 1.60, 95% CI 1.04–2.49, P = .035).

Nursing home admittance

Twenty-six (12.5%) participants in the intervention group and 33 (18.9%) in the control group were moved to nursing homes (HR 1.63, 95% CI 0.969–2.421, P = .024).

Participants’ sense of security in care

SEC-P scale scores did not differ significantly between groups at baseline. Care interaction scores were higher in the intervention group than in the control group at 12 (P < .001) and 24 months (P < .001), but identity and mastery scores did not differ significantly (Table 3).

HRQoL

Baseline EQ-5D-3 L scores were 0.62 in the intervention group and 0.63 in the control group. The primary analysis, including all participants and the 3 sensitivity analyses showed no significant difference in HRQoL between groups at baseline or after 12 or 24 months (Table 4).

Discussion

Although the CGA-based intervention involved the provision of comprehensive care and active follow-up by a multidisciplinary professional team, it was not significantly more expensive than usual care. The cost of ambulatory care was higher as a result of the increased level of services offered by the ambulatory geriatric unit, but the cost of inpatient hospital care was lower. Although the...
ambulatory geriatric unit often took the initiative to send participants to the emergency room or directly to a ward, participants in the intervention group spent fewer days in hospital and tended to spend fewer days in nursing homes than did those in the control group. The intervention resulted in a nonsignificant but potentially clinically relevant decrease in mortality; this reduction was significant in the per-protocol analysis. It had no observable effect on HRQoL, but improved participants’ sense of security in care interaction.

This study has several strengths. As the intervention was examined in a real-world municipal setting, the results are likely generalizable to other settings. As no additional training was provided to primary care centers, data were collected in a setting similar to that in the optimization of medications, minimization of fall risks, rehabilitation, initialization of osteoporosis treatment, attendance at meals to provide social support, and securing of participants’ ability to take walks outdoors if they so desired. The effects of such interventions in older people with multimorbidities likely manifest over a period longer than 24 months. We were not able to detect a significant reduction in total number of hospitalizations, which could be explained by an underpowered study regarding this outcome, but also that this measure may not be valid, as patients can be moved between wards and clinics several times within the same hospitalization period, with each move recorded as a new hospitalization event. The number of days in hospital would likely be a better primary outcome than the number of hospitalizations, as we believe that it is a better measure of the need for hospital care.

The different sizes in the groups could be explained by a limited availability of physicians at the end of the inclusion period. The participants in the intervention group were therefore asked earlier in the inclusion period if they wanted to participate than the participants in the control group. Because of an unexpected high refusal rate in December (which we should have been able to foresee because of Christmas time) we never managed to reach the desired number in the control group during the planned time for inclusion. Because of limited financial resources, we were not able to prolong the inclusion period beyond 2011.

The results of this study confirm previous findings regarding the provision of team-based care in a hospital setting: not more expensive due to shorter or similar length of stay in hospital. We found 3 reviews with preventive home visiting to frail older people as the intervention. In our study, home visiting was a part of the intervention, but phone calls and visits to the ambulatory were more often used. The reviews have shown diverging results with regard to reduction in mortality, reduction in admission to long-term institutional care, and reduction in admission to hospital, and the conclusions have been very cautious as to why it seems more comprehensive care is needed to give positive effects.

We have found only a few studies of the effects and outcomes of team-based care in an ambulatory setting as in ours. An early report by Tulloch and Moore showed that more health and social services were provided to the intervention group due to the identification of medical or social conditions that would otherwise remain untreated, as in our study. Similarly, Weinberger et al. determined that active follow-up after hospitalization increased rather than decreased the rate of rehospitalization, due to the identification of previously undetected health problems in an older population with heart failure.

The findings regarding health and social care costs with no significant differences are in agreement with those of a very similar RCT published in 2001. The lack of an effect on HRQoL is also in agreement with previous studies. This result may reflect participants’ poor health status and thus low overall HRQoL, and the limited ability to improve these aspects of health.

This study demonstrated that a shift from inpatient hospital or nursing home care to more preventive and accessible ambulatory care provision to older people with multimorbidity is possible without increasing costs. Thus, systematic assessment and the provision of personalized interdisciplinary care may be a promising means to improve outcomes. The similarity in cost may be explained by the identification of unmet needs, which led to more health care contacts (eg, to ensure compliance with medications and the receipt of adequate home help services). The reduced duration of hospitalization may be explained by the admission of patients in earlier disease stages and/or less serious conditions due to active follow-up. This type of support may have contributed to intervention group participants’ increased sense of security in their interactions with care.
These findings provide new insight on the effectiveness of ambulatory geriatric units and can aid the planning of future interventions for older people. The increased sense of security in care among intervention participants in the present study generates the political question of the monetary value of this improvement. To our knowledge, this study is the first to contribute scientific knowledge about these important aspects. The intervention should be studied further in multicenter studies with longer follow-up periods to evaluate the preventive actions taken by the ambulatory geriatric unit.

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