

Models of Care in the Transition from the Secondary to the Primary Sector among the Frailest Elderly +75; a Randomized Controlled Trial

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In most Western countries the elderly population increases rapidly. In Denmark, the population of elderly aged 75 years or older may amount to nearly 15 % of the entire population in 2050 compared to 9 % today (2017) (1). A large part of the elderly population is at high risk of hospitalization including more admissions and increased morbidity and mortality (2,3). The number of hospital beds is declining persistently (4), calling for shorter lengths of stay (LOS) (5,6). Increasingly complex treatments now take place outside hospital. Presently, many Danish regional hospitals establish geriatric wards and other geriatric in-hospital and outpatient services to overcome these challenges. The aim of the present PhD-study is to investigate the effects of different models of transitional care among the frailest elderly patients.

Readmission

Readmitted patients occupy many beds and other hospital resources. Patients are at a risk of high mortality (7) and decline of functional ability (8,9). More than 20 % of Danish medical patients aged 65 years or older become readmitted within 30 days after discharge (10), more frequently in the frail elderly (11). The risk of readmission is particularly high within the first week after discharge, where more than 40% of readmissions happen (12,13). Many reasons and factors for readmissions have been mentioned (11,14-16) such as: former or recent admission, duration of the index hospitalization, degree of comorbidity and low functional ability (11,15). To prevent readmissions it is important to identify the reason for admission and remove it, to ensure that the correct medication is implemented and make sure that adequate social service is provided, to convey unsolved problems to the primary care, ensure continuity during transfer and finally establish sufficient and timely follow-up after discharge (11,14-17).

Identification of patients at risk

Many factors leading to readmission and other adverse events are related to frailty (11,15,18). Prevention of adverse events has traditionally relied on clinicians' and caregivers' ability to anticipate the needs and requirements after discharge. Comprehensive Geriatric Assessment (CGA) is considered as the gold standard to detect frailty (19). To make this easier tools to determine frailty have been developed. In the present study the Multidimensional Prognostic Index (MPI; see Appendix 1A and 1B (slightly adjusted Danish version)) has been chosen to determine the level of frailty. MPI is fully applicable in the everyday clinical work and supplies useful information to clinicians, it is validated in a Danish context, predicts readmission and death (20), and is well-suited to assess the degree of frailty (18,21).

Usual care

Present usual care in Denmark with regard to discharge and transfer, consists of discharge planning. It relies largely on the GP's follow-up visits (see Appendix 2). This approach reduces readmission (22), but the use is limited due to poor implementation, lack of referral, and missing follow-up despite referral (23,24). Only a minor fraction of the frail receives a follow-up visit within the first week after discharge. The GP-based intervention is presently subject to discussion (23,24). Urgent or hospital-at-home-like treatment is needed to avoid readmission. This requires of a well-informed round the clock service. The urgency of follow-up of the frail elderly does not fit into the scheme-based workday of the GP and the on-call GP system. In some districts, additional specialized geriatric wards and outgoing teams exist, but the capacity and contents of these units are limited and vary. Community nurses might after some reorganization hold an untapped potential to improve transition.

Counteractions to readmission

Even though all possible precautions are made before discharge, readmissions still occur. They are often preceded by a series of events stressing the need for multifaceted care and intersectoral efforts in relation to discharge. Many approaches are already applied:

- To avoid obvious and predictable events leading to readmission, comprehensive discharge planning has been introduced in many different countries, probably reducing readmission and LOS without increasing mortality (25,26).
- In a Danish context discharge follow-up is largely based on GP-conducted visits within one week after discharge and offered to a fraction of the elderly.
- Multiple discharge support arrangements have been tested ranging from isolated follow-up telephone calls by a hospital nurse to highly specialized multidisciplinary geriatric teams doing home visits. Early follow-up visits by community nurses have been tested showing possible effect on mortality but not on readmissions (27). Another recent randomized clinical trial (RCT) reports considerable positive effect on readmission, LOS and direct discharge from the ED (12), while a second RCT performed in the same population shows a reduction of

mortality among patients living in their own homes (7). The study shows considerable effect of early team-based home visits applied on selected elderly at high risk of readmission (12).

- Comprehensive Geriatric Assessment (CGA) provides an individualized, multidisciplinary and intersectoral approach when applied by geriatricians in inpatient geriatric wards and in Emergency Departments (ED) and outpatient clinics, in order to improve outcomes of hospitalization. The effects of CGA on readmission, length of stay (LOS) or mortality has yet not been well-proven. It reduces medication and increases the probability of discharge at home (25,28). The effect of CGA combined with an early geriatric home visit has resulted in a significant reduction of the readmission rate within 30 days when compared to the GP-conducted follow-up visits after a week (12).

Outcome measures

According to the various interventions stated above, the outcomes of relevance are readmissions (8-12,15,17,22,24-26,28-44), mortality (7,8,10,12,25,27,28,30-32,38-41,44), length of stay (LOS) (12,25,28,29,32,38,41,45), direct discharge from the ED (12,29), time at home (10,25,27,34), duration of readmission (10,25,34) and physical functional status (8,25,27,28,30,31,34,40,43-45). A successful intervention may be reflected in a shorter LOS, lower risk of readmissions, longer time at home, maintained functional status and a shorter duration of readmission. We suggest that a significant and effective intervention under the best circumstances is reflected in these outcomes. Readmissions are usually considered as such, when the admission occurs within 4 hours after and before 30 days after discharge. Among the frail, in-hospital and post-discharge mortality is high, needing frequent assessment. As shown by Pedersen et al. (7), mortality differs with regard to type of dwelling. Former studies have shown a significant and remarkable reduction of LOS (reduction from median 3 days to median 2 days) and an increase from 49 % to 56 % of patients discharged directly from the ED due to the possibility of early follow up by a geriatric team (12). Functional status is of relevance, especially combined with mortality data, since a better survival of the frailest may be combined with a worsened functional status in the total group. Patient satisfaction and costs are other relevant outcome measures with regards to the triple aim principle, but will not be included in the present Ph.D. project.

Conclusion

While some previously tested interventions, including CGA and discharge support arrangements, have been futile (25,31,46), we believe that multidisciplinary, tailored interventions used in selected high-risk groups throughout hospitalization and discharge are effective (8,12,29,34,44). Most former studies regarding early follow-up visits and CGA are made in geriatric settings, somewhat distanced to usual care and municipality services. Many previous trials have included patients without looking in particular for frail high-risk patients, thereby probably underestimating the effects of the intervention. It is not known if an early visit by a community nurse would have the same effect as an early geriatric home visit. Selection of elderly patients who will benefit from home visits by a geriatric team after discharge compared with a community nurse visit or usual care may be useful. MPI has been able to predict mortality, LOS (47), and readmissions (48), but has not previously been tested as a selection tool to distinguish between different follow-up methods. It has been suggested that the major effect from early follow-up is more or less independent of the type of follow-up, but is caused by the early visit itself. The type of dwelling may influence the effect of an early visit, since the care setup in some nursing homes may resemble that of a hospital. The level of frailty may influence the effectiveness and efficacy of the different follow-up schemes. Some patients may be chronically frail and their frailty may already have been handled prior to admission, in a way that dilutes the effect of early follow-up visits. The length of stay and other secondary endpoints may rely largely on the planned follow-up approach. The level of frailty predicts the risk of readmission and mortality and can therefore be used as a major indicator when clinicians have to choose between different follow-up approaches.

Objectives

The aim of this study is to investigate the effects of two interventions using CGA and early post-discharge follow-up visits in a population of frail 75+ year-olds compared to usual care. The vision is to find feasible and durable approaches that can improve patient outcome in the transition from hospital to primary health care. We are aiming to identify subjects who will profit the most from each approach.

All frail patients admitted to the ED and the Department of Geriatrics are randomized 1:1 to one of two different follow-up efforts prior to CGA performed during hospitalization. Thereby the intervention is randomly split into two groups:

- An intervention (I) consisting of CGA during hospitalization and early post-discharge follow-up care by a community nurse and a GP
- An intervention (II) consisting of CGA during hospitalization and early post-discharge follow-up care, including continued CGA and tailored follow-up care, by a geriatric team

The intervention cohort will be compared to a control cohort consisting of similar frail elderly who receive usual care without involvement of geriatric care during hospitalization and after discharge.

Hypotheses

- The geriatric team follow-up is as effective as a community nurse and GP follow-up measured by readmission, mortality, LOS, direct discharge from ED and physical functional recovery
- The effects of three transitional follow-up approaches (community nurse and GP; multidisciplinary geriatric team; usual care) are similar measured in terms of readmission, time at home, duration of readmission, LOS, direct discharge from ED, and mortality
- When stratified into subgroups with regards to level of frailty (moderate and severe) and type of dwelling, the geriatric team follow up is as good as community nurse and GP follow-up measured by readmission, mortality, LOS, direct discharge from ED and physical functional recovery

Methods

Design

The first study is conducted as a randomized controlled trial (RCT) using two different degrees of intervention. The second study is a cohort study where the two groups in the RCT are compared to an unexposed control group. The third study is sub-group analyses of the RCT data according to frailty status and type of dwelling.

Study population

The population allocated to intervention comprises geriatric patients acutely admitted to the ED, Aarhus University Hospital (AUH) or transferred to one of the two geriatric wards at AUH. Subjects are included immediately on the day of admission at the ED, AUH and the Department of Geriatrics (wards 1 and 2), AUH, as shown in Fig. 1. Patients admitted to the ED at night and promptly discharged before enrollment to the intervention cohort can be performed the following day are not included. Likewise, patients to the control group are included immediately on the day of admission at the ED, Randers Regional Hospital (RRH), and at the medical wards 1, 2, 3 and 4, RRH. Patients transferred to other departments are excluded. Patients can only be included once. Enrollment and randomization to the intervention group are performed by therapists working in the ED or the geriatric wards. Enrollment to the control group is done by a Research Assistant. In the control group frailty screening is done by the PhD-student using a frailty screening tool based exclusively on data collected through medical records. The frailty screening tool will be validated by crosschecks performed by a blinded project Research Assistant. The results of the validation study will be analyzed and published during 2019.

Inclusion criteria:

- Aged 75 years or older
- Living within the municipality of Aarhus (except for the control group, see below)
- MPI-score = 2 (moderate frailty) or MPI score = 3 (severe frailty)

Exclusion criteria:

- Included in any other kind of follow-up schemes
- Declared terminally ill or undergoing palliative care at admission
- Admitted from one specific temporary nursing home with geriatric medical assistance (Vikærgården)
- Discharge or transfer to another department, including hospice
- MPI-score = 1 (low frailty)
- Discharged to one specific temporary nursing home with geriatric medical assistance (Vikærgården)
- The patient does not want a visit after discharge

Inclusion- and exclusion criteria to the control group are the same as for the two intervention groups, except that subjects eligible for the control group are living within the four municipalities of RRH: Randers, Favrskov, Norddjurs and Syddjurs. Patients referred to the geriatric ward at RRH are excluded from the control group.

Randomization

As shown in Fig. 2, all intervention group patients are allocated at the time of randomization on the day of admission to receive either early visit from the community nurse (I) or the multidisciplinary geriatric team (II). The randomization is stratified with regard to dwelling (living alone; cohabiting; nursing home) and number of drugs prescribed prior to

admission (0-3, 4-7, 8 or more drugs), and conducted using the randomization function in REDCap (49). Randomization is open throughout the whole admission with the purpose to enable early discharge planning.

Intervention I and II

Both intervention groups are assessed according to CGA, either by the geriatrician and the physiotherapist/geriatric nurse in the ED, or by a multidisciplinary team comprised of geriatricians, specialized nurses, physiotherapists and occupational therapists during hospitalization in the geriatric wards.

- Intervention (I): comprises early follow-up visit from the community nurse within 24 hours after discharge, and the possibility of consulting a nutritionist, thus supplementing usual care services including the possibility of consulting the patients' GP. Responsibility of treatment including implementation of suggested initiatives and any further assessment is handed over to the GP at discharge.
- Intervention (II): CGA is continued during early follow-up by the geriatric team. On weekdays visits are scheduled within 24 hours after discharge. For patients discharged during weekends or holidays, supporting telephone calls are provided by the geriatric team. If needed, the geriatric team nurse visits the patient. The concept of CGA in this stage does not differ from the above-mentioned. There are no standardized demands, but a part of the intervention can be to perform hospital services at home and continued treatment and diagnostics after discharge. The possible services provided by the geriatric team are further described in the geriatric team course description. The responsibility of treatment rests with the geriatric team until dispatch of the discharge summary. Patients then return to usual care. The geriatric team follow-up is planned to last a maximum of 7 days, yet allowing extension for as long as there is a need for services performed exclusively by the geriatric team as described in the geriatric team course description.

Control group

The patients in the control group are discharged to usual care and do not receive early follow-up visits. Usual care features municipality services and optionally a GP home visit (see Appendix 2). Eligible control patients are consecutively included by a Research Assistant. The estimated level of frailty will be assessed by the PhD-student based on a MPI-screening tool fitted to be performed using only medical record data. This fitted tool will be tested and validated prior to the inclusion of the control group. Clinicians will be blinded to the result of the MPI-screening of the control subjects to ensure that discharge is performed in accordance with usual care.

Outcomes

The primary outcome is readmission within 30 days after discharge. Secondary outcomes are:

- Mortality 30 days after discharge and 90 days after admission
- Length of stay during primary admission and total length of stay including following readmissions
- Direct discharge from the Emergency Department
- Time at home before readmission
- Duration of readmission
- Physical functional status 30 days after discharge (Functional Recovery Score)

Statistical analyses

Data are registered in REDCap and exported to STATA version 15 for the statistical analyses. Statistical significant results are defined as a p-value of 5% or less. The two intervention groups and the control group will be compared with regard to baseline measures. If needed, statistical corrections for demographical differences and level of frailty will be made. The use of services and other contents of follow-up will be assessed and compared if possible. Baseline data collected for the entire study population before discharge are: age, gender, date of admission, co-habitation status, number of drugs, and level of frailty measured by MPI including functional status by means of Functional Recovery Score (FRS) at discharge. Follow-up data for the control group will be collected on type of planned care after discharge. Follow-up data for the entire study population will be collected on: department of discharge, date of discharge, primary diagnosis at discharge, dwelling after discharge, readmission date, and death date. For the intervention cohort additional data are collected: date of follow-up, provided services after discharge, number and date of visits (team, GP, nurse) after discharge, phone-calls to the geriatric team or GP, nutritionist consultations, FRS after 30 days, date of dispatch of discharge summary. Additional data will be collected by review of the electronic patient records.

Outcomes

A hazard ratio (HR) for readmissions will be calculated using a Cox regression model with death as a 'competing risk' factor. The HRs of readmission with 95% confidence intervals (95% CI) for interventions I and II will be compared

individually and to the control group. The interventions will be tested in subgroup analyzes based on: patients discharged directly from the ED, type of dwelling and level of frailty. Median LOS, time at home before readmission and duration of readmission will be calculated and compared using the Wilcoxon rank-sum test. The mortality hazard ratio will be calculated also using the Cox regression model. The change in functional status at discharge and 30 days after discharge will be compared in a linear regression model. Data will be analyzed in accordance with intention-to-treat and per-protocol analysis.

Sample size

Power analysis is based on a pilot study performed from June to December 2017 using the method stated above, and earlier studies by Pedersen et al.(7,12), where patients selected by diagnoses associated with readmission were randomized to early geriatric follow-up visits or usual care. Readmissions were reduced from 23% to 12%. Data collected during the pilot study showed 13.7% readmissions in the Intervention group I compared to 8% readmissions in the Intervention group II. Based on the pilot study data, allowing a 5% drop-out rate and a 30-day mortality rate of 10%, the number of patients in each trial arm should be 758 in order to achieve a power of 90% and a level of significance of 5%. Data collected during the same pilot study showed a 90-day mortality rate of 20.6% in Intervention group I compared to 15.6 % in Intervention group II. To achieve a power of 80% and a level of significance of 5% with regards to mortality, the sample size of each arm should be 1,019, including a 5% drop-out rate.

Perspectives

This study may uncover a need for specialized and early efforts to support transfer of the frail elderly. We may find that some of the frail elderly are poorly supported by the present follow-up procedures, suggesting that comprehensive geriatric assessment and early follow-up intervention by a community nurse and a geriatric team should gain further currency in the future. This study may contribute to dimension health care services in the future. We hope to clarify the possible need for geriatric services outside university hospitals. The results are directly transferable to Danish regional hospitals and may be of importance in other Western countries.

Ethics

The study has been approved as a quality development project by the Regional Research Ethics Committee, Central Denmark Region (journal no. 197/2017), thereby no patient consent form is needed, and further referral to the committee not required. No patient will receive less than usual care, no extra treatment or examination will be applied, and no patient will be exposed to any additional risk because of the project. Participants may decline parts of or the entire intervention, including usual care, at any time. The project, which is a part of the national rate adjustment pool-project "Early post-discharge follow-up of the frail elderly – a intersectoral effort" in the Central Denmark Region, is approved by the Danish Data Protection Agency (journal no. 2012-58-006).

Organization and economy

The project is embedded in the Geriatric Department, Aarhus University Hospital. The project is conducted in cooperation with Aarhus Municipality, represented by health consultant, PhD, Monica Milter Ehlers, and Randers Regional Hospital, where professor, MD, PhD, Jens Meldgaard Bruun and MD, geriatric specialist, Seham Shahla will be co-supervisors. See Fig. 3. The Project Manager, MD, PhD-student Troels Kjærskov Hansen, will be employed at both hospitals as a clinical assistant. The day-to-day work will take place mainly in the Research Unit at the Geriatric Department, AUH under supervision of the main supervisor, professor, MD, PhD, Else Marie Damsgaard, and co-supervisor, clinical specialist, PhD, Merete Gregersen. Through the Geriatric Department, AUH, there will be available statistical expertise attached to the project. Data regarding the intervention group will be collected by the research assistants associated to the Geriatric Department, AUH with regard to the frailty screening and baseline characteristics. Functional status at follow-up will be assessed by Aarhus municipality research assistants. The three months' leave for writing the project protocol was sponsored by the Central Denmark Region's Health Research Foundation. Follow-up as well as the hospital and municipality research assistants are partly funded by the Rate Adjustment Pool, the Geriatric Department, AUH, and Aarhus Municipality. Future expenses will be PhD student salary, Study Fee, wage for a research assistant, costs of courses, congresses, transportation, and publication.

My part

The Project Manager is admitted to the PhD programme and PhD courses at Aarhus University. The PhD-student is responsible for the collection, storage, analysis and correctness of all data. The PhD-student will apply for the remaining funding and publish and present the data from the project in relevant peer-reviewed journals and at national and international congresses. The project is reported to ClinicalTrials.gov. Research Plan: see Appendix 3.

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