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A randomized controlled trial

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ORIGINAL ARTICLE

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A randomized controlled trial

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Abstract

Objectives. Many hospital admissions are due to inappropriate medical treatment, and discharge of fragile elderly patients involves a high risk of readmission. The present study aimed to assess whether a follow-up programme undertaken by GPs and district nurses could improve the quality of the medical treatment and reduce the risk of readmission of elderly newly discharged patients. *Design and setting.* The patients were randomized to either an intervention group receiving a structured home visit by the GP and the district nurse one week after discharge followed by two contacts after three and eight weeks, or to a control group receiving the usual care. *Patients.* A total of 331 patients aged 78+ years discharged from Glostrup Hospital, Denmark, were included. *Main outcome measures.* Readmission rate within 26 weeks after discharge among all randomized patients. Control of medication, evaluated 12 weeks after discharge on 293 (89%) of the patients by an interview at home and by a questionnaire to the GP. *Results.* Control-group patients were more likely to be readmitted than intervention-group patients (52% v 40%; p = 0.03). In the intervention group, the proportions of patients who used prescribed medication of which the GP was unaware (48% vs. 34%; p = 0.02) and who did not take the medication prescribed by the GP (39% vs. 28%; p = 0.05) were smaller than in the control group. *Conclusion.* The intervention shows a possible framework securing the follow-up on elderly patients after discharge by reducing the readmission risk and improving medication control.

Key Words: *Discharge, elderly, family practice, home visit, medication, primary care, readmission*

Because of their often frail condition, discharged, impaired elderly patients face a high risk of readmission [1–5] and they risk being "left in limbo" if a healthcare professional is not assigned explicit responsibility for their bio-psychosocial situation upon their discharge [6]. Readmission can be diminished according to studies of home follow-up on elderly patients involving advanced practice nurses and geriatric teams drawn from hospital staff and other kinds of intervention with improved discharge support for elderly patients with specific diseases [1–3,5,7,8]. Two reviews found that the documented impact of discharge planning *without* follow-up care was uncertain [4,5]. They concluded that more

research and health economic analysis were needed, exploring intervention across the hospital–community interface.

In Denmark (5.5 million inhabitants), the healthcare system is tax-financed with no payment at the point of care. GPs are independent contractors to public health insurance. They act as gatekeepers for 98% of the population. Municipalities run a district nurse system that mainly focuses on care for the frail elderly [9].

Inappropriate medical treatment often has inadvertent effects, and a considerable number of admissions are attributable to inappropriate medical treatment that could be avoided [10,11].

Fewer readmissions and better control of medication is generally strived for. A follow-up programme by the GPs and district nurses after discharge found:

- A 23% relative readmission risk reduction within six months after discharge.
- Better follow-up including better control of medication after discharge.
- A cost-neutral intervention featuring a tendency towards reduced costs.

Only a few trials have focused on the effect of improved effort by the existing staff in the primary sector [12]. The aim of this study was to evaluate a simple intervention aimed at improving the interdisciplinary care given by GPs and district nurses.

Material and methods

Participants

The study was conducted at Glostrup Hospital in the Capital Region of Denmark in November 2003 to June 2005. All local GPs and district nurses in seven municipalities were invited to join the study. 63% of the GPs and all the municipalities accepted attendance.

Inclusion criteria were aged 78+ years, discharged from the geriatric or internal medical ward, and hospitalization for a minimum of two days. Exclusion criteria were severe dementia, linguistic problems, and terminal illness. Patients not included in the study are listed in Figure 1. The inclusion was done during daytime on weekdays when discharge was planned.

Study design

Patients were enrolled in the study when discharge was planned and participated in a structured
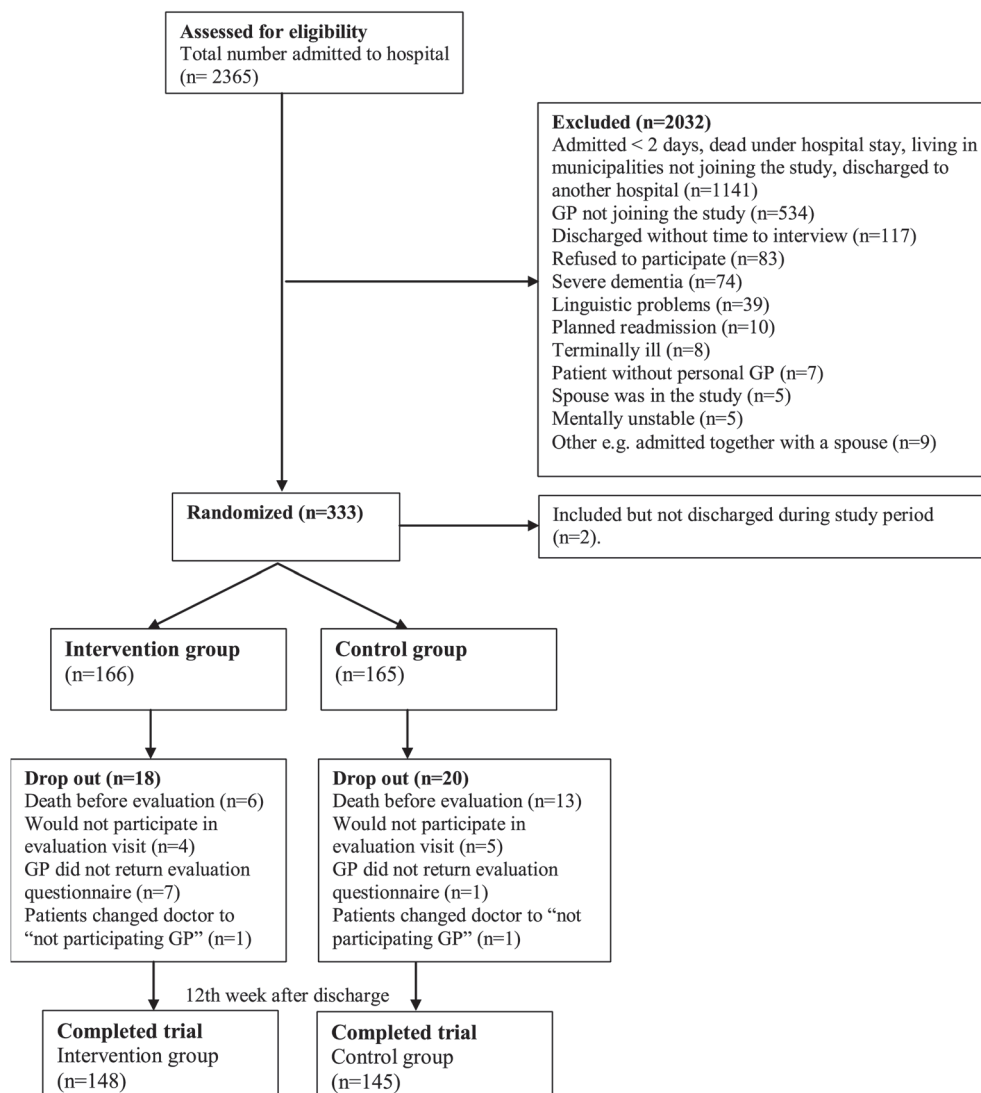

Figure 1. Patient flow.

interview conducted by a trained research occupational therapist (RT). Informed consent was obtained. Each intervention patient's GP and the local district nurse were contacted by fax in order to arrange the first study visit. Hospital staff were not informed about the randomization.

Randomization was done using a computer-generated algorithm with numbers in closed envelopes which were opened at the inclusion interview.

The intervention follow-up consisted of three contacts. The main intervention was a joint home visit involving both the GP and the district nurse. It was conducted approximately one week after discharge and was guided by an agenda (Figure 2). Two more contacts were conducted by the GP in the third and eighth week after discharge either in the GP's clinic or as a home visit depending on the patient's overall condition. The district nurse only attended the two follow-up

contacts if required. The GPs had no specific information on enrolment of control patients until the evaluation 12 weeks after discharge. No routines were changed. The contents and routines regarding discharge letters were not changed in either of the groups.

Outcome measures

The primary outcome measures were hospital readmissions of any kind and the concordance between the GP's knowledge of the medical treatment and what the patient was actually taking.

The secondary outcome measures were the degree to which the GP implemented the recommended follow-up as described in the hospital discharge letter, total healthcare costs, functional ability, death rate, patient satisfaction, and self-rated health.

Week 1
Structured home visit by GP and district nurse.
Agenda:
- **Checking the discharge letter for specific recommended paraclinical or clinical follow–up**
- **Check need for adjustment of medication**
- **Check if social and personal support was arranged**
- **Check of the family's medical cabinet**

What happened?
Visit/consultation performed: 155/166 (93%)
Contact form: Home visits 153 /155 (99%). Consultation 2/155 (1%)
Who participated: GP: 155/155 (100%). District nurse: 128/155 (83%)
Time consumption: 50 min. (range 15-100)
82% of patients had a special review of medical cabinet

Week 3
Appointment with the GP either as usual consultation or home visit.
Agenda – depending on needs. Follow-up on hospital treatment, medication and needs for remedial and care measures.
The district nurses joined depending on need.
What happened?
Visit/consultation performed: 129/166 (78%)
Contact form: Home visits 99/129 (77%). Consultation: 30/129 (23%)
Who participated: GP: 129/129 (100%). District nurse: 33/129 (26%)
Time consumption: 30 min. (range 5-80)

Week 8
Appointment with the GP either as usual consultation or home visit.
Agenda – the same as contact at week 3
What happened?
Visit/consultation performed: 119/166 (72%)
Contact form: Home visits 86/119 (72%). Consultation: 33/119 (28%)
Who participated: GP: 119/119 (100%). District nurse: 19/119 (16%)
Time consumption: 25 min. (range 5-80).

Figure 2. Agenda for intervention, participants, contact form.

Sample size

The sample size was calculated based on the degree of concordance on medication between the GP and the patient. Previous studies have found a lack of concordance for more than 50% of patients. With an 80% power and a 5% significance level and a possible 15% loss to follow-up, approximately 220 patients should be included in each group to detect a 30% difference.

Data collection

The RT collected baseline data at inclusion. Data were collected from the patient interviews, discharge letters, and patients' records. 12 weeks after discharge, a structured interview guided by a questionnaire was conducted in the patient's home by a member of the project staff. The GP and the district nurses simultaneously filled in individual questionnaires.

A register-based evaluation of readmissions and healthcare costs was done 26 weeks after discharge. Data on admission to hospital were based on the National Patient Register where costs were calculated on the basis of national DRG rates (Diagnosis Related Groups); costs of ambulatory treatment in hospitals were calculated on the basis of DAGS rates (Danish Ambulant Grouping System). Data on costs in the primary health sector were based on the Health Service Register (e.g. general practice, medication, specialists, and para-clinical activity). The official rate was used to convert Danish Krone into Euros. The National Register of Death provided information in the case of death.

Statistical analysis

The analyses followed the principle of intention to treat. All randomized patients discharged from hospital were included in the register-based analysis. The intervention and the control groups were compared using chi-squared tests and Monte Carlo Estimate for the Exact Test for categorical data and the Wilcoxon rank-sum test for continuous data. Time to first readmission was analysed using a Kaplan–Meier plot and a Cox regression model. Baseline comparisons showed a significant difference between the intervention and control groups for diagnosis (Table I). Logistic and Cox regression analysis was therefore used to adjust for these differences. These results are not shown since they did not differ from the unadjusted analysis. All tests were two-sided and were interpreted at the 5% level for primary and at the 1% level for secondary outcome measures, as multiple tests were made. Bootstrap (10 000 samples) was used in the economic analysis to obtain an empirical 95% confidence interval (CI). All analyses were done in SAS, version 9.1.

Ethics and approval

The protocol received ethical approval from the National Board of Health and was reported to the Danish Data Protection Agency. Approval from the Scientific Ethical Committee was not needed.

Results

99 (63%) of the local GPs and district nurses in all seven invited municipalities participated in the study. A total of 166 patients were randomized to the intervention group and 165 to the control group. Comparison of participating and non-participating patients showed minor differences on diagnosis, length of hospital stay, and type of housing. More participants in the intervention group than in the control group had a cardiovascular diagnosis (see Table I).

The evaluation in the 12th week was completed by 148 patients in the intervention group and by 145 in the control group. The 38 dropout patients had a significantly lower functional ability (Barthel Index in four groups; p = 0.03) and poorer self-rated health (63% vs. 37% rated their health as poor or less than good; p = 0.03) at inclusion than those who did not drop out. A total of 19 died before the evaluation interview was conducted.

The number of conducted follow-ups, the number of participants, the amount of time consumed, and the distribution among home visits and consultations are shown in Figure 2.

Primary outcomes

Readmission. Twenty-six weeks after discharge, 86 (52%) patients in the control group and 67 (40%) in the intervention group had been readmitted (p = 0.03); relative risk reduction (RRR) 23%. A Cox regression analysis of the number of days to first readmission showed a hazard ratio of 0.69 (95% CI: 0.50–0.95. p = 0.02). Figure 3 shows the time to first readmission for any reason. A tendency towards a reduced number of days spent in hospital within 26 weeks was seen in the intervention group (p = 0.07, Wilcoxon rank-sum test).

Control of medication. The concordance between the GPs' knowledge of the patients' medical treatment and what the patients were actually taking was higher in the intervention group than in the control

Table I. Sociodemographic and health characteristics in control and intervention groups at baseline.

Characteristics	Intervention (n = 148)	Control (n = 145)	p-value[1]
Sex – female	66%	66%	0.9
Age (median)	84 years	83 years	1.0[2]
Housing	95% living in private home	97% living in private home	0.4
Marital status	59% widow/widower	57% widow/widower	0.8
	30% spouse	29% spouse	
	11% divorced/single	14% divorced/single	
Contact with family and friends	61% daily/weekly	57% daily/weekly	0.4
	29% monthly	36% monthly	
	10% more seldom	7% more seldom	
Days spent in hospital within the last six			
months before the actual admission	(n = 166)	(n = 165)	
0 days	95 (57%)	95 (58%)	0.5[2]
1–7 days	24 (14%)	39 (24%)	
8–14 days	16 (10%)	10 (6%)	
15–28 days	14 (8%)	12 (7%)	
29 days or more	17 (10%)	9 (5%)	
Number of daily medications			
median (interquartile range)	6(4.5–9)	6 (4–8)	0.4
Receiving help			
From district nurse	65%	56%	0.1
Home helper	81%	77%	0.3
Self-rated health			
Excellent/very good	12 (8%)	16 (11%)	0.5
Good	73 (49%)	81 (56%)	
Fair/poor	63 (42%)	47 (33%)	
Dementia (MMSE, Max. 30) [24]			
Light (20–30 points)	132 (89%)	120 (83%)	0.6
Moderate (10–19 points)	13 (9%)	23 (16%)	
Severe (0–9 points)	2 (2%)	2 (1%)	
Functional status[3]			
Timed up and go [25]			
< 20 seconds	60 (40%)	56 (38%)	1.0
20–30 seconds	20 (14%)	20 (14%)	
> 30 seconds	14 (9%)	13 (9%)	
Could not carry out	54 (36%)	56 (38%)	
Barthel Index [26]			
Insignificant reduction (80–100 points)	115 (78%)	115 (79%)	1.0
Light reduction (79–50 points)	24 (16%)	22 (15%)	
Moderate reduction (49–26 points)	7 (5%)	6 (4%)	
Severe reduction (25–0 points)	2 (1%)	2 (1%)	
Diagnosis			
Cardiovascular	45 (30%)	28 (19%)	0.02
Other	103 (70%)	117 (81%)	

Notes: [1]Chi-squared test; [2]Wilcoxon rank-sum test on non-grouped data; [3]activities of daily living (ADL) measures developed by Avlund [27] were used and showed no differences. Data not shown.

group. Significantly more changes in medication and a higher number of drugs taken were found in the intervention group than in the control group (Table II).

Secondary outcomes

There was a trend towards better follow-up on the discharge plan in the intervention group (see Table II). An economic analysis of the total healthcare expenses showed a tendency towards a socioeconomic gain in favour of the intervention (see Table II). Patients in the intervention group felt that their GPs were better informed about their hospitalization (very well-informed 42% vs. 16%; p = 0.01). No significant differences were found in functional ability, self-rated health, or patient satisfaction with the whole admission to hospital or with the services given by the GPs and municipalities in general. 15 patients in the intervention group and 20 in the control group died within 26 weeks after discharge (hazard ratio 0.72 with 95% CI 0.37–1.41).

Discussion

The present study showed that intervention produced a 23% reduction in readmissions and better concor-
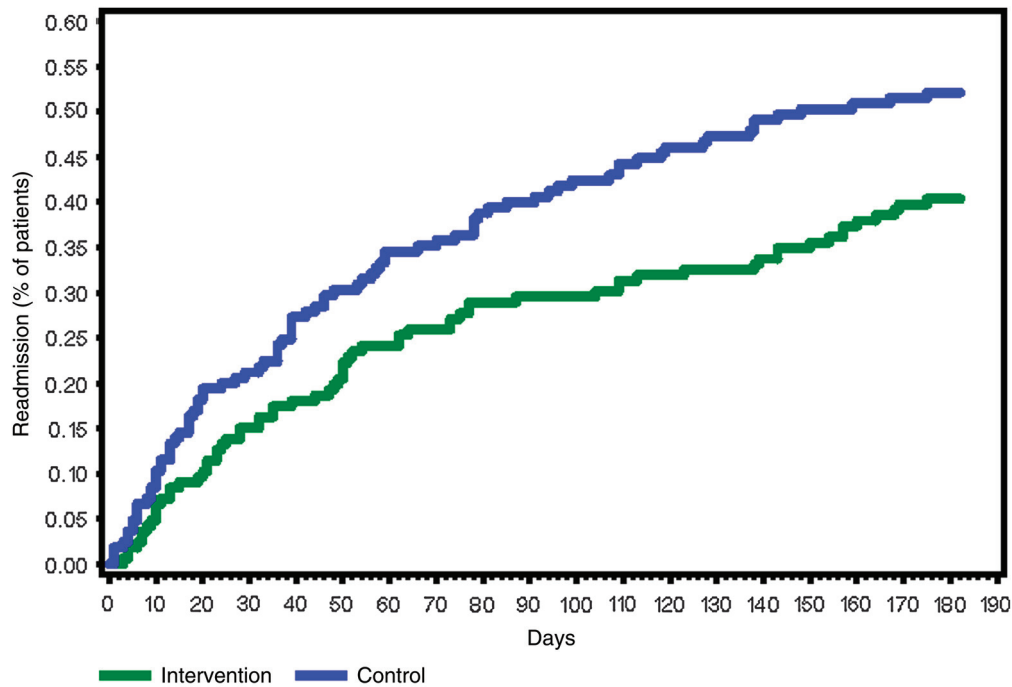
Figure 3. Time to first readmission to hospital for any reason (Kaplan–Meyer).

dance on prescription information. The intervention was characterized by improved interdisciplinary cooperation between the existing staff in primary healthcare, the GP, and the district nurse. The total number of days spent in hospital within 26 weeks was not significantly lower in the intervention group than in the control group as the intervention primarily eliminated admissions of short duration. The reduction in readmissions was comparable to that reported by other interventions concerning geriatric patients performed to improve discharge [1–2,7,13].

Table II. Follow-up on plan, medication, and health economic data.

Variable	Intervention	Control	p-value[3]
Follow-up on plan and medication 12 weeks after discharge	(n = 148)	(n = 145)	
GPs' knowledge regarding the actual medication (prescription)			
Patient taking medication that the GP does not know about	51(34%)	70(48%)	0.02
GP reporting medication that patients do not take	42(28%)	57(39%)	0.05
Follow-up on the discharge plan[1]			
Planned clinical control was completed as recommended	41(95%)	21(72%)	0.02
Planned para-clinical control was completed as recommended	38(88%)	21(68%)	0.09
Number of drugs taken – median (interquartile range)	7(5–10)	6(4–8)	0.0005[4]
Number of patients with adjusted medication since discharge[2]	84(59%)	63(44%)	0.01
Healthcare costs per patient after 26 weeks (€)	(n = 166)	(n = 165)	Extra cost in intervention group
Cost of intervention at hospital	7	0	7
Cost of GP's 1st home visit[5]	102	0	102
Costs of district nurses at first home visit	35	0	35
Total hospital costs	4.414	5.478	−1.064
Other cost in the primary sector (public health insurance)	856	667	190
Costs of medicine	208	146	62
Total	5.622	6.290	−668
			(95% CI € −2.334 to +916)

Notes: [1]Clinical control was recommended at 45 vs. 36 patients (I vs. C), para-clinical control was recommended at 51 vs. 33 patients. [2]Five intervention patients and two control patients had missing values. [3]Chi-squared test. [4]Wilcoxon rank-sum test on non-grouped data. [5]First visit. Other GP costs from the intervention are included in costs of public health insurance.

The present study confirms the GP's important but time-consuming role of dealing with elderly patients [14].

The economic analysis indicates that the intervention is cost-neutral, but that it tends to reduce costs. The savings in the intervention group were driven by substantially greater DRG expenses for readmission in the control group that more than compensated for the extra costs in the primary health sector (see Table II). The findings are in accordance with those of other studies [1,5,8,15]. The study confirms the large inconsistency between doctors' knowledge of medication and what the patients actually use [16–21]. As a considerable number of admissions are attributable to inappropriate medical treatment [10,11], the improved medication control obtained in the present study could be of importance for the outcome. In the present study there was an unexpected, greater consumption of medicine in the intervention group than in the control group. An overrepresentation of patients with cardiac disease in the intervention group, to whom multiple medications are recommended, may have contributed to the higher consumption. Adjustment for this did not entirely eliminate the difference. The study also indicates that better follow-up on the treatment plan specified in the discharge letter is, indeed, possible. Increased collaboration between the GP, the district nurse, and the patient may increase interdisciplinary knowledge and may change the patients' perspective when something goes wrong – making them more prone to contact their GP or district nurse instead of the hospital or the out-of-hours care staff. As expected, we found no impact on hard-core outcomes such as death [3,5], or on functional ability or self-rated health.

Bias

The baseline analysis showed no important differences between the intervention and the control groups. Data on readmission rate and economic data were based on register data which were obtained for all randomized patients. Good study adherence was found concerning data based on patient interview and questionnaires: only 38 patients dropped out.

The study could not be blinded to the GPs and nurses. They filled in several questionnaires during contact with the intervention patients. This fact may have biased our study towards a better effect than can be obtained in daily practice. On the other hand, the chosen method could have raised the GPs' attention towards both intervention and control patients and thereby given the control group increased attention. We do not consider that these conditions affect the overall results. Many of the non-included patients were discharged during weekends as the RT included only weekdays. Such patients are generally less impaired than other patients as municipal support cannot be arranged. On the other hand, the inclusion/exclusion criteria excluded many frail patients because the evaluation was partly based on patient interview which would not be possible with patients with, for example, severe dementia. Given the characteristics of these patients, their exclusion was not expected to affect the overall representativeness of our study population.

The data on cost in the primary healthcare sector have been limited by the fact that it was not possible to obtain data on the overall derived expenses in the municipalities.

Perspective

The effect of structured intervention in relation to discharge from hospital on the rate of readmission has already been demonstrated by outgoing hospital teams [1,2,7,8,13,22,23]. We have no knowledge of studies that have investigated strategies to improve control of medical care involving the GP as a key person. Even if the study does demonstrate a potential for savings from an overall perspective, GPs and district nurses have to make an extra effort for such savings to materialise. We conclude that there is a major potential within the existing organizational framework for reducing readmissions, and in a cost-efficient manner.

Authors' contribution

LR: Conception, design, interpretation, and drafting. HNJ: Conception, design, analysis, interpretation, and revising. FRH: Conception, design, interpretation, and revising. AVH: Analysis. AHA: Analysis, interpretation, and approval. AN: Conception, design, interpretation, and revising. JK: Analysis, interpretation, and approval.

Conflict of interest

The authors have no conflicts of interest to declare.

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