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Medical Assistant–Based Care Management for High-Risk Patients in Small Primary Care Practices

A Cluster Randomized Clinical Trial

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Background: Patients with multiple chronic conditions are at high risk for potentially avoidable hospitalizations, which may be reduced by care coordination and self-management support. Medical assistants are an increasingly available resource for patient care in primary care practices.

Objective: To determine whether protocol-based care management delivered by medical assistants improves care in patients at high risk for future hospitalization in primary care.

Design: Two-year cluster randomized clinical trial. (Current Controlled Trials: ISRCTN56104508)

Setting: 115 primary care practices in Germany.

Patients: 2076 patients with type 2 diabetes, chronic obstructive pulmonary disease, or chronic heart failure and a likelihood of hospitalization in the upper quartile of the population, as predicted by an analysis of insurance data.

Intervention: Protocol-based care management, including structured assessment, action planning, and monitoring delivered by medical assistants, compared with usual care.

Measurements: All-cause hospitalizations at 12 months (primary outcome) and quality-of-life scores (12-Item Short Form Health Survey [SF-12] and EuroQol instrument [EQ-5D]).

Results: Included patients had an average of 4 co-occurring chronic conditions. All-cause hospitalizations did not differ between groups at 12 months (risk ratio [RR], 1.01 [95% CI, 0.87 to 1.18]) and 24 months (RR, 0.98 [CI, 0.85 to 1.12]). Quality of life (differences, 1.16 [CI, 0.24 to 2.08] on SF-12 physical component and 1.68 [CI, 0.60 to 2.77] on SF-12 mental component) and general health (difference on EQ-5D, 0.03 [CI, 0.00 to 0.05]) improved significantly at 24 months. Intervention costs totaled $10 per patient per month.

Limitation: Small number of primary care practices and low intensity of intervention.

Conclusion: This low-intensity intervention did not reduce all-cause hospitalizations but showed positive effects on quality of life at reasonable costs in high-risk multimorbid patients.

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Primary care faces the challenge of caring for an increasing number of patients with multiple chronic conditions with a diminishing workforce (1, 2). These patients are at high risk for potentially avoidable hospitalizations, which result in substantial system-level health care spending (3) and affect patient quality of life (4). Although most hospitalizations are deemed unavoidable (5, 6), primary care physicians report that self-management support and intensified monitoring could prevent 40% of hospitalizations in patients with multiple chronic conditions (7).

Studies of nurse-led care management interventions that focus on patients at high risk for future health care use, such as Guided Care (8) or Geriatric Resources for Assessment and Care of Elders (9), have recently evaluated self-management support and intensified monitoring. Despite substantial improvements in quality of care (8) and reductions in health care use (10), these interventions did not reduce overall health care spending (8, 10), partly because savings from reduced health care use were offset by the costs of these interventions.

In small primary care settings (solo practices or 2-person partnerships), resources are often limited and extensive collaborative models, such as multiprofessional care management, may be difficult to implement. The medical assistant workforce is one of the fastest growing workforces in primary care practices in the United States (11), and all primary care practices in Germany employ medical assistants. Medical assistants in the United States are trained in a 3-year part-time curriculum in practice (3920 hours) and vocational school (840 hours). Despite recent attempts to involve medical assistants in chronic care, their work focuses primarily on clerical duties (including reception) and routine tasks, such as blood sampling or electrocardiogram recording, and their median annual salary is $28 860 (11). Certified medical assistants in the United States and Germany are comparable with regard to education, tasks, and remuneration (11).

Involving medical assistants in chronic care management may improve access to health services (12).

See also:

Editorial comment 1

Web-Only

Supplement

EDITORS' NOTES

Context

Dissatisfaction with traditional care for patients with chronic conditions is leading to new models of care.

Contribution

The investigators found that protocol-based care by medical assistants for patients with diabetes mellitus, chronic obstructive pulmonary disease, or chronic heart failure did not prevent rehospitalization but did improve quality of life at a reasonable cost.

Caution

Relatively few practices were included in the study.

Implication

Medical assistants can participate in new models of care for patients with chronic conditions.

Early programs that expanded the medical assistant's role to include chronic care services (under the supervision of primary care physicians), such as self-management support (13) or telephone monitoring in patients with osteoarthritis (14), major depression (15), or chronic heart failure (16), showed significant results in terms of specialist consultation rates (13, 14), medication management (14), depressive symptoms (15), and self-care behavior (16). All of these programs were "scripted," meaning that medical assistants followed evidence-based protocols and algorithms with defined interview questions.

We aimed to determine whether a medical assistant–based scripted care management intervention (primary care–based care management [PraCMan]) would reduce hospitalizations in primary care patients with type 2 diabetes, chronic obstructive pulmonary disease (COPD), or chronic heart failure who had a high predicted risk for future hospitalization.

METHODS

Design

We performed a cluster randomized clinical trial using primary care practices as units of randomization to minimize contamination bias. We have published details of the study design (17).

Setting and Participants

We conducted the study between July 2010 and June 2013 and enrolled patients from October to December 2010. Practices were eligible for the study if they employed at least 1 primary care physician (such as a general practitioner or general internist) and at least 1 medical assistant and if both were willing to participate in the study. Primary care physicians had to be enrolled in the primary care–centered care contract of a large health plan in Germany (AOK Baden-Württemberg) (18). Because "medical assistant" is a defined health profession in Germany (19), we did not need additional inclusion criteria for them. Practices were recruited from July to September 2010. We informed all 1177 primary care physicians within the health plan of AOK Baden-Württemberg about the study and invited all interested physicians to participate in the study.

Eligible patients were aged 18 years or older and were receiving medical treatment for at least 1 of the following index conditions: type 2 diabetes mellitus, COPD, or chronic heart failure. Furthermore, patients had to have a high risk for future hospitalization (that is, a predicted likelihood of hospitalization within the upper quartile of the total population of health plan patients, as determined by analysis of data from the preceding 18 months [20]). We calculated the likelihood of hospitalization by assessing the deidentified insurance claims data of all health plan beneficiaries from the participating practices using the validated prediction software Case Smart Suite Germany 0.7 (Verisk Health) (21).

We excluded patients who met the following criteria: active cancer (cancer diagnosis and current receipt of radiotherapy or chemotherapy), moderate to severe dementia, permanent residency in a nursing home, participation in a concurrent clinical trial (including telemonitoring studies), severe physical and mental disorders (such as dementia, psychotic disorder, or palliative care needs), or other problems that hindered active participation in the intervention (such as language barriers), as assessed by the primary care physician. Previous studies have validated this process of inclusion and exclusion (20). After providing written informed consent, participating patients provided baseline data. We concealed the allocation to intervention or control groups until each practice completed patient enrollment and baseline assessment.

Randomization and Interventions

Primary care practices were randomly allocated to care management or usual care in a 1:1 ratio by block randomization with variable block lengths. Because population density has a substantial effect on hospitalizations (22), we stratified randomization according to the population density of the participating practice sites (urban vs. rural), based on a map provided by the Federal Agency of Regional Development Planning. We used computer-generated randomization lists (SAS, version 9.2 [SAS Institute]). A research assistant who was not otherwise involved in the project performed the central randomization. We informed physicians about their allocation via an official letter and asked them to inform participating patients. Because of the nature of the intervention, blinding primary care physicians, medical assistants, and patients was not possible. However, we blinded the assessment of the primary and secondary end points as well as the responsible statistician to study group allocation.

Training of Practice Teams

We trained 71 medical assistants in a 2-day course on behavioral counseling strategies, symptom monitoring, medication assessment, and interprofessional communication by using a training manual (Appendix Table 1, available at www.annals.org). Training was complemented by 20 hours of self-study.

Intervention

Using early evidence on a collaborative care concept for patients with multiple chronic conditions in an established nonprofit U.S. HMO (23), we trained medical assistants by using a paper-based assessment checklist to reveal patients' needs and resources (17). Primary care physicians and patients negotiated patient-specific goals, with a special emphasis on self-management tasks (24). Medical assistants developed specific action plans to achieve these goals together with patients and caregivers. A folder that included health information and an optional emergency plan was offered to all patients. Medical assistants monitored goal achievement and symptom deterioration either face-to-face with patients in the clinic or by telephone using paper-based checklists (25, 26). Monitoring intervals were tailored to the patient's health status but were scheduled at least once every 6 weeks. Primary care physicians met with medical assistants weekly to review patient progress. We fixed the maximum caseload for medical assistants at 20 patients (in addition to their daily duties, such as reception and phlebotomy). We financially incentivized intervention practice teams by providing $135 per enrolled patient per year to cover staff costs.

Usual Care

Patients in the control group received the best primary care according to evidence-based practice guidelines (18).

Outcomes and Follow-up

The primary outcome was the number of all-cause hospitalizations at 12 months at the patient level. We set the date of randomization as the starting date of the intervention. We did not include hospitalizations that occurred before the start of the intervention (that is, before 3 November 2010), but we did include hospitalizations that persisted after the end of the intervention (that is, after 3 November 2012). Secondary measures included the number of days in the hospital; hospitalizations related to index conditions; patient-reported quality of life, which was assessed with the 12-Item Short Form Health Survey (SF-12) (mental and physical health scales ranging from 0 [poor] to 100 [good]) (27); general health, which was assessed with the EuroQol instrument (EQ-5D) (scores ranging from 0 [poor health] to 1 [perfect health]) (28); and all-cause mortality. We estimated intervention costs using standard wages for medical assistants' and physicians' working time.

Data on the number of hospitalizations were extracted from insurance claims by data analysts who were blinded to the intervention status of participating patients. We assessed mortality by using insurance claims data. We collected patient-reported data, including quality-of-life measures, by using self-administered paper-based questionnaires at the clinics.

Statistical Analysis

On the basis of data from our pilot study, we expected a mean of 0.7 all-cause hospitalization per patient per year (SD, 1.0) (29). We thus required a total of 1602 patients (1:1 randomization) to detect a between-group difference of 0.14 (20% reduction), with a power of 80% at the 5% significance level (2-sided). We estimated an intracluster correlation of 0.01 at the practice level on the basis of data from a similar intervention study (16). With an average cluster size of 17, we estimated a design effect of 1.16. Taking this design effect into account, we planned to enroll a total of 130 practices and 2210 patients. This would leave enough power for the questionnaire data, in which we expected a 15% loss to follow-up based on prior studies (16).

Characteristics and baseline assessments were summarized using standard descriptive statistics (mean and SD for continuous data and percentages for categorical data). We assumed that the primary outcome would follow a Poisson distribution with overdispersion because we expected the health status of patients to differ within and between practices. We compared hospitalization rates of the 2 treatment groups by using a negative binomial multilevel model (30), with "number of hospitalizations" as the response variable, "treatment group" (care management vs. usual care) and "practice location" (urban vs. rural [the stratification factor]) as fixed effects, and "practice identification" as a random intercept. We present the results as the risk ratio (RR) between care management and usual care, with the corresponding 2-sided 95% CI.

We analyzed quality-of-life data with linear mixed-effects models with fixed-effects treatment group, practice location, a random intercept for practices, and the baseline assessment as a covariate. For the 24-month follow-up, the average of the available 12- and 24-month quality-of-life assessments was used. We analyzed survival by using Cox mixed-effects models with shared frailty for patients in the same practice and fixed effects for treatment group and practice location (intention-to-treat analysis).

We based the primary analysis on the entire set of randomly assigned patients and practices, regardless of protocol violations in the later course. We conducted sensitivity analyses for the per protocol set (patients who received >50% of the planned intervention intensity, as detailed in the Supplement [available at www.annals.org]) with multivariable models. We assessed the primary end point for all patients by using data from insurance claims. The number of days in the hospital was analyzed in a manner similar to the primary outcome; patients who were not hospitalized were included with their number of days equal to zero. For the

Table 1. Practice Characteristics

Variable	Care Management	Usual Care
Practices, *n*	58	57
Solo, %	46	54
Located in rural area, %	55	56
Patients per quarter, %		
500–1000	25	25
1001–1500	29	33
1501–2000	27	25
>2000	19	17
Median cluster size (IQR), *n*	17 (14–20)	17 (15–20)
Mean SOAPC score (SD)*	2.73 (0.18)	2.79 (0.21)
Primary care physicians, *n*	69	63
Mean age (SD), *y*	51 (9)	53 (8)
Female, %	26	13
Mean professional experience (SD), *y*	18 (9)	18 (9)
Medical assistants, *n*	71	67
Mean age (SD), *y*	39 (11)	36 (11)
Female, %	100	100
Mean professional experience (SD), *y*	14 (10)	13 (10)

IQR = interquartile range; SOAPC = Survey of Organizational Attributes for Primary Care.
* Range of 1 to 5, with higher scores indicating higher organizational level.

quality-of-life measures, we performed analyses for the available cases (reported here) and used multiple imputation for incomplete data (Supplement).

The statistical analysis was performed with R, version 3.2.0 for Windows (R Foundation for Statistical Computing), using the glmmadmb command from the glmmADMB package and the coxme package (31). We provide details of the statistical analysis and the results of the sensitivity analyses in the Supplement.

Ethics

The Ethics Committee of University Hospital Heidelberg (S-232/2010) approved the study protocol before the start of the study.

Role of the Funding Source

AOK Baden-Württemberg and AOK Bundesverband funded the study but had no role in analysis, interpretation, or publication of the data.

RESULTS

Study Participants

We invited 366 primary care physicians by written letter. A total of 132 (36%) primary care physicians from 115 practices agreed to participate in the trial. Out of 73 499 AOK beneficiaries in the 115 practices, 7995 patients were potentially eligible as determined by predicted risk and index condition (11%). Primary care physicians performed additional screening for 6140 (77%) of the 7995 potentially eligible patients until we reached a maximum caseload of 20 per medical assistant. Of 2076 patients enrolled (1093 in the care management group and 983 in the usual care group), 1875 (90%) completed 12 months of follow-up (Appendix Figure, available at www.annals.org).

Enrolled patients were younger than those who declined to participate and had fewer all-cause hospitalizations in the year preceding the trial than those who were not enrolled (Supplement Table 5).

Practice and patient characteristics were similar between groups at baseline (Tables 1 and 2), except for a slightly higher proportion of patients with COPD in the intervention group and a higher proportion from ethnic minorities in the usual care group. More patients were enrolled in the care management group due to a higher number of group practices (each with up to 2 teams recruiting patients) in that group.

Intervention

Medical assistants completed assessment for all patients in the intervention group (mean duration, 35 minutes [SD, 14]). Medical assistants, patients, and physicians set collaborative goals for 89% of the patients; 84% of the patients received a patient diary; and 56% received an optional emergency plan. Medical assistants performed an average of 11 monitoring sessions (SD, 6) per patient (32% of them via telephone) and an average of 184 monitoring sessions (SD, 89) during the intervention. The mean duration of the monitoring sessions was 12 minutes (SD, 7). Medical assistants actively managed patients for a mean of 21 months (SD, 6), with a median delay between randomization and the start of the intervention of 47 days (range, 12 to 162 days). The estimated mean cost of the intervention, including all medical assistant contacts and physician supervision, was $153 per patient for the first year and $94 per patient for the second year (see the Appendix, available at www.annals.org, for details).

Primary and Secondary Outcomes

At 12 months, about 37% of the patients had been hospitalized at least once, and the number of all-cause hospitalizations per patient did not differ significantly between groups (0.62 in the intervention group and 0.61 in the usual care group; difference, 0.01 [95% CI,

Table 2. Patient Characteristics

Variable	Care Management (*n* = 1093)	Usual Care (*n* = 983)
Mean age (SD), *y*	71.6 (9.6)	72.4 (9.6)
Female, %	52	52
≥1 y of college, %	5	5
Ethnic minority, %*	2	5
Part- or full-time employment, %	9	9
Index condition, %		
Type 2 diabetes	68	69
COPD	29	23
Chronic heart failure	26	29
Mean co-occurring chronic conditions (SD), *n*†	4 (2)	4 (2)
LOH in following 12 mo, %	34	34
Mean all-cause hospitalizations in the 12 mo before trial (SD), *n*	0.68 (1.12)	0.71 (1.09)

COPD = chronic obstructive pulmonary disease; LOH = likelihood of hospitalization.
* Nonwhite, Asian, or Hispanic.
† From a list of 32 chronic conditions.

Table 3. Hospitalizations

Condition and Outcome	0 to 12 mo				0 to 24 mo			
	Care Management	Usual Care	Risk Ratio (95% CI)*	*P* Value	Care Management	Usual Care	Risk Ratio (95% CI)*	*P* Value
All causes								
Patients, *n*	1093	983			1093	983		
Mean hospitalizations (SD), *n*	0.62 (1.03)	0.61 (1.04)	1.01 (0.87–1.18)	0.89	1.19 (1.80)	1.21 (1.80)	0.98 (0.85–1.12)	0.75
Mean hospital days (SD), *n*†	2.1 (13.9)	1.9 (11.7)	0.99 (0.41–2.35)	0.98	3.3 (17.4)	3.7 (16.1)	0.85 (0.44–1.64)	0.63
Type 2 diabetes								
Patients, *n*	742	683			742	683		
Mean hospitalizations (SD), *n*	0.03 (0.18)	0.03 (0.19)	0.86 (0.43–1.73)	0.67	0.06 (0.33)	0.09 (0.39)	0.69 (0.41–1.16)	0.158
Mean hospital days (SD), *n*†	0.23 (2.24)	0.27 (2.66)	0.53 (0.10–2.70)	0.44	0.51 (3.54)	0.69 (4.49)	0.73 (0.24–2.17)	0.57
COPD								
Patients, *n*	321	222			321	222		
Mean hospitalizations (SD), *n*	0.03 (0.22)	0.11 (0.56)	0.27 (0.10–0.74)	0.011	0.14 (0.61)	0.26 (1.09)	0.54 (0.27–1.09)	0.086
Mean hospital days (SD), *n*†	0.14 (1.62)	0.61 (4.20)	0.18 (0.02–2.25)	0.185	0.73 (3.97)	1.55 (8.09)	0.49 (0.12–1.91)	0.30
Chronic heart failure								
Patients, *n*	285	284			285	284		
Mean hospitalizations (SD), *n*	0.12 (0.45)	0.10 (0.39)	1.16 (0.61–2.21)	0.65	0.21 (0.64)	0.26 (0.70)	0.81 (0.50–1.31)	0.39
Mean hospital days (SD), *n*†	0.65 (3.83)	0.55 (3.07)	0.85 (0.16–4.59)	0.85	1.30 (5.24)	1.64 (5.52)	0.78 (0.29–2.12)	0.63

COPD = chronic obstructive pulmonary disease.
* Values <1 favor the intervention.
† Calculated for all patients; 0 hospital days were noted for patients with no hospitalizations.

−0.09 to 0.11]; RR, 1.01 [CI, 0.87 to 1.18]) (**Table 3**). The number of COPD-related hospitalizations was lower in the intervention group (RR, 0.27 [CI, 0.10 to 0.74]; *P* = 0.011), but we found no significant differences in the number of diabetes-related or heart failure–related hospitalizations. At 24 months, there were no significant differences in the number of all-cause hospitalizations and hospitalizations related to COPD, diabetes, or heart failure. The number of all-cause and index condition–related hospital days did not differ significantly between the groups at any time point. Results of the per protocol analysis and the multivariable models were similar to the results of the intention-to-treat analysis (**Supplement Table 8**).

Quality-of-life scores (SF-12) and general health scores (EQ-5D) improved significantly in the intervention group compared with the usual care group at 24 months (**Table 4**). The effect was moderate (about 1.5 units on the SF-12 mental and physical scales and 0.03 on the EQ-5D scale).

Mortality

Over the 24-month trial, 62 patients in the care management group and 68 in the usual care group died (hazard ratio, 0.81 in favor of the care management group [CI, 0.57 to 1.15]; *P* = 0.24).

DISCUSSION

After 24 months of intervention, medical assistant–based care management in small primary care practices did not significantly reduce all-cause hospitalizations (the primary outcome) but did improve quality of life and general health.

Our findings are supported by studies of nurse-led care management interventions for single conditions. A meta-analysis of the effects of care management on hospitalizations for COPD found a significant reduction among studies focusing on high-risk patients (showing better short-term outcomes) (32). In our study, the num-

Table 4. Quality-of-Life Outcomes*

Outcome	Baseline				12 mo			
	Care Management		Usual Care		Care Management		Usual Care	
	Patients, *n*	Mean Score (SD)	Patients, *n*	Mean Score (SD)	Patients, *n*	Mean Score (SD)	Patients, *n*	Mean Score (SD)
SF-12 physical component	884	35.9 (9.6)	808	35.8 (9.4)	801	36.5 (9.7)	776	35.9 (9.7)
SF-12 mental component	884	47.6 (11.3)	808	46.7 (11.2)	801	48.8 (10.9)	776	46.9 (11.1)
EQ-5D	1002	0.63 (0.22)	934	0.61 (0.22)	918	0.64 (0.22)	878	0.61 (0.23)

EQ-5D = EuroQol instrument; SF-12 = 12-Item Short Form Health Survey.
* Values represent available cases.
† Baseline-adjusted difference between groups at 12 mo (values >0 favor the new intervention).
‡ Baseline-adjusted difference between groups at 12 and 24 mo (averaged).

ber of COPD-related hospitalizations was significantly lower at 12 months but not at 24 months, which may be due to the limited power after 24 months of intervention. Evidence for the effect of care management on diabetes-related hospitalizations is lacking (33). However, as the results of our study suggest, longer interventions and larger study populations may be needed to determine a positive effect of care management on diabetes-related hospitalizations. In our study, the number of heart failure–related hospitalizations increased slightly at 12 months before decreasing in the second year. Earlier studies have described this phenomenon (34, 35), which is probably due to the fact that care management raises awareness of warning signs and clinical deterioration associated with heart failure, which in turn results in increased hospitalizations in the short term, when patients and caregivers have not yet developed their self-management capabilities. Therefore, a longer intervention is necessary to reveal positive effects.

Evidence is limited on the effect of care management interventions on quality-of-life outcomes in multimorbid patients, with few studies showing benefits (36). Some of our specific intervention elements, such as self-management support, goal setting, and symptom monitoring (including depression and pain), may have contributed to improved quality of life. A minimum clinically important difference in SF-12 or EQ-5D score has not yet been determined for multimorbid patients. However, although the observed changes are small, they are similar in size to clinically important differences in the SF-12 mental component and the EQ-5D that have been reported in other studies (37, 38). In a population of patients with a substantial and increasing morbidity burden, and therefore an expected deterioration of quality of life over time (39), we believe that even a small beneficial effect (as observed in our study) would be relevant and could be achieved at a reasonable cost.

Medical assistants are a promising resource for delivery of care management to high-risk patients in small primary care practices. Working "at the top of their license" and supervised by physicians, medical assistants were able to assume a new role in chronic care management by means of specific protocols and scripts (now included in the software package PraCMan Cockpit [University Hospital Heidelberg]).

Time constraints of practice team members limited the number of practices we could enroll in the study. However, the practices we enrolled accurately represent small primary care practices in Germany with regard to location and list size (18). This study may not have detected some changes due to limited power in several outcomes, including health care use and patient survival at 24 months. We accounted for clustering within practices but were unable to account for clustering within physician/medical assistant teams within a practice (each of which had up to 2 teams). Furthermore, intervention intensity was limited to fit the additional tasks associated with PraCMan into medical assistants' daily workflow. In some patients, the delayed start of the intervention may have resulted in hospitalizations. Although the study took place in a limited number of small practices in Germany, it benefitted from a large study population, a long intervention, high patient acceptability, no loss to follow-up for the primary outcome, and a rigorous evaluation design.

In our study, a minority of hospitalizations was related to "causes deemed being potentially avoidable" (4). Therefore, we may need a stronger focus on patients with a high risk for "potentially avoidable" hospitalizations and a larger study population in future studies to better understand the extent to which medical assistant–based care management might decrease the rates of potentially avoidable hospitalizations in multimorbid patients.

Translating research into practice may be enhanced by using the RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) framework (40). Our intervention reached a substantial proportion of eligible patients and was adopted by primary care practices with scores below the German average on the Survey of Organizational Attributes for Primary Care (41), thereby precluding positive selection of "high-performing" practice teams. Implementation varied widely across participating practices, with limited time dedicated to the intervention. Therefore, we may need optimal organizational support (for example, software packages) to increase implementation fidelity. Since the end of the study, maintenance of the use of PraCMan has been high; as of 31 December 2015, it had become part of routine care in 834 practices.

In summary, medical assistant–based care management increases quality of life in multimorbid patients

Table 4–Continued

12 mo		24 mo					
Difference† (95% CI)	***P* Value**	**Care Management**		**Usual Care**		**Difference‡ (95% CI)**	***P* Value**
		Patients, *n*	**Mean Score (SD)**	**Patients, *n***	**Mean Score (SD)**		
0.70 (−0.28 to 1.68)	0.162	553	36.5 (10.6)	590	35.5 (10.2)	1.16 (0.24 to 2.08)	0.013
1.45 (0.24 to 2.67)	0.019	553	48.9 (10.8)	590	46.9 (11.6)	1.68 (0.60 to 2.77)	0.002
0.02 (0 to 0.04)	0.085	779	0.65 (0.22)	806	0.61 (0.23)	0.03 (0 to 0.05)	0.016

and could therefore complement primary care delivered by physicians and nurses at a reasonable cost.

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Reproducible Research Statement: *Study protocol:* Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC3141533. *Statistical code:* Provided in the Supplement. The complete code is available from Dr. Freund (e-mail, tobias.freund@med.uni-heidelberg.de). *Data set:* Not available.

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References

1. **Tinetti ME, Fried TR, Boyd CM.** Designing health care for the most common chronic condition—multimorbidity. JAMA. 2012;307:2493-4. [PMID: 22797447] doi:10.1001/jama.2012.5265
2. **Schwartz MD.** The US primary care workforce and graduate medical education policy [Editorial]. JAMA. 2012;308:2252-3. [PMID: 23212505] doi:10.1001/jama.2012.77034
3. **Wolff JL, Starfield B, Anderson G.** Prevalence, expenditures, and complications of multiple chronic conditions in the elderly. Arch Intern Med. 2002;162:2269-76. [PMID: 12418941]
4. **Purdy S.** Avoiding hospital admissions. What does the research evidence say? London: The King's Fund; 2010:7-8.
5. **van Walraven C, Bennett C, Jennings A, Austin PC, Forster AJ.** Proportion of hospital readmissions deemed avoidable: a systematic review. CMAJ. 2011;183:E391-402. [PMID: 21444623] doi:10.1503/cmaj.101860
6. **Joynt KE, Jha AK.** Thirty-day readmissions—truth and consequences. N Engl J Med. 2012;366:1366-9. [PMID: 22455752] doi:10.1056/NEJMp1201598
7. **Freund T, Campbell SM, Geissler S, Kunz CU, Mahler C, Peters-Klimm F, et al.** Strategies for reducing potentially avoidable hospitalizations for ambulatory care-sensitive conditions. Ann Fam Med. 2013;11:363-70. [PMID: 23835823] doi:10.1370/afm.1498
8. **Boult C, Leff B, Boyd CM, Wolff JL, Marsteller JA, Frick KD, et al.** A matched-pair cluster-randomized trial of guided care for high-risk older patients. J Gen Intern Med. 2013;28:612-21. [PMID: 23307395] doi:10.1007/s11606-012-2287-y
9. **Counsell SR, Callahan CM, Clark DO, Tu W, Buttar AB, Stump TE, et al.** Geriatric care management for low-income seniors: a randomized controlled trial. JAMA. 2007;298:2623-33. [PMID: 18073358]
10. **Counsell SR, Callahan CM, Tu W, Stump TE, Arling GW.** Cost analysis of the Geriatric Resources for Assessment and Care of Elders care management intervention. J Am Geriatr Soc. 2009;57:1420-6. [PMID: 19691149]
11. **Freund T, Everett C, Griffiths P, Hudon C, Naccarella L, Laurant M.** Skill mix, roles and remuneration in the primary care workforce: who are the healthcare professionals in the primary care teams across the world? Int J Nurs Stud. 2015;52:727-43. [PMID: 25577306] doi:10.1016/j.ijnurstu.2014.11.014
12. **Ghorob A, Bodenheimer T.** Sharing the care to improve access to primary care. N Engl J Med. 2012;366:1955-7. [PMID: 22621625] doi:10.1056/NEJMp1202775
13. **Ferrer RL, Mody-Bailey P, Jaén CR, Gott S, Araujo S.** A medical assistant-based program to promote healthy behaviors in primary care. Ann Fam Med. 2009;7:504-12. [PMID: 19901309] doi:10.1370/afm.1059
14. **Rosemann T, Joos S, Laux G, Gensichen J, Szecsenyi J.** Case management of arthritis patients in primary care: a cluster-randomized controlled trial. Arthritis Rheum. 2007;57:1390-7. [PMID: 18050178]
15. **Gensichen J, von Korff M, Peitz M, Muth C, Beyer M, Güthlin C, et al; PRoMPT (PRimary care Monitoring for depressive Patients Trial).** Case management for depression by health care assistants in small primary care practices: a cluster randomized trial. Ann Intern Med. 2009;151:369-78. [PMID: 19755362] doi:10.7326/0003-4819-151-6-200909150-00001
16. **Peters-Klimm F, Campbell S, Hermann K, Kunz CU, Müller-Tasch T, Szecsenyi J; Competence Network Heart Failure.** Case management for patients with chronic systolic heart failure in primary care: the HICMan exploratory randomised controlled trial. Trials. 2010;11:56. [PMID: 20478035] doi:10.1186/1745-6215-11-56
17. **Freund T, Peters-Klimm F, Rochon J, Mahler C, Gensichen J, Erler A, et al.** Primary care practice-based care management for chronically ill patients (PraCMan): study protocol for a cluster randomized controlled trial [ISRCTN56104508]. Trials. 2011;12:163. [PMID: 21714883] doi:10.1186/1745-6215-12-163
18. **Gerlach FM, Szecsenyi J.** Evaluation of family doctor centred care (HzV) according to §73b SGB V in Baden-Württemberg (2013–2016). Accessed at www.aok-gesundheitspartner.de/imperia/md/gpp/bw/arztundpraxis/hzv/bw_hzv_eval_2013-2014.pdf on 3 January 2016.

19. **Kultusministerkonferenz.** Rahmenlehrplan Medizinischer Fachangestellter/Medizinische Fachangestellte. 2005. Accessed at www.kmk.org/fileadmin/pdf/Bildung/BeruflicheBildung/rlp/MedizinischerFA.pdf on 17 December 2015.
20. **Freund T, Gondan M, Rochon J, Peters-Klimm F, Campbell S, Wensing M, et al.** Comparison of physician referral and insurance claims data-based risk prediction as approaches to identify patients for care management in primary care: an observational study. BMC Fam Pract. 2013;14:157. [PMID: 24138411] doi:10.1186/1471-2296-14-157
21. **Haupt C, Guenster C.** Statistical risk models: applicability for the optimization of patient care. Monitor Versorgungsforschung. 2013; 1:36-9.
22. **Ansari Z, Barbetti T, Carson NJ, Auckland MJ, Cicuttini F.** The Victorian ambulatory care sensitive conditions study: rural and urban perspectives. Soz Praventivmed. 2003;48:33-43. [PMID: 12756887]
23. **Katon WJ, Lin EH, Von Korff M, Ciechanowski P, Ludman EJ, Young B, et al.** Collaborative care for patients with depression and chronic illnesses. N Engl J Med. 2010;363:2611-20. [PMID: 21190455] doi:10.1056/NEJMoa1003955
24. **Bodenheimer T, Handley MA.** Goal-setting for behavior change in primary care: an exploration and status report. Patient Educ Couns. 2009;76:174-80. [PMID: 19560895] doi:10.1016/j.pec.2009.06.001
25. **Freund T, Baldauf A, Muth C, Gensichen J, Szecsenyi J, Peters-Klimm F.** [Practice-based home visit and telephone monitoring of chronic heart failure patients: rationale, design and practical application of monitoring lists in the HICMan trial]. Z Evid Fortbild Qual Gesundhwes. 2011;105:434-45. [PMID: 21843846] doi:10.1016/j.zefq.2010.06.027
26. **Gensichen J, Peitz M, Torge M, Mosig-Frey J, Wendt-Hermainski H, Rosemann T, et al.** [The "Depression Monitoring list" (DeMoL) with integrated PHQ-D-Rationale and design of a tool for the case management for depression in primary care]. Z Arztl Fortbild Qualitatssich. 2006;100:375-82. [PMID: 16955623]
27. **Ware J Jr, Kosinski M, Keller SD.** A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34:220-33. [PMID: 8628042]
28. **EuroQol Group.** EuroQol—a new facility for the measurement of health-related quality of life. Health Policy. 1990;16:199-208. [PMID: 10109801]
29. **Freund T, Wensing M, Mahler C, Gensichen J, Erler A, Beyer M, et al.** Development of a primary care-based complex care management intervention for chronically ill patients at high risk for hospitalization: a study protocol. Implement Sci. 2010;5:70. [PMID: 20858242] doi:10.1186/1748-5908-5-70
30. **Venables WN, Ripley BD.** Random and mixed effects. In: Venables WN, Ripley BD. Modern Applied Statistics With S. New York: Springer; 2002:271-300.
31. **Therneau TM.** coxme: Mixed Effects Cox Models. R package version 2.2. 2012.
32. **Lemmens KM, Nieboer AP, Huijsman R.** A systematic review of integrated use of disease-management interventions in asthma and COPD. Respir Med. 2009;103:670-91. [PMID: 19155168] doi:10.1016/j.rmed.2008.11.017
33. **Egginton JS, Ridgeway JL, Shah ND, Balasubramaniam S, Emmanuel JR, Prokop LJ, et al.** Care management for Type 2 diabetes in the United States: a systematic review and meta-analysis. BMC Health Serv Res. 2012;12:72. [PMID: 22439920] doi:10.1186/1472-6963-12-72
34. **Weinberger M, Oddone EZ, Henderson WG.** Does increased access to primary care reduce hospital readmissions? Veterans Affairs Cooperative Study Group on Primary Care and Hospital Readmission. N Engl J Med. 1996;334:1441-7. [PMID: 8618584]
35. **Jaarsma T, van der Wal MH, Lesman-Leegte I, Luttik ML, Hogenhuis J, Veeger NJ, et al; Coordinating Study Evaluating Outcomes of Advising and Counseling in Heart Failure (COACH) Investigators.** Effect of moderate or intensive disease management program on outcome in patients with heart failure: Coordinating Study Evaluating Outcomes of Advising and Counseling in Heart Failure (COACH). Arch Intern Med. 2008;168:316-24. [PMID: 18268174] doi:10.1001/archinternmed.2007.83
36. **Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T.** Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. BMJ. 2012;345:e5205. [PMID: 22945950] doi:10.1136/bmj.e5205
37. **Parker SL, Godil SS, Shau DN, Mendenhall SK, McGirt MJ.** Assessment of the minimum clinically important difference in pain, disability, and quality of life after anterior cervical discectomy and fusion: clinical article. J Neurosurg Spine. 2013;18:154-60. [PMID: 23176164] doi:10.3171/2012.10.SPINE12312
38. **Jerant A, Chapman BP, Franks P.** Personality and EQ-5D scores among individuals with chronic conditions. Qual Life Res. 2008;17: 1195-204. [PMID: 18839336] doi:10.1007/s11136-008-9401-y
39. **Fortin M, Lapointe L, Hudon C, Vanasse A, Ntetu AL, Maltais D.** Multimorbidity and quality of life in primary care: a systematic review. Health Qual Life Outcomes. 2004;2:51. [PMID: 15380021]
40. **Glasgow RE, McKay HG, Piette JD, Reynolds KD.** The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? Patient Educ Couns. 2001; 44:119-27. [PMID: 11479052]
41. **Ose D, Freund T, Kunz CU, Szecsenyi J, Natanzon I, Trieschmann J, et al.** Measuring organizational attributes in primary care: a validation study in Germany. J Eval Clin Pract. 2010;16:1289-94. [PMID: 20727060] doi:10.1111/j.1365-2753.2009.01330.x

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Appendix: Calculation of Intervention Costs

Intervention costs were calculated using staff salary and fringe benefit rates for medical assistants and wages of management for supervising primary care physicians plus an overhead of 20% (for such items as office space, administration, and materials) (Appendix Table 2). Resulting unit costs for medical assistants were $14 for assessments (typically 35 minutes) and $7 for monitoring sessions, including preparation and documentation (typically 17 minutes). Unit costs for supervising primary care physicians were $18 for assessments (typically 14 minutes for supervision) and $6 for monitoring sessions (typically 5 minutes for supervision).

Training costs for medical assistants were calculated as working time spent for training of 1 medical assistant (16 hours) divided by the average caseload of 18 patients and totaled $21 per patient.

Web-Only Reference

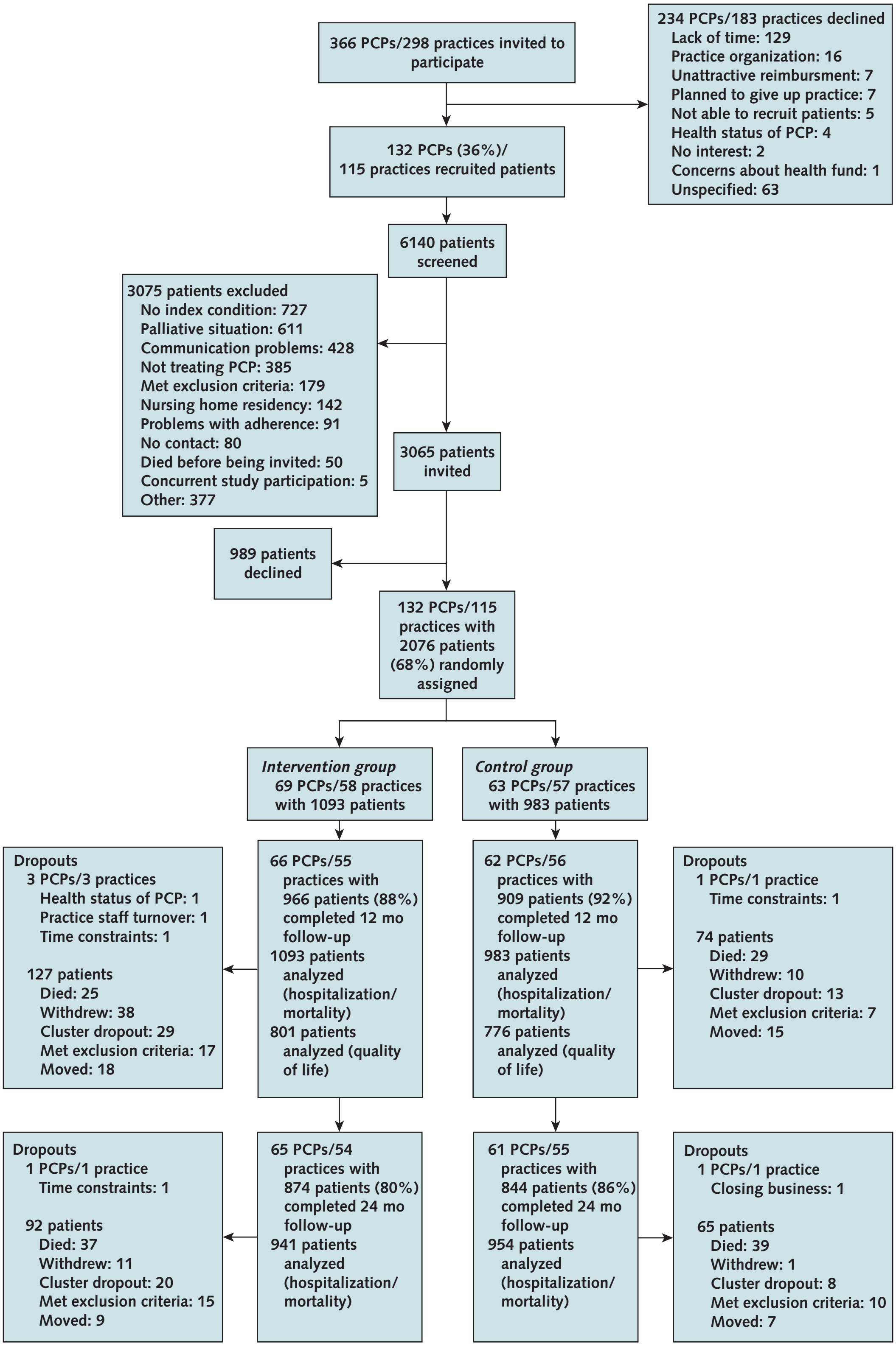
42. Holt S, Schmiedl S, Thürmann PA. Potentially inappropriate medications in the elderly: the PRISCUS list. Dtsch Arztebl Int. 2010;107: 543-51. [PMID: 20827352] doi:10.3238/arztebl.2010.0543

Appendix Table 1. Training Manual

Domain	HCA Competencies	Shared Competencies	PCP Competencies
X: General conditions for primary care practice-based care management	–	X1: Basic theoretical understanding of CM concept and its historical background [knowledge] X2: Overview of legal conditions of CM [knowledge] X3:Identification of internal and external interfaces within primary care practice-based CM [ability] X4: Knowledge of basic theories of communication [knowledge] X5: Ability to set up structures to transfer information between CM team members [ability]	–
A: Case finding	HCA_A1: Basic understanding of case-finding strategies in CM [knowledge] HCA_A2: Basic knowledge of pathomechanisms underlying frequent chronic conditions* [knowledge] HCA_A3: Rating symptoms of frequent chronic conditions* regarding urgency of medical services needed [ability] HCA_A4: Knowledge about basic therapeutic strategies in frequent chronic conditions* [knowledge]	–	PCP_A1: Basic understanding of case finding via predictive modelling [knowledge] PCP_A2: Knowledge of multimorbidity patterns frequently occurring in patients at high risk for hospitalization [knowledge]
Assessment	HCA_B1: Basic understanding of background of questions asked in assessment form [knowledge] HCA_B2: Performing comprehensive patient assessment independently by using an assessment form [skill] HCA_B3: Documenting results of assessment in a structured way to present them to PCP [skill]	B1: Structured and timely information transfer between HCA and PCP (skill)	PCP_A1: Specific knowledge about frequent health problems in multimorbid geriatric patients [knowledge] PCP_A2: Knowledge about predictors of avoidable hospitalizations in multimorbid patients [knowledge]
Planning	HCA_C3: Ability to inform patients and caregivers about community resources [ability] HCA_C4: Documentation of goals and action plans in patient diary and CM documents [skill]	C1: Understanding of "goal-setting" concept and self-efficacy theory [knowledge] C2: Confident use of communication techniques in encounters with multimorbid patients [skill] C3: Ability to define long-term goals and negotiate short-term action plans with patients and caregivers [skill]	–
Action	HCA_D1: Assisting patients and caregivers in organizing external support [skill] HCA_D2: Ability to train patients and caregivers in self-management of chronic conditions by using the patient diary [skill]	–	PCP_D1: Reflecting treatment guidelines for frequent chronic conditions* in presence of multimorbidity [ability] PCP_D2: Knowledge about inappropriate medication in multimorbid geriatric patients according to the PRISCUS list (42) [knowledge] PCP_D3: Information about community resources for patients with multimorbidity [knowledge]
Monitoring	HCA_E1: Firm understanding of background of monitoring items in scripted telephone monitoring lists [knowledge] HCA_E2: Planning, performing, and documenting telephone monitoring independently [skill] HCA_E4: Applying strategies to handle difficult situation in telephone monitoring [skill]	E1: Structured and timely information transfer between HCA and PCP (skill)	–
Evaluation	HCA_F1: Ability to support PCP actively in study documentation [ability] HCA_F2: Applying strategies to reflect opportunities and threads of new role in patient management [ability]	F1: Confident use of study documents [skill]	–

CM = care management; HCA = health care assistant; PCP = primary care physician.
* Chronic conditions specifically addressed: type 2 diabetes, chronic obstructive pulmonary disease, chronic heart failure, coronary heart disease, stroke, hypertension, osteoporosis, depression, constipation, and chronic pain.

Appendix Figure. Study flow diagram.



PCP = primary care physician.

Appendix Table 2. Cost of the Intervention per Patient, in U.S. Dollars

Variable	Cost	Cost During First Year	Cost During Second Year
Item 1. Patient assessment			
35 min of medical assistant time	14	–	–
14 min of physician time	18	–	–
Patient assessment subtotal	32	32	0
Item 2. Patient monitoring			
17 min of medical assistant time	7	–	–
5 min of physician time	6	–	–
Patient monitoring subtotal	13	78*	78*
Subtotal for items 1 and 2	–	110	78
Item 3. Overhead			
20% of items 1 and 2	–	22	16
Subtotal for items 1 to 3	–	132	94
Item 4. Medical assistant training			
16 h of medical assistant time/18 patients	21	21	0
Grand total	–	153	94

* Each patient is monitored ≥6 times per year.