Annals of Internal Medicine | ARTICLE

Medical Clinics Versus Usual Care for Patients With Both Diabetes and Hypertension

A Randomized Trial

David Edelman, MD; Sonja K. Fredrickson, MD; Stephanie D. Melnyk, PharmD; Cynthia J. Coffman, PhD; Amy S. Jeffreys, MStat; Santanu Datta, PhD; George L. Jackson, PhD; Amy C. Harris, BA; Natia S. Hamilton, BS; Helen Stewart, RN; Jeannette Stein, MD; and Morris Weinberger, PhD

Background: Group medical clinics (GMCs) are widely used in the management of diabetes and hypertension, but data on their effectiveness are limited.

Objective: To test the effectiveness of GMCs in the management of comorbid diabetes and hypertension.

Design: Randomized, controlled trial. (ClinicalTrials.gov registration number: NCT00286741)

Setting: 2 Veterans Affairs Medical Centers in North Carolina and Virginia.

Patients: 239 patients with poorly controlled diabetes (hemoglobin A_{1c} [HbA_{1c}] level ≥7.5%) and hypertension (systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mm Hg).

Intervention: Patients were randomly assigned within each center to either attend a GMC or receive usual care. Clinics comprised 7 to 8 patients and a care team that consisted of a primary care general internist, a pharmacist, and a nurse or other certified diabetes educator. Each session included structured group interactions moderated by the educator. The pharmacist and physician adjusted medication to manage each patient's HbA_{1c} level and blood pressure.

Measurements: Hemoglobin A_{1c} level and systolic blood pressure, measured by blinded research personnel at baseline, study midpoint (median, 6.8 months), and study completion (median follow-up, 12.8 months). Linear mixed models, adjusted for clustering within GMCs, were used to compare HbA_{1c} levels and systolic blood pressure between the intervention and control groups.

Results: Mean baseline systolic blood pressure and HbA_{1c} level were 152.9 mm Hg (SD, 14.2) and 9.2% (SD, 1.4), respectively. At the end of the study, mean systolic blood pressure improved by 13.7 mm Hg in the GMC group and 6.4 mm Hg in the usual care group ($P = 0.011$ by linear mixed model), whereas mean HbA_{1c} level improved by 0.8% in the GMC group and 0.5% in the usual care group ($P = 0.159$).

Limitation: Measurements of effectiveness may have been limited by concomitant improvements in the usual care group that were due to co-intervention.

Conclusion: Group medical clinics are a potent strategy for improving blood pressure but not HbA_{1c} level in diabetic patients.

Primary Funding Source: U.S. Department of Veterans Affairs Health Services Research and Development Service.

Ann Intern Med. 2010;152:689-696. www.annals.org

For author affiliations, see end of text.

Diabetes mellitus is a prevalent chronic condition that is associated with substantial morbidity, mortality, use of health services, and costs (1–3). Although self-management skills may improve glycemic control (4), self-management training is often time- and resource-intensive. Group visits have the potential not only to enhance self-management but also to improve access, decrease costs, and increase efficiency of care for patients with chronic diseases (5).

Models for group visits include self-management groups and group medical clinics (GMCs). The former emphasizes empowering patients to change their behavior to achieve better chronic illness control. However, although self-management groups improve empowerment, knowledge, pain, and anxiety, their effect on biological outcomes in chronic illnesses has been modest (6–8). Group medical clinics represent a more intensive model in which individualized medical management of chronic illness is added to self-management education (9). The GMC model has been shown to reduce urgent use in several settings (10–12). However, the few randomized, controlled trials of GMCs in diabetes have reported conflicting results (13–16). Despite the prevalence of hypertension (17) and the importance of blood pressure control among diabetic patients (18–20), previous trials have not reported the effect of GMCs on blood pressure.

We conducted a randomized trial to evaluate the effectiveness of GMCs on blood glucose and blood pressure in patients with comorbid diabetes and hypertension.

See also:

Print
Editors' Notes 690
Editorial comment. 745

Web-Only
Appendix
Appendix Figure
Conversion of graphics into slides

Context

Many practices lack the resources to train patients with chronic diseases to be active participants in their own care. Group visits during which multiple patients with the same disease receive training could be an efficient way to provide such training.

Contribution

Among 239 patients with poorly controlled hypertension and diabetes who received either usual care or care that involved group visits, patients who participated in group visits had better blood pressure control than, but similar diabetes control to, patients who received usual care.

Implication

Group visits are feasible and can improve outcomes for some, but not all, chronic diseases.

—The Editors

METHODS

We conducted a randomized, controlled trial that compared a GMC intervention with usual care among primary care patients at the Veterans Affairs Medical Centers (VAMCs) in Durham, North Carolina, and Richmond, Virginia. Both facilities' institutional review boards approved the protocol. A data safety and monitoring board evaluated enrollment, outcomes, and adverse events every 6 months.

Patients

Patients were eligible if they were enrolled in primary care at either center, had both diabetes and hypertension (outpatient or inpatient diagnostic codes), were receiving medication for diabetes, and had poorly controlled diabetes (most recent hemoglobin A_{1c} [HbA_{1c}] level >7.5%) and hypertension (most recent systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mm Hg). We excluded patients if they reported dual primary care outside the U.S. Department of Veterans Affairs; were enrolled in an endocrine clinic in the past 6 months; were hospitalized for a psychotic illness in the past 3 years or were cognitively impaired; or had a reduced life expectancy from severe chronic illness. We contacted eligible patients if their primary care provider gave permission.

Randomization and Interventions

Patients gave informed consent at the initial study visit. We excluded patients who were cognitively impaired (>5 errors on the Short Portable Mental Status Questionnaire) (21, 22). We then measured baseline HbA_{1c} and blood pressure to determine final eligibility (HbA_{1c} level >7.5% and either systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mm Hg). After we obtained baseline data, we randomly assigned eligible patients, usually by telephone 24 hours after consent. We stratified randomization by VAMC, baseline HbA_{1c} level (≥9.0% vs. <9.0%), and baseline systolic blood pressure (≥150 mm Hg vs. <150 mm Hg). We randomly assigned patients to the GMC and usual care groups in a 5:4 ratio to account for clustering of patients in the group medical visits group; patients in the usual care group received their usual VAMC primary care. An unblinded person with no responsibility for outcome ascertainment revealed study group allocation to patients. We used stratified, blocked randomization with block sizes of 11.

We allowed patients who were randomly assigned to the GMC group to choose a group that met on their preferred half-day. Each group comprised 7 to 8 patients and a care team (a primary care general internist, a pharmacist, and a nurse or certified diabetes educator). The groups met every 2 months (7 visits over 12 months). Each group met with the same care team at each visit; however, different groups had different care teams, and each provider could be a member of more than 1 care team. Patients received $10 for each GMC session they attended to offset travel costs; this is similar to U.S. Department of Veterans Affairs travel reimbursement rates.

Patients had their blood pressure checked and home blood glucose values collated when they arrived at each GMC session, and then they attended an educational session delivered by the nurse or educator. The group members chose topics from a list, so each GMC could tailor the education sessions to its members' needs. Sessions were interactive, and the nurse or educator facilitated conversation among the patients.

The pharmacist and the primary care internist reviewed patient medical records, blood pressures, and home blood glucose readings during each session and developed individualized plans for medication or lifestyle management directed toward improving blood pressure and HbA_{1c} level. We informed these patients' primary care providers of medication changes solely by means of the electronic medical record. Sessions lasted 90 to 120 minutes. The **Appendix**, available at www.annals.org, describes the GMC content and protocol.

We used signed attendance contracts to increase attendance (23, 24). Telephone contact with patients between GMC sessions was usually limited to communicating the results of laboratory tests on samples obtained during the GMC and any management changes that were indicated on the basis of those results.

All patients continued to receive their usual primary care. Patients in the usual care group received no active intervention. We maintained intervention fidelity with frequent calls and consultations between the Richmond and Durham VAMCs.

Outcomes and Measurements

Our a priori primary outcome measures were HbA_{1c} level and blood pressure, measured at baseline and at the midpoint and the end of the study. We chose systolic instead of diastolic blood pressure because it is more likely to

be uncontrolled in patients with hypertension (25). The clinical laboratories in each facility measured HbA_{1c} by using standard high-pressure liquid chromatography methods. We measured blood pressure twice (with a 5-minute interval) in the right arm, with the patient in the seated position, by using an electronic cuff (26); the average of the measures was the final outcome.

At baseline, we collected demographic characteristics, duration of diabetes, and distance between home and VAMC. We also scored patients on adherence by using Morisky and colleagues' self-reported medication adherence scale (27) and on self-efficacy by using the Perceived Competence Scale (28).

We ascertained adverse events in both groups by structured self-report (29) and medical record review at 6 months and at the end of the study. For ethical reasons, we also ascertained them for patients in the GMC group at each GMC session. We defined a hypoglycemic episode as a recorded blood glucose level less than 3.33 mmol/L (<60 mg/dL) or a self-report of symptomatic hypoglycemia and defined serious hypoglycemia as any such episode that required medical assistance. We defined other specific adverse events by either patient self-report (for example, lightheadedness) or medical record review (for example, a decrease in estimated glomerular filtration rate).

Using administrative data from the U.S. Department of Veterans Affairs, we ascertained use of health care services between 1 and 13 months after enrollment. We determined primary care and emergency care visits by using Veterans Affairs–specific codes. Visit counts are exclusive of group clinic sessions.

We estimated the cost of GMCs by totaling the labor costs associated with the group sessions (salary and fringe benefits), those associated with follow-up calls to patients, and nurse training costs (total of 2 hours). All patient care–related phone calls were logged throughout the study. Because equipment and material costs were minimal, we did not include them in the intervention cost. We estimated base-case, minimum, and maximum costs by using appropriate ranges of personnel salaries and call times. Costs are reported in 2009 U.S. dollars.

Follow-up Procedures

We measured HbA_{1c} and blood pressure and distributed questionnaires at baseline and at the midpoint (median follow-up, 6.8 months) and the end (median follow-up, 12.8 months) of the study. A research assistant who was blinded to treatment group assignment made all outcome measures at appointments. These appointments were separate from the GMC sessions for patients in the GMC group.

Statistical Analysis

Our primary outcome, specified a priori, was the proportion of patients who achieved treatment targets for HbA_{1c} level (<7.0%) and blood pressure (both systolic <130 mm Hg and diastolic <80 mm Hg). On the basis of these dichotomous outcomes, we estimated that we needed 288 patients (160 in the GMC group and 128 in the usual care group) to have 80% power to detect a 20% difference in the proportion of patients who achieved control in the GMC group compared with the usual care group. We assumed a 10% dropout rate at each of the 2 follow-up points, an α value of 0.05, a correlation between time points for blood pressure or glycemic control of 0.35, and an intraclass correlation coefficient of 0.05 in the GMC group. On the basis of this sample size, we also calculated that we would have greater than 80% power to detect a 6–mm Hg difference in systolic blood pressure and a 1% difference in HbA_{1c} level between the GMC and usual care groups. However, a study published (30) before data collection was complete and before we viewed any outcome data suggested that HbA_{1c} level was best analyzed as a continuous variable. We therefore decided to analyze our primary outcomes as continuous variables. We also decided that systolic blood pressure would be our primary indicator of hypertension control, because it is more likely than diastolic blood pressure to be uncontrolled (25).

All analyses were done on an intention-to-treat basis and performed by using SAS software (SAS Institute, Cary, North Carolina). We used chi-square tests to test for between-group differences in adverse events. For the primary analyses, we fit linear mixed models (31). Our primary predictors included indicator variables for the midpoint and end of the study and interaction variables for treatment group by follow-up. This model assumes that the groups have equal baseline means, which is appropriate for a randomized, controlled trial and is equivalent in efficiency to an analysis of covariance model (32). Analyses that did not assume equal baseline levels gave similar results (data not shown). We used all available patient data; no observations were deleted because of missing follow-up data. The estimation procedure used in the mixed-model framework for longitudinal analysis yields unbiased estimates of parameters when missing outcomes are assumed to be ignorable; that is, they are related to either observed covariates or response variables but not to unobserved variables (33).

We used an unstructured covariance model for the repeated measures; we also fit a random GMC effect to account for clustering within the GMCs. The final models also included our stratification variables for site and baseline blood pressure and HbA_{1c} control. We examined residual plots from the mixed models to assess model assumptions and the effects of potential outlier observations. Our primary inference was on the treatment by follow-up interaction model parameter—specifically, the treatment by end-of-study interaction—because this was the estimated difference between the GMC and usual care groups at the end of the study. We followed a similar modeling strategy for the continuous secondary outcomes of diastolic blood pressure and perceived competence. For the dichotomous secondary outcomes of medication adherence,

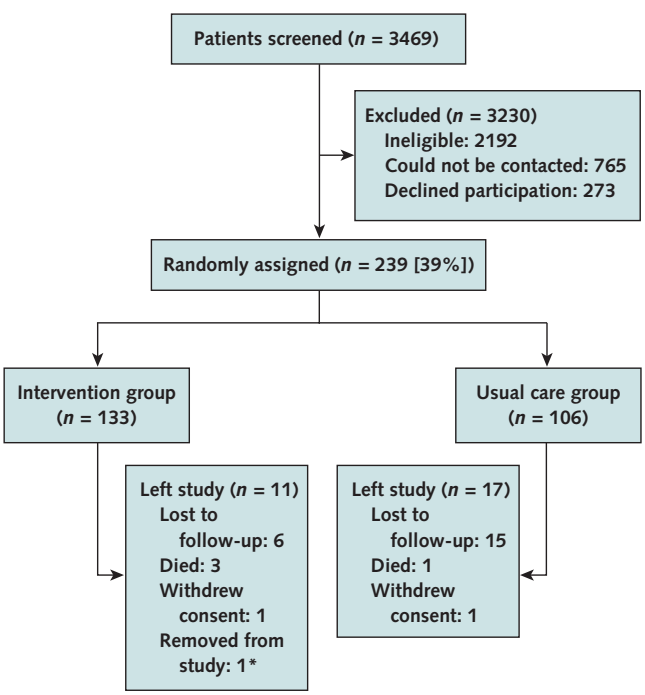
blood pressure, and HbA_{1c} control, we used generalized estimating equation (GEE) models (34), which account for clustering of both patients within intervention groups and repeated measures within patients. Because the outcomes were binary, we used a GEE with a logit link function and an unstructured correlation structure. We used empirical SEs for inference. Because all patients had uncontrolled blood pressure and blood glucose levels at baseline (inclusion criteria), outcomes for blood pressure and glycemic control were measured at the midpoint and end of the study. These models also included our stratification variables (site, baseline systolic blood pressure [≥150 mm Hg vs. <150 mm Hg] and baseline HbA_{1c} level [≥9.0% vs <9.0%]). We used the GENMOD procedure in SAS, version 9.1 (SAS Institute, Cary, North Carolina), to fit all GEE models.

For number of emergency department and primary care visits over 13 months, we fit linear mixed models that were adjusted for clustering of GMC within the intervention and for stratification variables. Because hospitalizations occurred infrequently, we dichotomized this variable (inpatient stay or no inpatient stay) and fit a GEE model.

Role of the Funding Source

Our study was funded by the U.S. Department of Veterans Affairs Health Services Research and Development Service, which had no direct role in the study's design, conduct, and reporting beyond approval of the scientific protocol in peer review for funding. The Health Services Research and Development Service assigned the independent data safety and monitoring board.

Figure 1. **Study flow diagram.**



* Developed exclusion criterion (cirrhosis).

Table 1. **Baseline Characteristics of the Study Population**

Characteristic	Usual Care Group (*n* = 106)	GMC Group (*n* = 133)
Mean age (SD), *y*	60.8 (10.0)	63.0 (9.4)
Men, %	96.2	95.5
Race, %		
White	28.3	42.9
African American	65.1	54.1
Other	6.6	3.0
Marital status, %		
Married	51.9	63.9
Divorced or separated	30.2	22.6
Widowed	11.3	6.0
Never married	6.6	7.5
Education, %		
High school or less	35.9	43.6
Some college	43.4	39.1
College graduate or more	19.8	17.6
Missing	0.9	0.0
Financial burden, %		
Can pay bills without cutting spending	65.1	65.4
Can pay bills only by cutting spending or cannot always pay bills	32.1	31.6
Don't know, declined to reply, or missing	2.8	3.0
Clinical data		
Mean hemoglobin A_{1c} level (SD), %	9.2 (1.5)	9.2 (1.3)
Mean systolic blood pressure (SD), *mm Hg*	151.9 (13.4)	153.7 (14.8)
Mean diastolic blood pressure (SD), *mm Hg*	84.2 (13.8)	84.7 (12.1)

GMC = group medical clinic.

RESULTS

Patients

We contacted 609 eligible patients out of 3469 patients screened, 239 of whom were randomly assigned (**Figure 1**). We excluded most patients because of improved blood pressure or HbA_{1c} control; serious comorbid illness also accounted for some exclusions. We enrolled patients between June 2006 and September 2007. Two hundred fifteen patients (90%) completed midpoint study follow-up, and 211 patients (88%) completed the trial; we obtained 93% of data points.

Patients in the GMC and usual care groups were similar at baseline (**Table 1**), although patients at the Durham VAMC were slightly younger and heavier and had higher HbA_{1c} levels and systolic blood pressure than those at the Richmond VAMC (data not shown). The 239 patients had 80 primary care physicians. Approximately 50% of pri-

mary care physicians had only 1 or 2 patients enrolled in the study.

GMC Structure and Attendance

We created 18 GMCs (9 in Durham and 9 in Richmond), with 6 to 8 patients per group. Overall, intervention patients attended 78.4% of the GMC sessions. Fifty-eight patients (44%) attended all sessions; another 29 (22%) missed only 1 session. Only 3 patients missed all 7 sessions. Attendance was higher at the Richmond VAMC (86% of sessions attended) than at the Durham VAMC (70% of sessions attended).

Primary Outcomes

After we adjusted for stratification variables and clustering within the GMC group, mean systolic blood pressure was 7.3 mm Hg (95% CI, 1.7 to 12.8 mm Hg) lower in the GMC group than the usual care group (**Figure 2**) at the end of the study. At the study midpoint, mean systolic blood pressure was 5.7 mm Hg (CI, 0.06 to 11.4 mm Hg) lower in the GMC group than in the usual care group. Mean HbA_{1c} levels were 0.33% (CI, −0.13% to 0.80%) lower in the GMC group than in the usual care group at the end of study (**Figure 2**); at the study midpoint, the between-group difference in HbA_{1c} level was 0.20% (CI, −0.25 to 0.66) (**Figure 2**). The intraclass correlation coefficients for systolic blood pressure and HbA_{1c} in the GMC group were 0.05 and 0.03, respectively.

Secondary Clinical Outcomes

At the end of the study, mean diastolic blood pressure was 3.8 mm Hg (CI, 0.76 to 6.9 mm Hg) lower in the GMC group than in the usual care group. At the study midpoint, 24% of patients and 21% in the usual care group had adequate blood pressure control in the GMC group (**Table 2**). At the end of the study, 22% of patients in the GMC group and 12% in the usual care group had achieved blood pressure control (odds ratio [OR], 2.0 [CI, 1.0 to 4.2]) (**Table 2**). Glycemic control (HbA_{1c} level ≤7.0%) did not differ between the groups (OR, 1.5 [CI, 0.7 to 3.3]) (**Table 2**).

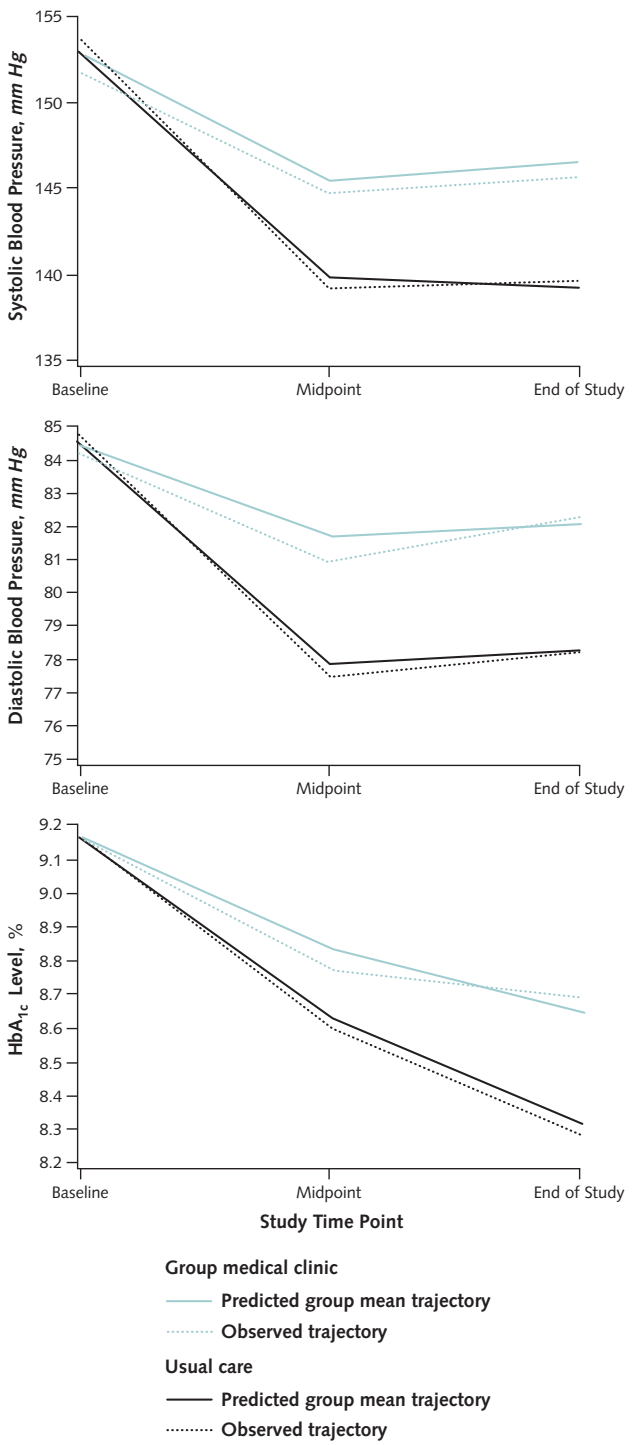
Potential Mechanisms of GMC Action

At the end of the study, self-reported perfect medication adherence did not differ between the GMC and usual care groups (OR, 0.8 [CI, 0.5 to 1.4]) (**Table 2**); however, we found a 1.6-point (CI, 0.9 to 2.4 points) improvement in perceived competence scores in the GMC group compared with the usual care group (**Table 2**).

Adverse Events

Most adverse events were similar between the groups (**Table 3**); however, fewer patients in the GMC group reported falls or lightheadedness ($P = 0.006$) (**Table 3**). More than 50% of patients in the GMC group reported no falls or lightheadedness, compared with 37% in the usual care group. Few serious study-related adverse events occurred in either group.

Figure 2. **Observed and predicted group mean trajectories from linear mixed models for blood pressure and HbA_{1c}.**



The corresponding estimates and 95% CIs from the midpoint of the study were systolic blood pressure, −5.7 mm Hg (CI, −11.4 to 0.1 mm Hg); diastolic blood pressure, −3.8 mm Hg (CI, −6.9 to −0.8 mm Hg); and HbA_{1c}, −0.20% (CI, −0.66% to 0.25%). The corresponding estimates and CIs from the end of the study were systolic blood pressure, −7.3 mm Hg (CI, −12.8 to −1.7 mm Hg); diastolic blood pressure, −3.8 mm Hg (CI, −6.9 to −0.8 mm Hg); and HbA_{1c}, −0.33% (CI, −0.80% to 0.13%). HbA_{1c} = hemoglobin A_{1c}.

Table 2. **Results of Linear Mixed and Generalized Estimating Equation Models**

Measurement and Study Time Point	GMC Group (n = 133)	Usual Care Group (n = 106)	Mean Difference Between Groups (95% CI)	*P* Value
Primary outcomes				
Mean systolic blood pressure, *mm Hg*				
Baseline*	152.9	152.9		
Midpoint	139.7	145.4		
Final	139.2	146.5	−7.3 (−12.8 to −1.7)	0.011
Mean HbA_{1c} level, %				
Baseline*	9.2	9.2		
Midpoint	8.6	8.8		
Final	8.3	8.6	−0.33 (−0.80 to 0.13)	0.159
Secondary outcomes				
Mean diastolic blood pressure, *mm Hg*				
Baseline*	84.5	84.5		
Midpoint	77.8	81.7		
Final	78.3	82.1	−3.8 (−6.9 to −0.8)	0.015
Mean perceived competence score				
Baseline*	14.1	14.1		
Midpoint	15.7	14.9		
Final	16.1	14.5	1.6 (0.9 to 2.4)	<0.001
			Odds Ratio (95% CI)	
Adherence, %†				
Baseline*	34	34		
Midpoint	35	37		
Final	38	42	0.8 (0.5 to 1.4)	0.53
Blood pressure control, %‡				
Midpoint	24	21		
Final	22	12	2.0 (1.0 to 4.2)	0.064
HbA_{1c} control, %‡				
Midpoint	12	14		
Final	17	12	1.5 (0.7 to 3.3)	0.33

GMC = group medical clinic; HbA_{1c} = hemoglobin A_{1c}.
* We assumed a common baseline value between treatment groups.
† Using the scale of Morisky and colleagues (27).
‡ Uncontrolled in all patients at baseline (inclusion criterion).

Use and Costs

Patients in the GMC group had 0.4 (CI, 0.20 to 0.70) fewer emergency care visits than the usual care group (0.9 vs. 1.3 visits per patient-year; $P < 0.001$). Patients in the GMC group also had 0.9 (CI, 0.2 to 1.5) fewer primary care visits (5.3 vs. 6.2 per patient-year; $P = 0.010$); this difference did not offset the number of GMC visits. For inpatient stays, 23 patients (17%) in the GMC group were hospitalized a total of 32 times and 23 patients (22%) in the usual care group were hospitalized a total of 39 times (OR, 0.8 [CI, 0.4 to 1.4]).

We estimated that an average GMC visit required 1.5 hours of physician time and 2 hours each of pharmacist and nurse time. In addition, physicians and pharmacists placed 104 brief (<5-minute) calls and 71 longer (5- to 30-minute) follow-up calls to the 133 patients in the GMC group. In 2009 dollars, we estimated a cost of $504 (range, $445 to $578) to conduct each group visit. Because each group visit can accommodate 8 patients, the per-patient cost is $63 (range, $56 to $72). If patients attended all 7 GMC sessions, the annual per-patient cost would be $441 (range, $389 to $506). Follow-up calls cost an additional $19 (range, $4 to 48), which brings the annual per-patient cost to $460 (range, $393 to $554).

Discussion

Group medical clinics can improve the quality, outcomes, and efficiency of care for patients with chronic diseases. Our results show that veterans with uncontrolled diabetes and hypertension who attended GMCs had better blood pressure control than those who received usual care at 6 months; this difference was sustained at 1 year. The 7–mm Hg difference between our intervention and control groups is similar to that seen in the intervention groups of ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) (35) in the year after patients began receiving drug therapy. Group medical clinics did not improve HbA_{1c} level. Patients in the GMC group had significantly fewer emergency department visits (0.4 per patient-year), and we observed no increase in adverse events from intensification of therapy. The annual cost of GMCs was $460 per patient.

Table 3. **Frequency of Adverse Events per Person-Year**

Adverse Event*	Usual Care Group, %	GMC Group, %	*P* Value
Hypoglycemia (*n* = 217)			0.70
0 events	21.5	24.2	
1 event	37.6	42.7	
2 events	33.3	26.6	
3 events	7.5	6.5	
Systolic blood pressure <100 mm Hg (*n* = 197)			0.97
0 events	85.5	86.0	
1 event	13.3	13.2	
2 events	1.2	0.9	
Lightheadedness or fall (*n* = 211)			0.006
0 events	37.4	53.3	
1 event	37.4	36.7	
2 events	25.3	10.0	
Decrease in eGFR >10 mL/min per 1.73 m^2 (*n* = 212)			0.49
0 events	52.3	46.8	
1 event	36.4	36.3	
2 events	11.4	16.9	
AST or ALT level >50 U/L (*n* = 203)			0.72
0 events	97.6	98.3	
1 event	2.4	1.7	

ALT = alanine aminotransferase; AST = aspartate aminotransferase; eGFR= estimated glomerular filtration rate (by the Modification of Diet in Renal Disease Study equation); GMC = group medical clinic.
* Numbers in parentheses are the number of patients who reported that adverse event on their form at either the midpoint or the end of the study.

Two factors probably led to the relative success of our intervention compared with previous evaluations of GMCs. First, attendance was higher than in other studies (14). Using attendance contracts (23, 24), having a consistent care team, and providing small incentives to pay for transportation costs may have accounted for this finding. Second, we enrolled patients with both blood pressure and HbA_{1c} level greater than the target values, so all patients had room for improvement. This target population also derives the greatest clinical benefit from improvement (36, 37).

The major effect that we observed was on blood pressure control. We considered several possible mechanisms of action that might lead to this improvement. First, the lack of between-group differences in medication adherence in our study suggests that improved adherence to blood pressure medications does not account for our finding. Second, we observed less improvement in self-efficacy in the GMC group than in the usual care group, which may have resulted from bringing patients together to teach each other how to manage their blood pressure with support from a consistent care team. These improvements may have led to improvements in blood pressure. Finally, blood pressure may have improved in patients because of medication intensification and increased time with a pharmacist and physician.

We are uncertain why the benefit seen for the GMC intervention for blood pressure did not extend to glycemic control. More clinical support may have been available for glycemic management than for blood pressure management at our facilities. This support would serve as a cointervention, making it less likely that we would observe improvement in HbA_{1c} than in blood pressure. Better support for HbA_{1c} management may also mean that these patients were more "recalcitrant" to improving HbA_{1c} than blood pressure, because they would have been more likely to experience failed attempts at more intensive management of HbA_{1c} than of blood pressure before study enrollment.

Our study has limitations. First, we conducted it among veterans who received primary care at VAMCs, which may limit generalizability. We mitigated this somewhat by using 2 sites and including diverse personnel in the care teams at each site. Of note, the magnitude and pattern of the effect was similar across sites despite observed baseline differences among patients at each site. Second, we cannot determine which, if any, single component of the intervention was most effective. Finally, we designed our study to address the effectiveness of the intervention if implemented in a system that did not use other enhanced primary care options; we therefore used a usual care control group. The observed differences may have resulted from the extra attention provided to the GMC group rather than its content.

We found that GMC visits for veterans with poorly controlled hypertension and diabetes resulted in a clinically and statistically meaningful improvement in blood pressure but not glycemic control. Given the high attendance at group visits, the intervention seemed to be well received by patients. This strategy is also consistent with improved processes and outcomes of care for patients with other chronic diseases. Group medical clinics also hold great promise because blood pressure control is more important than glycemic control for reducing cardiovascular morbidity and mortality among patients with diabetes. Finally, the reductions in emergency and primary care visits may offset the costs of the intervention. If found to be cost-effective and efficient, GMCs could be implemented in a wide range of settings and become important in the remodeling of long-term care in the United States.

From Durham Veterans Affairs Medical Center, Durham, North Carolina, and Hunter Holmes McGuire Veterans Affairs Medical Center, Richmond, Virginia.

Acknowledgment: The authors thank Mike Newell, BS, Durham Veterans Affairs Medical Center, for technical support and Drs. Susan Kirsh, MD, and David C. Aron, MD, Cleveland Veterans Affairs Medical Center, for assistance in refining the intervention.

Grant Support: By the Department of Veterans Affairs Health Services Research and Development Service (grant IIR 03-084).

Potential Conflicts of Interest: Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M09-0952.

Reproducible Research Statement: *Study protocol:* Available from Dr. Edelman (e-mail, dedelman@duke.edu). *Statistical code and data set:* Potentially available from Dr. Edelman (e-mail, dedelman@duke.edu), on the basis of request and written agreements regarding data use.

Requests for Single Reprints: David Edelman, MD, Durham Veterans Affairs Medical Center, 508 Fulton Street, Durham, NC 27705; e-mail, dedelman@duke.edu.

Current author addresses and author contributions are available at www.annals.org.

References

1. **American Diabetes Association.** Economic costs of diabetes in the U.S. in 2007. Diabetes Care. 2008;31:596-615. [PMID: 18308683]
2. **Centers for Disease Control and Prevention.** National Diabetes Fact Sheet, United States, 2005. Atlanta; Centers for Disease Control and Prevention: 2005. Accessed at www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf on 5 April 2010.
3. **American Diabetes Association.** Third-party reimbursement for diabetes care, self-management education, and supplies. Diabetes Care. 2009;32 Suppl 1:S85-6. [PMID: 19118293]
4. **Norris SL, Engelgau MM, Narayan KM.** Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. Diabetes Care. 2001;24:561-87. [PMID: 11289485]
5. **Schmucker D.** Group Medical Appointments: An Introduction for Health Professionals. Sudbury, MA; Jones & Bartlett: 2006.
6. **Lorig KR, Ritter PL, Laurent DD, Fries JF.** Long-term randomized controlled trials of tailored-print and small-group arthritis self-management interventions. Med Care. 2004;42:346-54. [PMID: 15076811]
7. **Lorig KR, Ritter P, Stewart AL, Sobel DS, Brown BW Jr, Bandura A, et al.** Chronic disease self-management program: 2-year health status and health care utilization outcomes. Med Care. 2001;39:1217-23. [PMID: 11606875]
8. **Lorig KR, Sobel DS, Stewart AL, Brown BW Jr, Bandura A, Ritter P, et al.** Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care. 1999;37:5-14. [PMID: 10413387]
9. **Jaber R, Braksmajer A, Trilling JS.** Group visits: a qualitative review of current research. J Am Board Fam Med. 2006;19:276-90. [PMID: 16672681]
10. **Beck A, Scott J, Williams P, Robertson B, Jackson D, Gade G, et al.** A randomized trial of group outpatient visits for chronically ill older HMO members: the Cooperative Health Care Clinic. J Am Geriatr Soc. 1997;45:543-9. [PMID: 9158573]
11. **Coleman EA, Eilertsen TB, Kramer AM, Magid DJ, Beck A, Conner D.** Reducing emergency visits in older adults with chronic illness. A randomized, controlled trial of group visits. Eff Clin Pract. 2001;4:49-57. [PMID: 11329985]
12. **Coleman EA, Grothaus LC, Sandhu N, Wagner EH.** Chronic care clinics: a randomized controlled trial of a new model of primary care for frail older adults. J Am Geriatr Soc. 1999;47:775-83. [PMID: 10404919]
13. **Sadur CN, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S, et al.** Diabetes management in a health maintenance organization. Efficacy of care management using cluster visits. Diabetes Care. 1999;22:2011-7. [PMID: 10587835]
14. **Wagner EH, Grothaus LC, Sandhu N, Galvin MS, McGregor M, Artz K, et al.** Chronic care clinics for diabetes in primary care: a system-wide randomized trial. Diabetes Care. 2001;24:695-700. [PMID: 11315833]
15. **Trento M, Passera P, Tomalino M, Bajardi M, Pomero F, Allione A, et al.** Group visits improve metabolic control in type 2 diabetes: a 2-year follow-up. Diabetes Care. 2001;24:995-1000. [PMID: 11375359]
16. **Clancy DE, Huang P, Okonofua E, Yeager D, Magruder KM.** Group visits: promoting adherence to diabetes guidelines. J Gen Intern Med. 2007;22:620-4. [PMID: 17443369]
17. **Mancia G.** The association of hypertension and diabetes: prevalence, cardiovascular risk and protection by blood pressure reduction. Acta Diabetol. 2005;42 Suppl 1:S17-25. [PMID: 15868115]
18. **Patel A, MacMahon S, Chalmers J, Neal B, Woodward M, Billot L, et al; ADVANCE Collaborative Group.** Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial): a randomised controlled trial. Lancet. 2007;370:829-40. [PMID: 17765963]
19. **Heart Outcomes Prevention Evaluation (HOPE) Study Investigators.** Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: results of the HOPE study and MICRO-HOPE substudy. Lancet. 2000;355:253-9. [PMID: 10675071]
20. **CDC Diabetes Cost-effectiveness Group.** Cost-effectiveness of intensive glycemic control, intensified hypertension control, and serum cholesterol level reduction for type 2 diabetes. JAMA. 2002;287:2542-51. [PMID: 12020335]
21. **Pfeiffer E.** A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. J Am Geriatr Soc. 1975;23:433-41. [PMID: 1159263]
22. **Callahan CM, Hendrie HC, Tierney WM.** Documentation and evaluation of cognitive impairment in elderly primary care patients. Ann Intern Med. 1995;122:422-9. [PMID: 7856990]
23. **Villano CL, Rosenblum A, Magura S, Fong C.** Improving treatment engagement and outcomes for cocaine-using methadone patients. Am J Drug Alcohol Abuse. 2002;28:213-30. [PMID: 12014813]
24. **Ossip-Klein DJ, Vanlandingham W, Prue DM, Rychtarik RG.** Increasing attendance at alcohol aftercare using calendar prompts and home based contracting. Addict Behav. 1984;9:85-9. [PMID: 6331100]
25. **Lloyd-Jones DM, Evans JC, Larson MG, O'Donnell CJ, Roccella EJ, Levy D.** Differential control of systolic and diastolic blood pressure: factors associated with lack of blood pressure control in the community. Hypertension. 2000;36:594-9. [PMID: 11040241]
26. **Kim JW, Bosworth HB, Voils CI, Olsen M, Dudley T, Gribbin M, et al.** How well do clinic-based blood pressure measurements agree with the mercury standard? J Gen Intern Med. 2005;20:647-9. [PMID: 16050862]
27. **Morisky DE, Green LW, Levine DM.** Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24:67-74. [PMID: 3945130]
28. **Heisler M, Vijan S, Anderson RM, Ubel PA, Bernstein SJ, Hofer TP.** When do patients and their physicians agree on diabetes treatment goals and strategies, and what difference does it make? J Gen Intern Med. 2003;18:893-902. [PMID: 14687274]
29. **Bent S, Padula A, Avins AL.** Brief communication: Better ways to question patients about adverse medical events: a randomized, controlled trial. Ann Intern Med. 2006;144:257-61. [PMID: 16490911]
30. **Pogach LM, Rajan M, Aron DC.** Comparison of weighted performance measurement and dichotomous thresholds for glycemic control in the Veterans Health Administration. Diabetes Care. 2006;29:241-6. [PMID: 16443867]
31. **Verbeke G, Molenberghs G.** Linear Mixed Models for Longitudinal Data. New York; Springer-Verlag: 2000.
32. **Fitzmaurice G, Laird N, Ware J.** Applied Longitudinal Analysis. Hoboken, NJ; J Wiley: 2004.
33. **Little RJ, Rubin DB.** Statistical Analysis With Missing Data. Hoboken, NJ; J Wiley: 2002:112–144.
34. **Diggle PJ, Heagerty P, Liang KY, Zeger SL.** Analysis of Longitudinal Data. Oxford; Oxford Univ Pr: 2002.
35. **ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group; The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial.** Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). JAMA. 2002;288:2981-97. [PMID: 12479763]
36. **Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, et al.** Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ. 2000;321:405-12. [PMID: 10938048]
37. **Sega R, Facchetti R, Bombelli M, Cesana G, Corrao G, Grassi G, et al.** Prognostic value of ambulatory and home blood pressures compared with office blood pressure in the general population: follow-up results from the Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study. Circulation. 2005;111:1777-83. [PMID: 15809377]

Current Author Addresses: Drs. Edelman, Melnyk, Coffman, Datta, Jackson, Stein, and Weinberger; Ms. Jeffreys; Ms. Harris; and Ms. Hamilton: Durham Veterans Affairs Medical Center, 508 Fulton Street, Durham, NC 27705.
Dr. Fredrickson and Ms. Stewart: Hunter Holmes McGuire Veterans Affairs Medical Center, 1201 Broad Rock Boulevard, Richmond, VA 23249.

Author Contributions: Conception and design: D. Edelman, S.K. Fredrickson, C.J. Coffman, S. Datta, G.L. Jackson, M. Weinberger.
Analysis and interpretation of the data: D. Edelman, S.K. Fredrickson, S.D. Melnyk, C.J. Coffman, A.S. Jeffreys, S. Datta, G.L. Jackson, M. Weinberger.
Drafting of the article: D. Edelman, C.J. Coffman, A.S. Jeffreys, S. Datta, N.S. Hamilton, M. Weinberger.
Critical revision of the article for important intellectual content: D. Edelman, S.K. Fredrickson, S.D. Melnyk, C.J. Coffman, A.S. Jeffreys, S. Datta, G.L. Jackson, A.C. Harris, N.S. Hamilton, M. Weinberger.
Final approval of the article: D. Edelman, S.K. Fredrickson, S.D. Melnyk, C.J. Coffman, A.S. Jeffreys, S. Datta, G.L. Jackson, M. Weinberger.
Provision of study materials or patients: D. Edelman, S.D. Melnyk, S. Datta.
Statistical expertise: C.J. Coffman, A.S. Jeffreys.
Obtaining of funding: D. Edelman.
Administrative, technical, or logistic support: D. Edelman, S.K. Fredrickson, S.D. Melnyk, G.L. Jackson, A.C. Harris, N.S. Hamilton, J. Stein, M. Weinberger.
Collection and assembly of data: S.K. Fredrickson, S.D. Melnyk, S. Datta, A.C. Harris, N.S. Hamilton, H. Stewart.

Appendix: Intervention Description

After random assignment, we contacted patients by phone to arrange the first GMC session. We offered sessions on particular half-days of the week; patients selected which GMC to attend on the basis of available half-days. Usually, the next GMC's half-day had already been set, and patients were offered assignment into this group. However, if the date and time for this meeting would not work with their schedule, they could defer starting until the following GMC. During this initial phone conversation, patients received an explanation of the sequence of events for each session, instructions to bring all their medications and their glucometer to each appointment, and the room location of the first GMC session. The initial phone call was followed by a letter that confirmed the date and time of the group medical visit. We mailed reminder letters to all patients at least 1 week before each subsequent GMC Session.

Each group comprised 7 to 9 patients. The care team for each group was composed of a primary care general internist, a clinical pharmacist, and a nurse or other certified diabetes educator. Groups met every 2 months for 7 visits, and the same patients met with the same care team each visit. However, different groups may have had different care teams, and each participating provider could be a member of more than 1 care team. All members of the care team were employed at least part-time in primary care at that Veterans Affairs Medical Center.

Each GMC session was scheduled for 2 hours; however, visits after the first typically lasted approximately 90 minutes. Each session was divided into 3 phases (**Appendix Figure**). We called the first phase of each session the "intake and data collection phase." On presentation to each GMC, the patient completed a brief medical questionnaire to exclude any acute medical issues that required emergent medical attention. During intake, patients also had their blood pressure checked in the group room by either the pharmacist or the nurse assigned to the care team. We expected patients to bring either their glucometer or a log of their self-monitored blood glucose levels to each appointment. A member of the care team collated the self-monitored blood glucose levels at the beginning of each visit. These data were collected to be used by the internist and clinical pharmacist as they collaborated on each treatment plan. Intake also allowed time for informal conversations among the group members and between the members and the care team, to promote cohesiveness and bonding.

Phase 2 began approximately 30 minutes into the session. Two overlapping activities occurred during this approximately 30-minute time frame. In the main room, patients engaged in an interactive educational session provided by the assigned educator (usually the team nurse). Group members selected the schedule of educational topics for subsequent visits at the initial group visit. We offered the following sessions: Foot Care, Medications and How They Work, Signs and Symptoms of Hyper- and Hypoglycemia, Diet, Managing Illness Days, Blood Glucose Monitoring, and Exercise. Patients selected both the topics and the sequence of presentation; our intent was to empower groups to identify their own educational needs. Each educational session was interactive, and each educator had received previous instruction on facilitating group interactions. Some of the nutrition discussions also included a dietitian, who was also trained in facilitating group interactions.

Meanwhile, the pharmacist and primary care internist developed a treatment plan for each patient. The day before the GMC session, the clinical pharmacist reviewed each patient's chart to determine whether his or her health care status had changed, evaluate any pertinent laboratory findings, and assess adherence to and changes in diabetes or hypertension medications since the last GMC session. While the patients were attending the interactive education session, the internist and clinical pharmacist reviewed the information gathered by the pharmacist and the patient blood pressures and self-monitored blood glucose levels that were collected during intake. They then developed a plan for medication and lifestyle management directed toward improving hemoglobin A_{1c} level and blood pressure. Apart from lipid management (a secondary aim), we did not perform any other primary care functions during GMC visits because of requests from primary care physicians during the pilot study that these not be addressed in GMC sessions.

After the education session, each patient participated in a one-on-one breakout session with either the pharmacist or the internist. During this time, the health care provider could gather any additional patient-specific information not found in the medical record about medication-taking behavior, possible adverse drug events, or other changes in health care status that could alter the treatment plan. The patient and care team provider then negotiated a final plan for improved disease control. A record of the plan was entered into the electronic medical record

and forwarded electronically to the primary care provider. At the conclusion of the meeting, patients received an updated list of their medications, with instructions for any medication or lifestyle changes and a written reminder of the time of the next GMC visit.

Appendix Figure. **Session work flow.**