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ORIGINAL RESEARCH

A Randomized Controlled Open Trial of Population-based Disease and Case Management in a Medicare Plus Choice Health Maintenance Organization

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PEER REVIEWED

Abstract

Introduction

The object of this study was to examine the effect of population-based disease management and case management on resource use, self-reported health status, and member satisfaction with and retention in a Medicare Plus Choice health maintenance organization (HMO).

Methods

Study design consisted of a prospective, randomized controlled open trial of 18 months' duration. Participants were 8504 Medicare beneficiaries aged 65 and older who had been continuously enrolled for at least 12 months in a network model Medicare Plus Choice HMO serving a contiguous nine-county metropolitan area. Members were care managed with an expert clinical information system and frequent telephone contact. Main outcomes included self-reported health status measured by the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), resource use measured by admission rates and bed-days per thousand per year, member satisfaction, and costs measured by paid claims.

Results

More favorable outcomes occurred in the intervention group for satisfaction with the health plan ($P < .01$) and the social function domain as measured by SF-36 ($P = .04$). There was no difference in member retention or mortality between groups. Use of skilled nursing home services was significantly lower in the intervention group than in the control (616 vs 747 days per thousand members per year, $P = .02$). This reduction, however, did not lead to lower mean total expenditures in the intervention group compared with the control ($6828 per member for 18 months vs $7001, $P = .61$).

Conclusion

Population-based disease management and case management led to improved self-reported satisfaction and social function but not to a global net decrease in resource use or improved member retention.

Introduction

Although the United States is a wealthy country, our elders suffer from high rates of chronic disease, social isolation, poor diet, lack of mobility, and suboptimal function (1,2).

Indeed, chronic disease has now become the greatest challenge to the health care system, accounting for 76% of

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direct health care costs (not including nursing home care) (3). By not adequately addressing these issues, our elderly population ranks lower than many other industrialized countries on a number of public health measures (4-6).

To give Medicare recipients the option to enroll in health maintenance organizations (HMOs), Congress created the Medicare Plus Choice program with passage of the Balanced Budget Act in 1998. Many HMOs attempt to improve health outcomes and reduce medical expenditures through disease management and case management. Several case management demonstration projects have failed to affect service use, cost, or health outcomes (7). As one senior health services researcher notes, "The case for case management still remains to be established definitively" (8). Still, managing chronic disease through a combination of traditional institutional-based health care and community-based interventions, supported by clinical information systems, remains a compelling model (8-11). Several variations of this comprehensive approach to preventive and chronic care are being tested (12).

A newer paradigm is that of population-based disease management, wherein subgroups of patients that have modifiable risk factors for adverse medical outcomes are identified and then entered into a program designed to improve self-care (13). Because it is not known if disease management programs can improve health outcomes or produce long-term savings (14), the concept of testing population-based disease management in fee-for-service Medicare is under study at the Centers for Medicare & Medicaid Services (13).

Most reported trials have investigated the efficacy of disease management on single disease states, such as congestive heart failure or chronic obstructive lung disease. We report a randomized controlled open trial of case management and population-based disease management that addressed multiple disease states in a parallel, concurrent, and patient-centric fashion.

Methods

The Senior Life Management program

The Senior Life Management (SLM) program was designed to provide population-based disease management (helping members with certain disease states — such as congestive heart failure, identified through analysis of plan data — to improve self-care) and case management (helping individual members with complex problems to obtain needed medical and social services). The program comprised enhanced administrative services rather than new benefits. SLM was also crafted to be patient-centric (in which one manager would develop a relationship with the member), rather than disease-specific (in which a member would be directed to multiple managers for different problems and disease states). Central to the program were the following components: creation of an electronic care-management record; comprehensive, periodic member health status assessments; telephonic case management; patient education materials; community physician education; and coordination with community services.

SLM services were added to existing services of a Medicare Plus Choice HMO. The basic benefits included a deductible representing only 10% of the deductible for traditional Medicare for hospitalization, enhanced skilled nursing benefits with no three-day hospitalization prerequisite and no copayments for 100 days, and a limited pharmacy benefit.

SLM also included a drug utilization review program for thirty medications considered to be relatively contraindicated for use in the elderly based upon published guidelines (15). The filling of one of these prescriptions triggered a fax to the prescribing physician asking for reconsideration of this therapeutic maneuver and soliciting physician feedback concerning the usefulness of this alert and his or her response.

The Master Console, an electronic health care management record, was created to deliver just-in-time information to the program's administrative and case management staff. This electronic record integrated historical medical claims, daily updates of current medical claims data, monthly updates of laboratory test results and prescription information, and data from assessments of members' health through a survey and regularly scheduled phone calls. The Master Console was developed with a Visual Basic client, which allowed rapid prototyping, revision based on end-user feedback, and deployment of upgrades. No physician-based medical records were part of Master Console. Decision support algorithms built into the Master Console alerted program staff to potential changes in the clinical status of a patient, need for case management

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screening (actual assignment to case management being at the judgment of the nurse care coordinator [NCC] based at the HMO), or the potential need for a service intervention. For example, authorization of a joint replacement procedure would trigger a task/reminder for an outbound phone call by a registered nurse care coordinator the following day to determine anticipated therapy needs in addition to a prompt to perform both a home-safety assessment and a falls-risk assessment. As another example, the filling of a prescription for flurazepam would trigger a fax to the prescribing physician about the relative contraindication of long-acting benzodiazepines in the elderly and asking for reconsideration of this therapeutic maneuver.

Prior to initiating SLM, 72% of the 8504 study participants completed either 1) a mailed health assessment (the Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36]) (16) along with satisfaction questions from the Medicare Beneficiary Survey or 2) follow-up telephone surveys if they had not returned their mail-in form. Participant responses were summarized and entered into the Master Console. Subsequently, periodic 18-item short assessments of program participants were performed quarterly over the telephone by program staff, and the data were entered into the database.

Program staff were organized into four teams, each managing 800 to 1000 SLM participants. A team consisted of an NCC, who supervised two personal service representatives (PSRs). The PSR was a new level of staffing created specifically for this intervention. PSRs were not required to have clinical training but were selected based on communication skills and sensitivity to geriatric issues as ascertained by interviews with experienced nurse clinicians. PSRs were provided with eight weeks of intensive training consisting of didactic sessions covering common geriatric issues, in addition to direct critiquing and refinement of telephone communication skills by allowing trainees to handle customer service calls in tandem with supervisors. After training, PSRs handled outbound phone contacts and performed periodic health screenings with scripted questionnaires. The NCC was responsible for outbound contact to all those in complex case management (50 to 70 participants per team), communicating with treating physicians and office staff, following up on hospitalizations and ER visits, and arranging for home health care and durable equipment through the primary care physician.

A full-time medical director, administrator, and social worker also staffed the SLM program. Prior to the program's onset, the medical director conducted visits with more than 100 of the primary care doctors who cared for SLM members to brief them on the intervention and to solicit their cooperation in coordinating services. The medical director and social worker provided ad hoc consultation to care management teams for any issues related to their areas of expertise.

SLM members who scored in the lowest quintile of the General Health scale on the SF-36 were further assessed by phone for possible case management by NCCs. At least every three months, PSRs contacted all members in the intervention group not currently in case management to perform an 18-question short assessment. This questionnaire was designed to probe for significant changes in physical health, mental health, or social supports. Questions dealt with such domains as stresses and losses, falls, pain, changes in activities of daily living, incontinence, nutrition, and mood. Logic built into the short assessment triggered further evaluation by other clinicians. For example, report of a fall would trigger a home safety assessment, whereas loss of a loved one or pet would trigger a depression evaluation by the social worker. PSRs also fulfilled a customer service role, fielding inbound calls from members. This provided an opportunity to probe further for changes in health status.

Disease management modules were developed for congestive heart failure, falls (home safety), nutrition, depression, and diabetes mellitus. These conditions were chosen because they were prevalent, contributed to morbidity, and were deemed actionable. Based upon decision support algorithms, targeted educational materials (selected by program staff and purchased from Channing Bete Corporation, South Deerfield, Mass) were sent to members. PSRs made follow-up phone calls within two weeks of patient receipt of such materials. During phone contact, patients might be referred to a range of care providers, including primary care physicians or mental health providers, or connected to community services, such as Meals On Wheels, transportation services, or adult day care.

Study design

This model was tested as a randomized controlled

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prospective open trial. The study protocol was reviewed and approved by the Thomas Beam Institutional Review Board, New York, NY, and the surveys and promotional materials were reviewed and approved by the Center for Medicare and Medicaid Services. Study participants were derived from approximately 13,000 members of an Medicare Plus Choice HMO who resided in nine contiguous counties surrounding Pittsburgh, Pa. To be eligible, participants had to be aged 65 or older, have signed consent on their health plan enrollment form to participate, and have been continuously enrolled with the health plan for all of 1999. Members who declined to participate in the study or who opted out during the study continued to receive their usual benefits.

A subset of members receiving medical care under a special financial risk arrangement with certain providers was excluded from the study. This was done because of the potentially different nature of utilization in a full-risk provider relationship. All other eligible health plan members in the targeted counties were randomized and included in the study. To minimize the chances that spouses or neighbors would be split between study and control groups, members were grouped by zip code and these zip codes were randomized with a random number generator within SAS statistical software (SAS Institute Inc, Cary, NC). Neither subjects nor clinicians could be blinded to the intervention. Aside from two physician group practices, no providers had more than 5% of their practice composed of study subjects. This low penetration may have made it less likely that physician behavior would be influenced much by whether or not a patient was part of this study. Of the 8504 eligible members who participated, 4247 were randomly assigned to the control and 4257 to the intervention group. A summary of enrollment and attrition versus retention throughout the study is shown in the Figure.

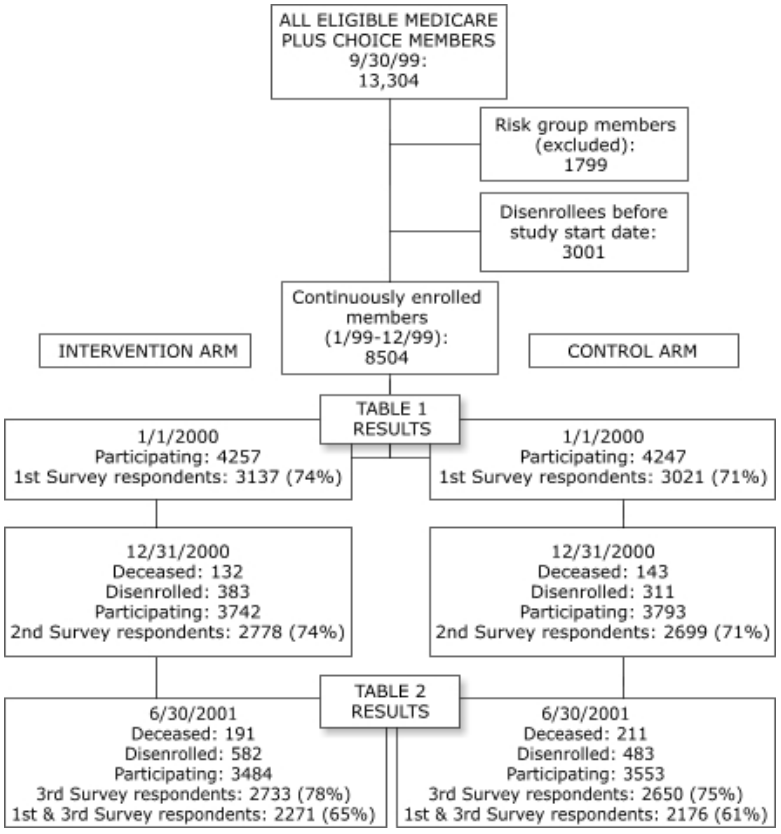

Figure. Flow chart illustrating participant eligibility, exclusion, enrollment, retention, survey participation, and attrition, including a comparison of the intervention and control groups, throughout the randomized controlled open trial.

Measurements and outcomes

The primary outcomes analyzed included self-reported health status, member satisfaction, costs measured as paid claims, and use of hospital and nursing home resources measured as bed-days per thousand per year. Secondary outcomes included survival and disenrollment from the health plan.

Analyses were based on the intention to treat principle (i.e., for those who disenrolled from the health plan data were analyzed up to the point of disenrollment). For 151 members who declined to continue to participate in SLM but remained in the plan, all 18 months of data were analyzed as part of the intervention group. Health status was measured by administering the SF-36 at entry, at 12 months, and at 18 months. Surveys were conducted by a vendor (Geriatric Health Services, San Francisco, Calif) using personnel blinded to the study objectives. All active and enrolled intervention and control members were surveyed at each of the three points. Response rates were nearly identical in both groups. At baseline, 73.7% of intervention and 71.1% of control subjects responded. For the final survey, response rates for active participants were 78% for the intervention group and 75% for the control group. Data collected by mail and by telephone survey

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were analyzed together. Comparisons of baseline and 18-month data were used for the primary analysis. Patient satisfaction was assessed based on the Medicare Beneficiary Survey.

The cost of the intervention included the salaries and overhead of all personnel delivering care services (including the medical director and administrative staff) plus all mailings, educational materials, and vendor costs specific to the program. This amounted to an additional $10.50 per member per month.

Statistical analyses

For baseline comparisons, bivariate analyses described the characteristics of study participants using *t*-tests to compare the intervention and control groups. All variables were subjected to two-tailed tests of significance with statistical significance set at $P = .05$. Disenrollments from the study (voluntary disenrollments and death) were analyzed with Kaplan-Meier and log-rank tests.

Health care resource use and costs were analyzed for the baseline period (January 1999 through December 1999) and for the study period (January 2000 though June 2001). Cost outcomes were actual paid amounts on claims for services incurred in the baseline and study periods. Cost data from outsourced mental health services could not be obtained for use in this analysis. All primary care services were capitated in both the intervention and control groups, were therefore essentially identical, and were thus also not included in the final analysis. Based on plan estimates, claims data were 98% complete. Claims were identified using a unique program code assigned at the outset of the study by information services personnel not involved in the analysis. Costs per member in both baseline and study periods for the intervention and control groups were not normally distributed due to small numbers of individuals with very high aggregate costs. Despite the non-normal distribution, means were reported and *t*-tests were used to assess differences in cost outcomes, as has been recommended for the economic evaluation of health care randomized trials (17,18). Additional analyses using log transformation yielded identical conclusions.

Resource use is reported for inpatient and skilled nursing/rehabilitation facility categories and was measured using actual days incurred on paid claims. To assess differences in rates of use, chi-squared tests were performed using the number of individuals who did or did not have an admission in each group. Admissions and bed-days were also reported per 1000 members per year, thus automatically adjusting for attrition by the change in denominator.

To assess change in self-reported health outcomes, health assessment baseline scores were subtracted from final scores for individuals who responded to both surveys, and a matched-pair *t*-test was used to compare the first and final surveys and report results for each of the SF-36 domains.

Role of funding sources

Employees of Coventry Health Care, Inc (Bethesda, Md) and Merck & Company, Inc (West Point, Pa) participated in the study as coinvestigators. They implemented protocols, coordinated data collection, and performed statistical analyses. Data interpretation and decisions about the paper's content resided with the investigators.

Results

At baseline, there were no significant differences between the two groups in demographic and health status characteristics (Table 1). Data on race and socioeconomic status were not available. Health care costs were higher in the intervention group for the one-year preenrollment period (mean $3553 vs $3417), but this was not significant. During the 18 months of this study, SLM participants received substantially augmented services in comparison to the control group. The following data illustrate the scope of the intervention. PSRs administered more than 24,186 health status short assessments by telephone. A total of 1640 (38.5%) intervention group members were evaluated for case management. Two hundred seventy-three home safety assessments were performed, 419 clinical summaries were mailed to treating physicians, and more than 800 alerts were faxed to physicians regarding potential medication safety issues. No similar activities were performed for the control group.

Over the 18 months of the study, self-reported satisfaction with the health plan improved significantly in the intervention group ($P < .01$) and self-reported social function declined less ($P = .04$) as measured by the SF-36 (Table 2). There was a trend toward slower decline in

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general health in the intervention group, which did not reach significance ($P = .09$). There was no meaningful difference in subject attrition between the two groups.

There was a 10% difference in mortality rate favoring the intervention group, but the difference was not statistically significant by Kaplan-Meier analysis. In the intervention group, there were 191 deaths out of 4257 (4.5%) and in the control group, there were 211 deaths out of 4247 (5.0%) ($P = .18$). The study was never powered to detect a difference in survival in post hoc analysis; however, the power to detect a mortality difference at a = .05 was 17.8%. Disenrollment rates from the health plan were also examined with Kaplan-Meier methodology, and again there was no difference between intervention and control.

Costs were greater during the 18-month study period than during the prior 12 months in both SLM and control groups, reflecting double-digit medical-cost inflation. There were no significant differences in mean costs during either the baseline or intervention periods. Pharmacy costs were nearly identical during the intervention period ($57.20 per member per month in control and $56.39 per member per month in intervention groups). The cost of the intervention was $10.50 per member per month or $189 per member per month over the 18-month period of the study. Hospital inpatient utilization was not different between the intervention and control groups during the study (Table 3). Use of nursing homes, however, was lower in the intervention group during the study period (616 vs 747 days per thousand members per year, $P = .02$). Economic savings in the intervention group offset the costs of the program so that total costs (including the cost of the intervention) in the two groups were nearly identical (Table 3). As a check against retention bias, the costs of members lost through death or disenrollment were examined and found to be the same in both the intervention and control groups.

Discussion

Because a small proportion of Medicare beneficiaries account for a large fraction of expenditures (approximately 10% of the noninstitutionalized patients accounting for 70% of expenditures) (20), and because a person with a chronic disease may be expected to incur costs that are 80% to 300% higher than average (21), substantial savings might be realized by managing the high cost of the "sickest of the sick." This is the rationale for traditional disease management and case management strategies and has been recently reiterated as a method of reducing Medicare spending (22).

Historical attempts to target and intervene in the subset of patients who might use a high volume of health service resources have yielded mixed results. A program designed to increase access to primary care after hospital discharge increased rather than decreased rates of rehospitalization (23), and a case management program using nurse case managers increased emergency department visits without favorably influencing any other measures (24). A review of three Medicare case management demonstration projects revealed that none improved self care, reduced symptoms, reduced hospital admission rates, or reduced Medicare spending (7). These failures were attributed to poor cooperation from clients' physicians, lack of focus on interventions, and lack of financial incentive to reduce expenditures. Another review of 16 demonstration projects concluded that the projects generally failed to meet their goal of overall cost savings (25). A third review of 36 studies led the authors to conclude that there was little or no effect on survival, functional health, or use of hospitals or nursing homes (26). While one of the earlier studies of a geriatric evaluation and treatment program yielded both cost savings and lower mortality (27), this encouraging result was not confirmed in larger, multisite trials (28,29). In a study similar to the one we report, social-work–directed case management in a Medicare Plus Choice plan did not reduce cost of health care of high-risk members (30).

Other reports have suggested that targeted interventions may be worthwhile. For example, early comprehensive discharge planning and home follow-up with an advance practice nurse lowered readmission rates rates and resulted in increased time between admissions with attendant cost savings (31). A case-management study reported significant reduction in costs, fewer readmissions, and higher quality of life through careful targeting of patients with congestive heart failure (32), and a nurse case-management program for chronic heart failure implemented by telephone lowered inpatient costs by 45.5% at six months (33). An intriguing study of substituting telephone care for clinic visits not only reduced clinic visits as expected but also resulted in fewer hospital admissions, lower medication use, and an estimated 28% lower total expenditure per patient (34).

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SLM was an effort to determine if interventions that have been found to be efficacious in experimental settings would be scalable to broader implementation. Demonstrating population-level changes with the interventions described is challenging, because large changes in a small number of individuals are diluted, and differences are often obscured by year-to-year variation. The short 18-month intervention period for this study compounded the challenge of demonstrating improved health outcomes and cost savings. Some savings were achieved by shifting from higher-cost, institution-based, long-term care to lower-cost, community-based care, which confirms the findings of others (25). From a global perspective, however, these savings barely offset the cost of the intervention. Because start-up costs would be expected to be higher than maintenance costs, and because economies of scale might be realized in program expansion, adding more members to the program might enhance its efficiency.

Although there was no difference in mortality, other benefits, such as improved social well-being and greater satisfaction with care, were demonstrated. Even though these benefits did not translate into improved member retention, preservation of social relations is a health goal highly valued by elderly patients (35). During the time of this study, three competing Medicare Plus Choice health plans served the nine-county region. Because voluntary disenrollment rates from Medicare Plus Choice plans can range from 10% to 15% per year, improved member retention was a hoped-for effect that did not materialize.

This study had several limitations. Measures of health status and satisfaction relied on self-reporting, and the study was conducted as an open trial. Another possible weakness was that primary care physicians caring for patients in this study were reimbursed under a capitation model. Thus, there was a financial disincentive for providers to see patients more frequently in the office to address concerns raised by case managers. Under a fee-for-service model, physicians might have been more motivated to see patients early and more frequently to address concerns disclosed by case mangers. While this might have helped avoid costly hospital admissions, the more frequent visits would themselves drive up costs, thereby making the cost-offset analysis less favorable. It is impossible to know which of these trends would dominate, and one cannot conclude that the model would perform better under a fee-for-service model.

Although historical plan data were used to flag members for evaluation for case management, the final selection for case management was based more on clinical judgment than on a highly refined methodology such as risk modeling. This targeting issue, and difficulties encountered in coordinating services in the provider community and preprogram sources of care, represented weaknesses in the intervention.

Strengths of the SLM design were comprehensiveness, proactive case finding, and attempts to deal with the myriad challenges affecting the health status of the elderly. Since the study was broadly implemented to include all members of a community eligible for Medicare Plus Choice, and because the demographic and health assessment characteristics were similar to those observed elsewhere (nearly identical to the published norms in the case of Mental and Physical Summary Scores for the SF-36) (36), the findings may be generalizable to other Medicare Plus Choice plans. However, this study reflected one geographic area and only members of one Medicare Plus Choice plan.

While from a scientific perspective it would have been desirable to extend the study time, this duration represented a real-world compromise that acknowledged both business and scientific objectives. It is unknown whether the effectiveness of SLM might have been greater over a longer time frame.

Lessons learned from this project point the way to potentially more rewarding implementations. Interventions could have been better targeted, perhaps through risk modeling. More cooperation from the provider community would have greatly enhanced attempts at early intervention. Future studies should explore better ways to share information and ways to reward provider efficiency and high-quality care. Finally, the algorithms used in the electronic management record to identify actionable issues and prompt the case manager could be improved with higher levels of medical logic and sophistication.

In summary, this broad implementation of population-based disease management and case management does not represent a panacea for escalating medical costs and raises a cautionary note.

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Tables

Table 1. Baseline Demographic and Health Status Characteristics, Survey Participants in Medicare Plus Choice Health Maintenance Organization (n = 6158), Pittsburgh, Pa, 1999[a]

Characteristics	Intervention Group (n = 3137)	Control Group (n = 3021)	*P*
Demographics			
Age, mean (SD), years	72.9 (5.78)	72.9 (5.82)	.82
Male, %	47.0	47.2	.88
Historical health care resource use			
1999 Medical claim expenditure, mean (SE), $	3553 (150)	3417 (149)	.41
Satisfaction			
How would you rate all your experiences with the plan now? (0 = worst to 10 = best)	8.92	8.79	.16
SF-36 domains[b]			
General health	64.92	65.13	.70
Bodily pain	67.60	67.00	.30
Mental health	78.11	78.02	.84
Physical function	71.23	70.59	.36
Role limitation — emotional	81.15	80.98	.85
Role limitation — physical	66.73	66.53	.85
Social function	84.37	84.44	.91
Vitality	59.73	60.05	.57
Mental component — summary score	53.04	53.13	.68
Physical component — summary score	43.66	43.48	.54

[a]All data are weighted.
[b]The SF-36 generates a health profile consisting of eight scales and two summary measures relating to 1) behavioral functioning, 2) perceived well-being, 3) social and role disability, and 4) personal evaluation of general health. Raw scores are translated into a scale of 0 to 100, with higher scores indicating better functioning (19).

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Table 2. Change in Health Status and Satisfaction from Baseline to 18 Months, Study Participants, Medicare Plus Choice Health Maintenance Organization, Pittsburgh, Pa, 2000–2001

	Intervention Group	Control Group	*P*
SF-36 domains[a]			
General health	-1.50	-2.29	.09
Bodily pain	-0.78	-1.42	.35
Mental health	-0.13	0.01	.74
Physical function	-4.29	-4.04	.67
Role limitation — emotional	-2.73	-2.24	.66
Role limitation — physical	-3.09	-4.45	.28
Social function	-1.42	-2.77	.04
Vitality	-1.53	-2.28	.14
Mental component — summary score	-0.16	-0.23	.79
Physical component — summary score	-1.25	-1.56	.21
Satisfaction			
How would you rate all your experiences with the plan now? (0 = worst to 10 = best)	0.32	0.12	<.01

[a]The SF-36 generates a health profile consisting of eight scales and two summary measures relating to 1) behavioral functioning, 2) perceived well-being, 3) social and role disability, and 4) personal evaluation of general health. Raw scores are translated into a scale of 0 to 100, with higher scores indicating better functioning (19).

Table 3. Financial and Resource Utilization Summary, Study Participants, Medicare Plus Choice Health Maintenance Organization, Pittsburgh, Pa, 2000–2001

Measure	Study Period (18 months)		
	Intervention	Control	*P*
Mean medical cost per member $ (SE)	6828 (230)	7001 (249)	.61
Intervention cost per member $	189	0	NA[a]
Total mean cost per member $	7017	7001	NA
Inpatient admissions per 1000 per year	430	421	.89
Inpatient days per 1000 per year	1929	1989	.46
Skilled nursing facility admissions per 1000 per year	36	37	.73
Skilled nursing facility days per 1000 per year	616.3	747.7	.02

[a]NA indicates not applicable.

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