Maintenance after Pulmonary Rehabilitation in Chronic Lung Disease

A Randomized Trial

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Pulmonary rehabilitation is beneficial for patients with chronic lung disease. However, long-term maintenance has been difficult to achieve after short-term treatment. We evaluated a telephone-based maintenance program after pulmonary rehabilitation in 172 patients with chronic lung disease recruited from pulmonary rehabilitation graduates. Subjects were randomly assigned to a 12-month maintenance intervention with weekly telephone contacts and monthly supervised reinforcement sessions (n = 87) or standard care (n = 85) and followed for 24 months. Except for a slight imbalance between sexes, experimental and control groups were equivalent at baseline and showed similar improvements after rehabilitation. During the 12-month intervention, exercise tolerance (maximum treadmill workload and 6-minute walk distance) and overall health status ratings were better maintained in the experimental group together with a reduction in hospital days. There were no group differences for other measures of pulmonary function, dyspnea, self-efficacy, generic and disease-specific quality of life, and health care use. By 24 months, there were no significant group differences. Patients returned to levels close to but above prerehabilitation measures. We conclude that a maintenance program of weekly telephone calls and monthly supervised sessions produced only modest improvements in the maintenance of benefits after pulmonary rehabilitation.

Keywords: patient compliance; behavior therapy; exercise therapy; health status; quality of life

Pulmonary diseases have become increasingly important causes of morbidity and mortality in the modern world. Chronic obstructive pulmonary diseases (COPD) are the most common lung diseases and major causes of disability and death (1, 2). Standard therapy is important in alleviating symptoms of COPD, particularly the distressing symptom of breathlessness. However, many patients are left to cope with a chronic, irreversible, and disabling disease process.

Pulmonary rehabilitation has been well established as a means of enhancing standard therapy to control and alleviate symptoms, optimize functional capacity, and reduce the medical and economic burdens of disabling lung disease (3–10). Benefits include improved exercise tolerance, symptoms, and quality of life with decrease in health care expenditures; results of published trials provide a sound scientific basis for the overall intervention as well as specific components (3, 4, 6). Despite documented benefits, longer-term effects are less clearly defined. In a previous randomized trial comparing comprehensive pulmonary rehabilitation with an education control group with 6 years of follow-up, we reported substantial improvements in exercise tolerance, symptoms (e.g., dyspnea), and self-efficacy for walking after rehabilitation (11). However, these benefits gradually declined over 1 to 2 years. After 2 years, there were no significant differences between the two groups. Similar findings have been reported in most other studies with longer-term follow-up (7, 12–17).

Successful pulmonary rehabilitation requires patients to incorporate a complex array of changes in behavior (e.g., exercise, compliance with medications/oxygen, breathing retraining methods, lifestyle changes). Failure to obtain long-term benefit from short-term intervention is common in behavioral medicine and is a consistent finding across many different behavioral interventions (18, 19). The use of telephone-based interventions has gained increased attention as a viable alternative to conventional counseling in behavioral medicine and may be particularly attractive in the maintenance phase after acquisition of a new health behavior (20). Therefore, on the basis of the results of the previous clinical trial, we developed and evaluated a telephone-based maintenance program after pulmonary rehabilitation to better retain the benefits. In this randomized trial, we compared the effects of the maintenance program versus routine care after pulmonary rehabilitation on physiologic and psychosocial outcomes over 2 years of follow-up.

METHODS

Subjects and Experimental Design

Patients with chronic lung disease were recruited from University of California, San Diego (UCSD) Pulmonary Rehabilitation Program graduates. Selection criteria and details of the 8-week program including components of education, physical and respiratory care instruction, exercise reconditioning, and psychosocial support are provided in an online supplement. All subjects recruited from each rehabilitation program were randomized together as a group to the same experimental intervention with an allocation ratio of 1:1 (*see* additional details about the randomization process in the online supplement) The UCSD Human Subjects Program approved the protocol and consent form used to obtain written informed consent from all subjects.

Standard care control group. "Standard care" included referral back to the patient's primary care provider for continued medical care with a letter outlining the recommended home care rehabilitation program. Subjects were invited to regular monthly alumni group meetings.

Experimental maintenance program. The experimental maintenance intervention, implemented immediately after completion of the rehabilitation program included (*1*) weekly telephone calls and (*2*) monthly supervised reinforcement sessions. To ensure continuity, the same clinical staff member (with one backup) was responsible for phone contact for each subject. A brief, semistructured telephone interview elicited specific information about compliance with the individual home care plan (e.g., frequency of exercise training, oxygen use, use of health care resources, etc.) as well as open-ended information about recent health problems. Staff members provided patients with advice and assistance,

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if needed. Monthly reinforcement sessions were similar to the initial rehabilitation program sessions. They were designed to review information previously taught, re-evaluate each patient's home treatment program, and provide encouragement and reinforcement. These sessions included 1.5 hours of supervised exercise, 1.0 hour of topic review, and 0.5 hours of social time.

Assessments

Outcome measures, including physiologic tests of pulmonary function and exercise tolerance and psychosocial measures of dyspnea, depression, quality of life, overall health status, and health care use were obtained before and after pulmonary rehabilitation and 6, 12, and 24 months later. Research staff separate from clinical staff performed the assessments. Because of the frequent contacts with maintenance group subjects in the same location as assessments, group assignment could not be totally blinded, but assessments were performed without identification.

Physiologic measures. Pulmonary function tests included spirometry, lung volumes and airway resistance by body plethysmography, single-breath diffusing capacity, maximal inspiratory and expiratory pressures, and maximal voluntary ventilation (MVV). Testing and quality control procedures were in accordance with standard and recommended methods (21, 22). At the prerehabilitation evaluation only, spirometry was repeated after use of an inhaled bronchodilator.

Maximal exercise tolerance was evaluated with an incremental, symptom-limited treadmill test with expired gas measurements. Maximal treadmill workload was estimated in terms of metabolic equivalents (METS) (estimated oxygen uptake in METS) based on speed and grade (11). Rest and exercise arterial blood gases were obtained only at the prerehabilitation assessment. Sa_{O_2} was monitored with cutaneous oximetry. Perceived symptoms of breathlessness and muscle fatigue were rated at the end of exercise with a scale adapted from Borg ranging from 0 (none) to 10 (maximum) (23). Subjects who required supplemental oxygen during training (rest or exercise $Pa_{O_2} \leq 55$ mm Hg, $Sa_{O_2} \leq 88\%$) were retested on oxygen (without expired gases) to guide oxygen therapy.

For the 6-minute walk tests, subjects received standardized instructions to cover the maximum distance possible in 6 minutes. Scripted reinforcement was provided each minute. For the first assessment, subjects were tested twice to compensate for learning; the maximum distance on either test was recorded. Subjects rated perceived symptoms of breathlessness and muscle fatigue at the end of the test (23).

Psychosocial measures. Dyspnea was assessed with two measures: (*1*) the UCSD Shortness of Breath Questionnaire self-reported dyspnea during activities of daily living (11, 24) and (*2*) the Baseline and Transition Dyspnea Indices administered by an interviewer (25).

The Centers for Epidemiologic Studies-Depression Scale was used as a general measure of depression (26, 27).

Self-efficacy was evaluated with a questionnaire adapted by Kaplan and colleagues that emphasizes walking (28, 29). Subjects rated the highest of nine levels of walking intensity that they were 100% confident they could complete.

Quality of life was evaluated using three instruments: a generic utility measure, a profile instrument, and a disease-specific measure.

The Quality of Well-Being Scale (QWB) was administered by an interviewer (30, 31). Mean QWB was calculated as a combined index of morbidity and mortality by averaging in 0 for deaths. The index was also calculated as a living-person measure excluding deaths (11, 32).

The Rand 36-Item Health Survey was self-administered as a general health profile. It includes eight dimensions of health plus a single item rating change in health (33). Summary scores of physical and mental function were also calculated. The Rand instrument is very similar to the Short-Form Health Survey (34) with the same questions and minor scoring differences.

The Chronic Respiratory Questionnaire (CRQ) was administered by an interviewer. This disease-specific quality of life instrument evaluates four domains: dyspnea, fatigue, emotional function, and mastery (35–37).

Patients were asked to rate overall health status on a 10-point scale ranging from 0 (dead) to 10 (excellent). In addition, this was obtained routinely by rehabilitation staff at the first contact (to assess the effect of screening).

Health care use. Use of health care services in the most recent 3 months was obtained from a self-reported questionnaire including information on hospitalizations, outpatient visits, and telephone calls.

Statistical Analyses

Data before and after rehabilitation for all subjects (prerandomization) were evaluated with descriptive statistics and analysis of variance with repeated measures. Experimental groups were compared with postrehabilitation data using independent *t* tests for continuous variables and χ^2 tests for discrete variables.

Effects of the maintenance program were evaluated in a two-way analysis of variance (group × time) with repeated measures. Data from postrehabilitation, 6-month, and 12-month assessments were used to evaluate the maintenance program. Data from 12- and 24-month assessments were used to evaluate residual changes after the maintenance sessions were discontinued.

Mortality was evaluated using the Kaplan-Meier product-limit method of survival analysis; groups were compared with the log-rank test.

RESULTS

Pulmonary Rehabilitation Program

Over a 4-year period, 340 patients enrolled in the 8-week UCSD Pulmonary Rehabilitation Program. A total of 190 patients completed the program (attended at least 8 of 12 sessions within 3 months) and were eligible for the study; of these, 172 (91%) agreed to participate and were randomized to either the experimental maintenance program (E; n = 87) or standard care control (C; n = 85) for 1 year. Eight randomized subjects were subsequently withdrawn: six (3E, 3C) failed to complete required postrehabilitation assessments before the experimental intervention; two (1E, 1C) had lung volume reduction surgery within 6 months. Of the remaining 164 subjects, 16 did not complete the 1-year intervention period because 13 died (7E, 6C) and 3 withdrew (1E, 2C). Figure 1 summarizes participant flow in the trial.

Table 1 summarizes selected descriptive characteristics and changes after pulmonary rehabilitation in all 164 subjects before randomization. Overall, these patients had moderate to severe pulmonary impairment with markedly reduced exercise tolerance and quality of life. As expected, there were significant improvements after pulmonary rehabilitation in measures of exercise performance (maximal treadmill workload in METS, 6-minute walk distance), symptoms (perceived breathlessness and muscle fatigue during exercise tests and questionnaire measures of dyspnea), self-efficacy for walking, depression, quality of life including both general (QWB, Rand 36-Item Health Survey) and disease specific (CRQ) instruments, and overall health status. After randomization, the two experimental groups were comparable on all measures with a few notable differences. There were significantly more females in the standard care control (46/81 = 57%) compared with the maintenance (29/83 = 35%) group. Also, the overall rating of health status was significantly higher in the control group (6.4 ± 1.7 vs. 5.8 ± 1.9). Additional data before and after rehabilitation and comparing groups at baseline are provided in the online supplement.

Effects of 1-Year Maintenance Intervention

The main results of the 1-year maintenance intervention for the 138 subjects who completed assessments at 6- and 12-month follow-ups are summarized in Table 2. Thirteen patients died before the 12-month follow-up (7E, 6C). Compared with the 138 subjects who completed both the 6- and 12-month assessments, baseline data for the 13 deceased patients indicated significantly ($p < 0.05$) more lung volume hyperinflation (total lung capacity 8.50 versus 6.86 L; residual volume/total lung capacity ratio 0.64 versus 0.57), lower 6-minute walk distance (390 vs. 456 m), and

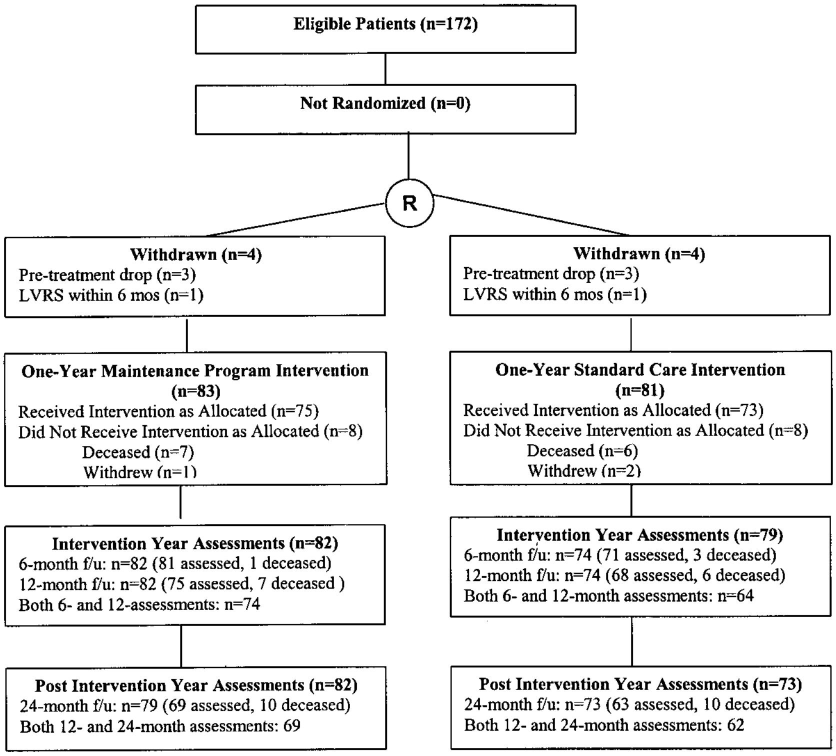

Figure 1. Subject participation.

higher dyspnea ratings on the UCSD Shortness of Breath Questionnaire (57.5 vs. 43.8). Other measures also indicated worse baseline function and symptoms in the deceased patients, but these did not reach statistical significance. In addition, 13 subjects (2E, 11C) did not complete at least one of the follow-up assessments. There were no significant differences in baseline measures for these subjects compared with the 138 subjects who completed both follow-ups. Compliance with the maintenance intervention was excellent. Eighty-eight percent of subjects attended at least 8 of the 12 monthly sessions; 70% attended at least 10 of 12. For the weekly telephone calls, 97% of the maintenance subjects completed at least 50 calls during the intervention year.

Over the 12-month intervention period after pulmonary rehabilitation, measures of exercise tolerance (maximum treadmill workload in METS, 6-minute walk distance) and overall health status ratings were significantly better maintained in the experimental subjects compared with control subjects. Maximal treadmill workload and overall health status were maintained in the experimental subjects and declined in control subjects. The 6-minute walk distance declined in both groups, but it declined more in control subjects. There was significant decline over time in both groups in measures of lung function (FEV_1, total lung capacity, MVV), 6-minute walk distance, and questionnaire assessments of self-efficacy, depression, dyspnea (UCSD Shortness of Breath Questionnaire, Baseline and Transition Dyspnea Indices), QWB (including deaths), CRQ, and summary scores of Rand 36-Item Health Survey. There were no significant changes in $\dot{V}O_2max$, perceived symptom ratings during exercise, and QWB (excluding deaths).

Because of the potential importance of the effects the sex of a person has on the response to rehabilitation and to the maintenance program, we performed additional exploratory analyses for selected outcome measures (maximal treadmill workload, 6-minute walk distance, UCSD Shortness of Breath Questionnaire, health status, and QWB) and found no significant effects the sex of a person has on the results.

Postintervention Year

Results of the post-intervention year are presented in Table 3 for the 131 subjects who completed the 24-month follow-up. Thirty-three subjects (14E, 19C) did not complete at least one of the assessments for the following reasons: 20 deceased (10E, 10C), 13 refused (4E, 9C). In general, these findings indicate progressive, continued decline in lung function, exercise performance, symptoms, and quality of life in both groups. In general, by 24 months subjects had returned to levels that were close to, but still slightly above, prerehabilitation measures.

Results for all three phases of the trial are depicted graphically for selected variables in Figure 2 (maximum treadmill workload) and Figure 3 (QWB, excluding deaths). Figure E1 in the online supplement presents results for the overall health status measure. Three separate analyses are presented, including: (*1*) pre- and postrehabilitation in 164 subjects who completed the program; (*2*) postrehabilitation, 6-month, and 12-month follow-up in 138 subjects who completed those assessments; and (*3*) 12- and 24-month assessments in 131 subjects who completed those assessments. The overlap at the postrehabilitation (Analyses 1 and 2) and 12-month (Analyses 2 and 3) time periods indicate that there was no significant effect of differential loss to follow-up.

Health Care Use

Results of the Health Care Utilization Questionnaire are presented in Table 4. As in Tables 2 and 3, these data are reported separately for patients who completed 6- and 12-month follow-ups during the 12-month intervention period (A) and those who completed both 12- and 24-month follow-ups in the year after the intervention period (B). During the intervention year, there was a significant group × time interaction for hospital days with an overall reduction in favor of the maintenance group. Similar trends in favor of the maintenance patients were observed for other variables, but these did not reach statistical significance. During the second year of follow-up (after the intervention pe-

TABLE 1. PATIENT CHARACTERISTICS AND RESULTS BEFORE AND AFTER THE PULMONARY REHABILITATION PROGRAM IN 164 ELIGIBLE PATIENTS

Variable	Prerehabilitation	Postrehabilitation
Sex, male/female	89/75	
Age, yr	67.1 ± 8.2	
Diagnosis		
Obstructed	143	
Mixed obstructed/restricted	17	
Restricted	4	
Pulmonary function		
FEV_1, L (% predicted)	1.06 ± 0.43 (45)	1.08 ± 0.44 (46)
Maximum treadmill exercise		
Workload, METS	4.4 ± 2.2	5.4 ± 2.6*
$V_E$max, L/min	40.0 ± 14.5	39.4 ± 14.8
$\dot{V}O_2$max, L/min	1.14 ± 0.44	1.15 ± 0.45
$\dot{V}O_2$max, ml/kg/min	14.8 ± 3.9	15.0 ± 4.1
Perceived symptom score		
Breathlessness	5.4 ± 1.9	4.5 ± 1.8*
Muscle fatigue	3.2 ± 2.1	2.8 ± 1.9†
Six-minute walk		
Distance, m	427.2 ± 104.9	450.2 ± 104.6*
Perceived symptom score		
Breathlessness	4.5 ± 1.9	4.0 ± 1.7*
Muscle fatigue	3.0 ± 2.2	2.6 ± 2.0†
Psychosocial measures		
Self-efficacy, walking	3.6 ± 2.9	4.6 ± 2.7*
CES-D depression	13.2 ± 8.9	10.2 ± 7.7*
Score $>$ 18, n(%)	41(25)	24(15)
UCSD SOBQ	55.5 ± 20.8	45.5 ± 20.3*
BDI/TDI		
Functional status	1.7 ± 1.0	+1.0 ± 1.0*
Magnitude of task	1.7 ± 0.8	+0.8 ± 0.8*
Magnitude of effort	1.6 ± 0.7	+1.0 ± 1.0*
Total	5.0 ± 2.0	+2.7 ± 2.3*
Quality of life measures		
QWB	0.626 ± 0.098	0.657 ± 0.114*
CRQ		
Dyspnea	17.6 ± 4.8	22.3 ± 5.5*
Fatigue	15.8 ± 4.9	19.5 ± 4.4*
Emotional	35.4 ± 8.2	39.1 ± 7.1*
Mastery	19.8 ± 5.1	23.1 ± 3.9*
Total	88.4 ± 17.3	103.9 ± 16.6*
Rand-36		
Physical functioning	35.3 ± 20.8	47.1 ± 21.9*
Role functioning/physical health	30.3 ± 36.3	47.9 ± 41.8*
Role functioning/emotional health	69.5 ± 40.0	81.7 ± 33.3*
Energy/fatigue	43.3 ± 20.4	56.5 ± 19.7*
Emotional well-being	72.7 ± 18.3	78.8 ± 15.6*
Social functioning	69.4 ± 27.0	78.4 ± 23.3*
Pain	75.3 ± 22.4	77.6 ± 24.4
General health	43.9 ± 20.2	47.7 ± 21.4†
Health change	41.6 ± 29.0	59.8 ± 31.2*
Physical component summary	32.8 ± 8.3	36.3 ± 9.1*
Mental component summary	51.2 ± 11.1	55.0 ± 8.6*
Health status	5.5 ± 1.7	6.1 ± 1.8*

Definition of abbreviations: BDI/TDI = Baseline and Transition Dyspnea Indices; CES-D = Centers for Epidemiologic Studies-Depression Scale; CRQ = Chronic Respiratory Questionnaire; QWB = Quality of Well-Being Scale; Rand-36 = Rand 36-Item Health Survey; UCSD SOBQ = University of California, San Diego Shortness of Breath Questionnaire.

Values are expressed as mean ± SD.

* $p \leqslant 0.001$.

† $p \leqslant 0.01$.

riod), both the number of physician/clinic visits and phone calls were significantly lower in the maintenance subjects.

Over 2 years of follow-up, there was no difference in survival between the two groups. Twenty patients were deceased, 10 in each group.

DISCUSSION

The results of this study indicate definite and significant benefits of an 8-week comprehensive pulmonary rehabilitation program in patients with chronic lung disease that declined gradually over 2 years of follow-up. Overall, these findings are comparable with those observed in our previous study (11). In the current study, the 12-month maintenance intervention of weekly telephone calls and monthly reinforcement visits had a modest effect in the first year of follow-up. Measures of exercise tolerance (maximal treadmill workload and 6-minute walk distance) and overall ratings of health status were better maintained in the experimental maintenance compared with the usual care control group. In addition, there was a modest effect on health care use. Other outcome measures of symptoms and quality of life declined similarly in both groups over 2 years. Over the second year of follow-up (without intervention), exercise performance, symptoms, and quality of life declined in both groups to levels that approached, but were still slightly above, the prerehabilitation baseline. Thus, some residual effect of rehabilitation was still evident at that time.

These results of short-term rehabilitation parallel other studies with a similar design. Griffiths and colleagues randomly assigned 200 patients with chronic lung disease to either a 6-week multidisciplinary rehabilitation program or standard medical care and followed them for 1 year (12). Compared with control subjects, rehabilitation patients demonstrated significantly greater improvement in exercise tolerance and both general (Short-Form Health Survey) and disease-specific quality of life (CRQ and St. Georges Respiratory Disease Questionnaire). After 1 year, there was a progressive loss of the rehabilitation effects, although differences between groups were still statistically and clinically significant. Only the rehabilitation patients were invited to join a weekly, patient-run group that included supervised exercise—although only 25% attended these sessions.

Several studies have evaluated longer-term rehabilitation interventions with mixed results. Guell and colleagues randomized 60 patients with COPD to either 12 months of intervention (6 months of intensive daily rehabilitation, 6 months of weekly supervised maintenance) or standard care and followed them for 2 years (38). Improvements were noted in the experimental group, compared with the control group, in exercise tolerance, symptoms (dyspnea), and quality of life (CRQ). Benefits were present, but diminished, over the second year of follow-up. Troosters and colleagues randomized 100 patients with COPD to either 6 months of exercise training or usual care and followed them for 18 months (13). In the 70 patients who completed the intervention and 6-month follow-up, exercise tolerance and quality of life (CRQ) improved in the training group at 6 months and persisted over the next year. Engstrom and colleagues randomized 50 patients with COPD to a 12-month intervention (with a tapering schedule) or usual care (15). Exercise tolerance improved significantly in experimental subjects, but there was no significant improvement in quality of life (St. Georges Respiratory Questionnaire, Sickness Impact Profile). Wijkstra and colleagues randomized 36 patients with COPD into three groups (39). Two experimental groups received 18 months of home rehabilitation therapy with 3 months of twice weekly sessions followed by either weekly or monthly maintenance. The control group received no rehabilitation. All subjects were followed for 18 months. They reported improved quality of life (CRQ) in the experimental groups compared with control groups, although the benefits diminished over the 18-month course of the study. There were no significant group differences in measured exercise tolerance (6-minute walk).

TABLE 2. RESULTS OVER 12-MONTH INTERVENTION PERIOD IN 138 PATIENTS WHO COMPLETED BOTH 6- AND 12-MONTH FOLLOW-UPS

Variable	Baseline	6 Months	12 Months
Patients			
Maintenance group	74	74	74
Control group	64	64	64
Pulmonary function			
FEV_1, L			
Maintenance group	1.07 ± 0.43	1.05 ± 0.45	1.03 ± 0.43*
Control group	1.14 ± 0.42	1.12 ± 0.40	1.10 ± 0.42
MVV, L/min			
Maintenance group	44.2 ± 18.9	41.4 ± 18.8	43.4 ± 20.1*
Control group	47.2 ± 17.8	45.4 ± 17.1	44.6 ± 16.2
Maximum treadmill exercise			
Workload, METS			
Maintenance group	5.6 ± 2.6	5.5 ± 2.4	5.7 ± 2.6†
Control group	5.6 ± 2.4	5.4 ± 2.8	5.0 ± 2.5
$\dot{V}_E$max, L/min			
Maintenance group	39.6 ± 15.9	38.9 ± 14.5	39.1 ± 14.3
Control group	39.3 ± 13.8	40.0 ± 14.6	37.7 ± 13.4
$\dot{V}O_2$max, L/min			
Maintenance group	1.15 ± 0.53	1.14 ± 0.52	1.14 ± 0.53
Control group	1.16 ± 0.38	1.14 ± 0.41	1.11 ± 0.37
Perceived breathlessness			
Maintenance group	4.6 ± 1.8	4.6 ± 1.7	4.7 ± 1.8
Control group	4.4 ± 1.6	4.9 ± 1.8	5.0 ± 1.8
Perceived muscle fatigue			
Maintenance group	2.7 ± 1.8	2.5 ± 1.7	2.7 ± 2.2
Control group	3.0 ± 2.0	2.6 ± 2.2	2.9 ± 2.5
Six-minute walk			
Distance, m			
Maintenance group	458.0 ± 98.6	442.5 ± 102.9	440.1 ± 114.9*†
Control group	473.0 ± 94.0	436.3 ± 107.3	430.8 ± 130.7
Perceived breathlessness			
Maintenance group	4.0 ± 1.9	4.1 ± 1.8	4.2 ± 2.0
Control group	3.9 ± 1.8	4.0 ± 1.8	3.9 ± 2.0
Perceived muscle fatigue			
Maintenance group	2.5 ± 1.8	2.4 ± 1.7	2.8 ± 2.0
Control group	2.2 ± 1.6	2.4 ± 2.2	2.6 ± 2.3
Psychosocial measures			
Self-efficacy for walking			
Maintenance group	4.9 ± 2.7	4.6 ± 2.7	4.5 ± 3.1*
Control group	4.5 ± 2.7	4.4 ± 2.9	3.8 ± 2.9
CES-D depression			
Maintenance group	9.6 ± 7.8	11.3 ± 9.6	11.8 ± 8.3*
Control group	9.4 ± 7.0	11.1 ± 8.8	12.4 ± 8.8
UCSD SOBQ			
Maintenance group	44.1 ± 19.4	45.9 ± 20.4	51.1 ± 23.4*
Control group	43.3 ± 20.9	46.5 ± 22.9	50.4 ± 23.7
TDI			
Maintenance group	+2.9 ± 2.4	+1.5 ± 2.8	+0.8 ± 2.8*
Control group	+2.7 ± 2.2	+1.0 ± 2.9	+1.0 ± 2.8
Quality of life measures			
QWB			
Maintenance group	0.665 ± 0.114	0.645 ± 0.157	0.593 ± 0.214*
Control group	0.645 ± 0.112	0.597 ± 0.170	0.580 ± 0.215
QWB (deaths excluded)			
Maintenance group	0.663 ± 0.107	0.666 ± 0.119	0.650 ± 0.116
Control group	0.651 ± 0.110	0.626 ± 0.116	0.634 ± 0.125
CRQ total			
Maintenance group	103.0 ± 18.0	99.6 ± 19.8	96.0 ± 21.3*
Control group	105.9 ± 14.3	100.8 ± 19.6	95.9 ± 21.1
Rand-36 physical component summary			
Maintenance group	36.7 ± 9.7	36.7 ± 9.8	34.1 ± 9.8†
Control group	36.6 ± 8.6	34.8 ± 10.1	34.4 ± 9.9
Rand-36 mental component summary			
Maintenance group	55.4 ± 8.9	52.9 ± 12.2	52.3 ± 10.1*
Control group	55.7 ± 8.2	54.0 ± 9.4	53.0 ± 9.9
Health status			
Maintenance group	5.9 ± 1.9	5.9 ± 1.8	5.8 ± 1.9*†
Control group	6.6 ± 1.6	6.2 ± 1.8	5.9 ± 2.1

Patients in analyses	n	Maintenance Group	Control group
Pulmonary function	116	64	52
Maximum treadmill	115	63	52
With expired gases	87	45	42
6-minute walk	116	65	51
Questionnaires	138	74	64

Definition of abbreviations: CES-D = Centers for Epidemiologic Studies-Depression Scale; CRQ = Chronic Respiratory Questionnaire; MVV = maximal voluntary ventilation; QWB = Quality of Well-Being Scale; Rand-36 = Rand 36-Item Health Survey; TDI = Transition Dyspnea Index; UCSD SOBQ = University of California, San Diego Shortness of Breath Questionnaire.

* Time: $p \leqslant 0.05$.

† Group × time: $p \leqslant 0.05$.

TABLE 3. RESULTS OVER 12 MONTHS AFTER INTERVENTION PERIOD IN 131 PATIENTS WHO COMPLETED BOTH 12- AND 24-MONTH FOLLOW-UPS

Variable	12 Months	24 Months
Patients		
Maintenance group	69	69
Control group	62	62
Pulmonary function		
FEV_1, L		
Maintenance group	1.05 ± 0.43	1.01 ± 0.44
Control group	1.08 ± 0.42	1.07 ± 0.45
MVV, L/min		
Maintenance group	45.0 ± 20.6	42.0 ± 19.3*
Control group	42.9 ± 16.2	44.5 ± 20.1
Maximum treadmill exercise		
Workload, METS		
Maintenance group	6.0 ± 2.6	5.1 ± 2.5†
Control group	5.2 ± 2.5	4.8 ± 2.7
$V_E$max, L/min		
Maintenance group	39.1 ± 14.6	36.3 ± 13.1†
Control group	36.9 ± 12.5	36.4 ± 13.2
$\dot{V}O_2$max, L/min		
Maintenance group	1.14 ± 0.53	1.07 ± 0.50†
Control group	1.09 ± 0.33	1.03 ± 0.36
Perceived breathlessness		
Maintenance group	4.8 ± 1.8	5.1 ± 2.0
Control group	5.0 ± 1.9	5.0 ± 1.8
Perceived muscle fatigue		
Maintenance group	2.9 ± 2.4	2.6 ± 2.3
Control group	3.0 ± 2.6	2.8 ± 2.2
Six-minute walk		
Distance, m		
Maintenance group	450.7 ± 105.5	415.5 ± 119.4†
Control group	439.3 ± 120.0	427.9 ± 121.3
Perceived breathlessness		
Maintenance group	4.1 ± 1.8	4.6 ± 1.7†
Control group	4.1 ± 2.2	4.3 ± 2.0
Perceived muscle fatigue		
Maintenance group	2.7 ± 1.9	3.2 ± 2.5
Control group	2.6 ± 2.3	2.8 ± 2.2
Psychosocial measures		
Self-efficacy for walking		
Maintenance group	4.5 ± 3.1	3.7 ± 3.0†
Control group	4.0 ± 2.8	3.7 ± 2.8
CES-D depression		
Maintenance group	11.1 ± 7.9	10.5 ± 7.8
Control group	11.6 ± 8.0	10.9 ± 7.2
UCSD SOBQ		
Maintenance group	49.6 ± 23.1	51.4 ± 23.0†
Control group	48.5 ± 23.1	53.9 ± 24.4
TDI		
Maintenance group	+0.9 ± 2.8	+0.2 ± 3.4†
Control group	+0.9 ± 2.8	−0.1 ± 3.4
Quality of life measures		
QWB		
Maintenance group	0.593 ± 0.217	0.546 ± 0.233†
Control group	0.582 ± 0.216	0.535 ± 0.225
QWB (deaths excluded)		
Maintenance group	0.657 ± 0.115	0.625 ± 0.109†
Control group	0.640 ± 0.126	0.613 ± 0.099
CRQ Total		
Maintenance group	98.0 ± 20.1	96.6 ± 20.5
Control group	97.5 ± 21.0	94.5 ± 22.5
Rand-36 physical component summary		
Maintenance group	34.5 ± 9.5	32.2 ± 9.8†
Control group	35.5 ± 10.0	33.6 ± 10.6
Rand-36 mental component summary		
Maintenance group	53.1 ± 9.9	55.0 ± 7.9
Control group	53.8 ± 9.8	53.7 ± 9.7
Health status		
Maintenance group	5.8 ± 2.0	5.7 ± 2.0
Control group	6.0 ± 2.0	5.9 ± 1.9

Definition of abbreviations: CES-D = Centers for Epidemiologic Studies-Depression Scale; CRQ = Chronic Respiratory Questionnaire; QWB = Quality of Well-Being Scale; Rand-36 = Rand 36-Item Health Survey; TDI = Transition Dyspnea Index; UCSD SOBQ = University of California, San Diego Shortness of Breath Questionnaire.

Values are expressed as mean ± SD.

* Group × time: $p \leqslant 0.05$.

† Time: $p \leqslant 0.05$.

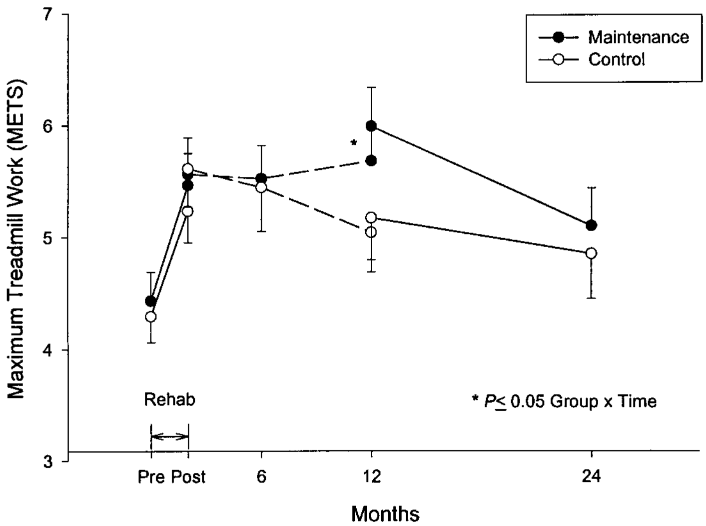

Figure 2. Changes in maximum treadmill work (measured in metabolic equivalents [METS]) in the experimental maintenance and control groups for the three phases of the study: (*1*) 164 eligible patients before and after the pulmonary rehabilitation program; (*2*) 138 patients who completed both 6- and 12-month follow-ups during the intervention period; and (*3*) 131 patients who completed both 12- and 24-month follow-ups in the year after the intervention period.

In a small randomized trial of repeat pulmonary rehabilitation programs administered 1 and 2 years after initial treatment with 61 patients with COPD, Foglio and colleagues reported that retreatment produced improvements in exercise tolerance, dyspnea, and quality of life but that overall changes over 2 years did not differ between the experimental and control groups (40). However, there were significantly fewer exacerbations in the retreatment group compared with the control group. These results are intriguing, but conclusions are limited by the high dropout rate (25/61—41% of subjects did not complete the 24-month evaluation).

The ability of pulmonary rehabilitation programs to produce clinically significant and meaningful changes in exercise function, symptoms, and quality of life has now been well documented (3, 4, 6). Studies that have followed patients longer than 6 months show that benefits tend to diminish after about 1 year (7, 11–17). Following a behavioral change model, changes in health behavior over this time period are reasonable for a short-term intervention like that typically provided in pulmonary rehabilitation.

Failure to obtain long-term benefits from short-term intervention parallels the literature for other behavior change studies. Behavioral intervention is designed to teach new habits. In theory, behavioral treatment can be applied at a single point in time to achieve lasting behavior change. However, behavioral research relevant to health habit changes rarely demonstrates long-term effects of such intervention. Difficulty in maintaining positive health behavior change is not unique to pulmonary rehabilitation. Long-term maintenance of behavior change has also been difficult to demonstrate in research on smoking cessation, weight loss, or exercise adherence (41–43). Indeed, the finding that patients show behavior change while on treatment that is not maintained after treatment is common and consistent across many different intervention studies in behavioral medicine (18). Epstein suggests that this failure to maintain treatment effect is explained by behavioral theory (19). It is a common finding that variables responsible for behavior acquisition may differ from variables that influence maintenance of behavior change. Although continuous schedules of reinforcement are required during acquisition, intermittent reinforcement schedules may be more effective for producing long-term change.

One of the interesting differences between the current study and our prior clinical trial (11) is the significant improvement observed in the QWB scores that did not occur in the earlier study. We were puzzled by this previous observation and, for this reason, included several other measures of qualify of life including both general and disease-specific instruments. In this study, significant improvements were observed in all measures of quality of life consistent with the results of other clinical trials. Although we cannot clearly explain the absence of QWB changes in the prior study, there are some differences in the subjects in the two studies worth noting. In the present study there were more females (46 vs. 27%), and the patients had more severe lung disease (FEV_1 1.06 L [45% predicted] vs. 1.23 L [52% predicted] and were older [mean age 67 vs. 63 years]).

Overall, this randomized clinical trial showed that weekly telephone contacts and monthly supervised rehabilitation sessions produced modest effects in maintaining improvements in exercise tolerance and ratings of overall health status over the course of the 12-month intervention. However, it failed to extend the period of benefit in pulmonary rehabilitation for other outcome measures. There are several possible explanations for the modest effects of the maintenance intervention and the failure to demonstrate stronger long-term benefits after short-term rehabilitation treatment. Among these, we will consider three explanations: weakness of outcome measures, ineffectiveness of intervention, and the challenges and changes associated with chronic disease.

One possible reason for the modest effects of the maintenance intervention is that the measures, particularly the psychosocial outcomes, included so much error that it would be difficult to detect a true treatment effect. However, there were significant changes in most of these measures before and after rehabilitation. If the measures were insensitive, such changes might not have been expected. Furthermore, changes between postrehabilitation and final follow-up were also observed. Also, we had multiple outcome measures. Even without adjustment for multiple comparisons, there was little evidence for differential maintenance between the experimental and control groups for most of these measures. Thus, it seems unlikely that weak psychosocial outcome measures can explain the failure to detect differences between groups.

A second consideration is that the treatment was not of sufficient strength to produce the anticipated changes. As a purely behavioral intervention after short-term rehabilitation treatment, this explanation has some merit. It is certainly possible that a telephone-based intervention alone does not provide sufficient

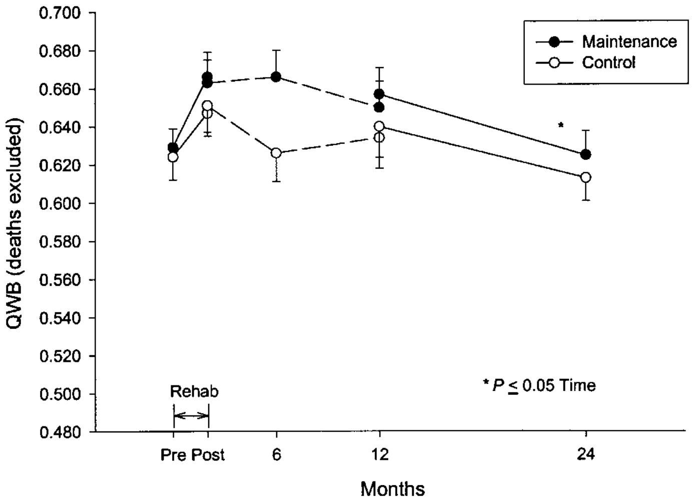

Figure 3. Changes in the Quality of Well-Being Scale—excluding deaths—in the experimental maintenance and control groups for the three phases of the study: (*1*) 164 eligible patients before and after the pulmonary rehabilitation program; (*2*) 138 patients who completed both 6- and 12-month follow-ups during the intervention period; and (*3*) 131 patients who completed both 12- and 24-month follow-ups in the year after the intervention period.

support to overcome significant barriers to maintenance in this challenging patient group. This is one reason why we also included monthly, supervised in-person reinforcement sessions. The rationale for behavioral interventions has been that they provide skills for coping with illness, but it is assumed that overall health status is relatively stable. Even among stable, less impaired individuals, it is difficult to maintain the complex behavior changes associated with an intervention like pulmonary rehabilitation. The barriers and challenges for a sicker patient population are even greater and may require more intensive maintenance strategies.

A final consideration is the inherent unstable nature of severe, disabling chronic lung diseases. Chronic problems require chronic evaluation and treatment. For example, the treatment of hypertension, diabetes mellitus, and congestive heart failure all require continuing intervention. The challenges of chronic illness create an ongoing series of new and different problems. Not only are there continuing problems associated with progressive illness and associated complications but also the aging process and deteriorating health create a continual stream of new challenges. Furthermore, social contacts for older patients often change. Death of spouses and friends are common; these create major disruptions in behavior patterns. Patients with chronic lung diseases are particularly susceptible to periodic exacerbations that produce profound, sustained changes in symptoms and function. Deterioration in health status may make it impossible for such patients to resume or maintain a treatment plan developed previously. Patients with chronic disease need ongoing reassessment and changes in their treatment regimen.

Current rehabilitation strategies incorporated into an acute care model as a short-term intervention, even with optimal maintenance strategies, may not work for many patients with disabling lung disease.

In summary, the results of this study suggest that a maintenance program of weekly telephone contacts plus monthly supervised reinforcement sessions was only modestly successful in maintaining health benefits and was not sufficient to fully prevent regression of beneficial health outcomes after successful pulmonary rehabilitation in patients with advanced chronic lung disease. More work is needed to evaluate optimal methods for incorporating rehabilitation strategies into disease management programs for patients with chronic lung disease.

TABLE 4. RESULTS OF SELF-REPORTED HEALTH CARE USE OVER THE PREVIOUS 3 MONTHS IN PATIENTS WITH COMPLETE FOLLOW-UP

	Intervention Year				Postintervention Year		
Variable	n	Prerehabilitation	6 Months	12 Months	n	12 Months	24 Months
Hospital days							
Maintenance group	74	0.6 ± 2.3	0.2 ± 0.9	0.9 ± 2.7†	68	0.6 ± 1.9	0.9 ± 3.3
Control group	62	0.4 ± 2.2	1.3 ± 4.8	0.6 ± 2.0	60	0.6 ± 2.3	1.3 ± 3.5
Doctor/clinic visits							
Maintenance group	73	3.6 ± 3.1	2.6 ± 2.6	3.3 ± 2.7	67	3.4 ± 2.9	2.7 ± 2.0†
Control group	62	3.1 ± 2.7	3.4 ± 3.7	3.1 ± 3.2	59	2.6 ± 2.2	3.4 ± 3.8
Doctor/clinic phone calls							
Maintenance group	74	1.9 ± 2.9	1.7 ± 2.1	2.3 ± 4.0	67	2.4 ± 4.2	1.8 ± 1.9†
Control group	62	1.6 ± 2.2	1.6 ± 2.0	1.3 ± 1.5	60	1.3 ± 1.7	2.2 ± 4.1
Emergency room/urgent care visits							
Maintenance group	74	0.5 ± 2.4	0.2 ± 0.4	0.3 ± 0.6	68	0.2 ± 0.5	0.3 ± 0.7
Control group	63	0.1 ± 0.3	0.4 ± 1.0	0.3 ± 0.6	60	0.4 ± 0.6	0.4 ± 0.6

Values expressed as mean ± SD.
* Group: p ≤ 0.05.
† Group × time: p ≤ 0.05.
‡ Time: p ≤ 0.05.

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