

# Group-Mediated Activity Counseling and Traditional Exercise Therapy Programs: Effects on Health-Related Quality of Life Among Older Adults in Cardiac Rehabilitation

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## ABSTRACT

**Background:** Regular physical activity has been consistently related to improvements in health-related quality of life (HRQL) in older adults. Nevertheless, systematic investigations of the influence of exercise therapy on older men and women enrolled in cardiac rehabilitation remain sparse. **Purpose:** The primary purpose of this investigation was to compare the effects of a group-mediated cognitive behavioral physical activity intervention program (GMCB) to a traditional cardiac rehabilitation program (CRP) with regard to changes in HRQL in a community-dwelling sample of older adults. **Methods:** This randomized clinical trial assigned 147 participants who were eligible for inclusion in cardiac rehabilitation to the GMCB or traditional CRP arms. Changes in HRQL at 3 and 12 months were assessed using the Short Form-36 (SF-36) from the Medical Outcomes Study. **Results:** Mixed-model analyses yielded significant Baseline  $\times$  Gender  $\times$  Treatment interactions for the self-reported mental health component and the Vitality subscale of the SF-36. Decomposition of these interactions revealed that men in both exercise therapy groups and women in the GMCB treatment with low baseline values demonstrated more favorable improvements in the HRQL perceived mental health measures than women in the CRP treatment. **Conclusions:** Improvements in HRQL among older adults enrolled in cardiac rehabilitation differ as a function of treatment, gender, and initial mental health status. Results are discussed in terms of the implications for the design of future physical activity interven-

tions among older adults with cardiovascular disease and the measurement of their HRQL.

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## INTRODUCTION

Cardiovascular disease (CVD) presents significant challenges to the physical functioning and maintenance of independence among older adults (1,2) and thus to their health-related quality of life (HRQL) (3). Although improving medical outcomes such as physical functioning through exercise therapy is an indisputable goal of cardiac rehabilitation programs (CRPs), it is also increasingly acknowledged that patients' appraisals of their physical functioning and quality of life are indispensable to gaining a comprehensive understanding of the disease process (4).

### HRQL as a CRP Outcome

Following cardiovascular events, many patients experience reactive psychological disturbances and reductions in HRQL (5,6). Elevations in psychological distress are associated with increased mortality and morbidity during recovery from CVD (5,7,8). Thus, perceptions of mental and physical health status following a cardiovascular event and during recovery from an event are clearly associated with negative health outcomes.

More recent findings suggest that CRP is associated with reductions in psychological distress (9) and depression (7). Linden et al. (10) conducted a meta-analysis of 23 CRP studies to examine the hypothesis that psychosocial interventions plus standard-care CRP improved a variety of physical and psychosocial outcomes as compared to standard care alone. They noted that reductions in psychosocial distress were observed across studies (i.e., anxiety and depression) as reflected by a significant but modest effect size. Dusseldorp et al. (5) since concluded that the meta-analytic evidence on psycho-educational programs, including that from the Linden et al. review, may be equivocal. In Dusseldorp et al.'s (5) study, it was

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suggested that the divergent results observed between the two meta-analyses may be attributable to the inclusion of two large-scale trials, both of which yielded negative results. Whereas the factors responsible for the mixed findings remain unclear, these contrasting meta-analytic results suggest that further research is warranted on the effect that CRP interventions have on quality of life.

### Differential Treatment Response

Although CRPs may produce improvements in a variety of health outcomes, including HRQL, it is important to acknowledge that the favorable effects of CRP on HRQL may not be consistent across all participants (5). To illustrate the importance of considering differential treatment response, examples of the influence of gender and of initial health status are presented.

*Gender.* The psychosocial benefits of CRPs have been investigated more extensively in men than in women (8), and women have been found to report significantly higher depression than men during CRPs (11). Women also exhibit poorer psychosocial profiles at entry into CRP (12) and demonstrate significantly greater attrition and lower attendance during exercise therapy (8). Some of the probable reasons for a number of these disparities may be attributable to the fact that women have lower rates of entry into CRPs (13), and thus results may be based on selective sampling. On a more promising note, recent investigations suggest that women who successfully complete cardiac rehabilitation experience improvements in both health status (14) and psychological well-being similar to those observed in male CRP patients (12). However, the mitigating factors of nonrandom sampling and inconsistency of study design (15) restrict the generalizability of these positive findings. Unfortunately, systematic examinations of gender differences in cardiac rehabilitation remain sparse (3).

*Initial health status.* Initial health status is another possible cause of differential patient responsiveness to treatment. For example, the treatment impact observed in various studies concerning reduction in emotional distress was found to occur only among CRP patients who reported high distress when initially hospitalized (5). This observation suggests the possibility that individuals most at risk for distress have the greatest to gain, whereas those not at risk show little change in their response to treatment on this aspect of HRQL. Also, not all studies report postintervention results adjusted for pretest health status differences. It appears to be atypical to use baseline levels of HRQL as predictors to consider their interactive effects with response to treatment. Consequently, differential responsiveness of more frail patients within and across treatments could be overlooked and the impact of treatment on HRQL misinterpreted. A systematic analysis of the psychosocial outcomes associated with exercise therapy among older adults enrolled in CRPs has yet to be delineated (3).

### The Need for a Different Approach

Exercise therapy has been consistently shown to improve the functional capacity of older adults (16). However, a cognitive-behavioral component may be required for physical activity interventions to have positive effects on other relevant outcomes such as HRQL and long-term adherence (16,17). Although the use of cognitive-behavioral models of change to encourage adherence to physical activity is consistent with the recommendations of Meichenbaum and Turk (18), relatively few investigations have examined the role of such approaches in CRP (5,10). Also, in their recent meta-analysis of psycho-educational programs for coronary heart disease patients, Dusseldorp et al. (5) noted that future interventions should be based on theory-driven research.

For most patients, traditional exercise therapy provides neither the motivation nor the instruction and practice in developing self-regulatory skills necessary for the transition from structured, center-based exercise to home-based lifestyle physical activity and adherence to this change (19). Accordingly, a different approach to CRP is needed to encourage patients to learn lifestyle adaptations and to adhere to the skills that encourage self-regulation of health behavior. Our investigation examined the effectiveness of a different approach to CRP as it relates to change in subjective health status (HRQL).

We developed and tested the efficacy of a new multi-component CRP approach for use in cardiac rehabilitation with older adults. This intervention is based on research on social-cognitive theory (20) and group dynamics (21,22) and has been successful in stimulating increased adherence to independent physical activity in sedentary, asymptomatic older adults (19).

Although the results of a recent review suggest that CRP produces a variety of health benefits among the elderly (23), surprisingly few randomized trials have been devoted to the study of older adults (24) enrolled in CRP. Several behavior change strategies have been incorporated into structured, multi-component CRPs to improve compliance (25). However, most studies have been pre- or quasi-experimental and have not been based on established theories of behavior change (26). Consequently, knowledge of the efficacy of multicomponent CRPs across gender and age is limited (3). Furthermore, adherence to CRPs remains problematic, with approximately 50% of all patients demonstrating recidivism within 6 months of initiating therapy (3). Therefore, determining how to maintain exercise adherence for CRP participants in general, and for underrepresented population subgroups in CRPs specifically (i.e., women and older adults), represents a major public health challenge.

This investigation had several objectives. First, among older adults enrolled in cardiac rehabilitation, we sought to compare a theoretically driven, group-mediated cognitive-behavioral physical activity program (GMCB) with traditional CRP on changes in subjective health status at 3 and 12 months. Second, we wished to address the research problems associated with the study of gender differences in the psychosocial outcomes of CRP, by recruiting and analyzing the responses of a

stratified sample based on gender. Third, and finally, we wished to examine whether changes in HRQL measures were influenced by preintervention levels of these variables, because it has been suggested that baseline values may moderate the observed effects in randomized trials of physical activity (4,27).

## METHOD

### Participants

Participants for this study were recruited from the Triad region of North Carolina, within a 50-mile radius of Wake Forest University. To enable us to make a gender comparison, the study design was such that we stratified the sample by gender. Recruitment strategies consisted of mass mailings, mass media advertisements, and requests from local physicians targeting age-eligible older adults with CVD. One hundred forty-seven older adults (77 men and 70 women) over the age of 50 were randomized into the trial. The sample was heterogeneous with regard to income. In addition, nearly 50% of the participants had arthritis, and over 70% were found to be hypertensive. Approximately 75% of the sample had documented heart disease, with the remainder of the sample diagnosed at risk for heart disease. A more comprehensive description of the sample's demographic characteristics has been provided elsewhere (28,29). The final sample consisted of 132 older adults with a mean age of 64.80 years ( $SD = 6.94$ ). All participants met the following inclusion criteria: (a) between the age of 50 and 80 years; (b) documented evidence of a myocardial infarction, percutaneous transluminal angioplasty, chronic stable angina, New York Heart Association Type I or Type II congestive heart failure, or cardiovascular surgery (coronary artery or valvular heart disease) in the past 6 months, or self-reported presence of two or more major risk factors for cardiovascular disease; (c) disability, defined as self-reported disability with walking 0.25 mile, climbing stairs, lifting and carrying groceries, or performing other household chores, such as cleaning and doing yard work; and (d) not actively engaging in exercise or cardiac rehabilitation for the preceding 6 months.

Self-reported exclusion criteria at screening included (a) psychiatric illness, such as treatment for major depression or schizophrenia within the past 5 years; (b) severe symptomatic heart disease, such as evidence of unstable angina, New York Heart Association Type III or IV congestive heart failure, or exercise-induced complex ventricular arrhythmias; (c) severe systemic disease, such as chronic liver, kidney, or rheumatic disease; (d) active treatment for cancer; (e) hearing or sight impairments; (f) cognitive impairment; (g) alcohol consumption greater than 21 drinks/week, or alcoholism; (h) inability to speak or read English; (i) judgment of clinical staff; and (j) current participation in another medical intervention study.

### Measures

*Short Form-36.* The Short Form-36 (SF-36) is a generic measure of health status/HRQL. This measure consists of two norm-based composite T-scales (Mental Health and Physical Health) and eight subscales (Physical Functioning, Mental Health, Role-Physical, Role-Emotional, Bodily Pain, General

Health, Vitality, and Social Functioning), with higher scores representing better functioning. The norm-based composite scales both have a mean of 50 and a standard deviation of 10, whereas the subscale scores range from 0 to 100. Extensive data have been published in support of the psychometric properties of this instrument (30), and it has been used in randomized clinical trials involving physical activity interventions among older adults (27,31).

*Attendance.* Attendance to structured exercise therapy sessions during the intensive phase of the trial (i.e., first 3 months) was recorded for each participant. We wished to determine whether compliance to the frequency component (a goal of at least 3 days/week) of the exercise prescription was similar between the GMCB and CRP conditions and between male and female participants. Attendance was calculated by dividing the number of sessions attended by the number of sessions possible. However, given that the number of center-based sessions offered was different between the CRP and GMCB groups, it should be recognized that calculating attendance in the GMCB treatment involved the consideration of both center-based and home-based exercise sessions. A more detailed explanation of the attendance calculations has been provided elsewhere (28,29).

### Trial Design

Prior to participation in the intervention, patients visited the laboratory on three separate occasions for preliminary screening tests, baseline assessments, and completion of informed consent. During the first screening visit, a blood sample was collected from each participant; psychological instruments assessing HRQL, depression, and affect were administered; and participants completed a 6-min walk test. During the second screening visit, each participant completed a symptom-limited graded exercise test, his or her height and weight were measured, and body fat was assessed using a three-site skinfold caliper method. In addition, an activity accelerometer, a pedometer, an activity log, and a 3-day food record was given to each participant to record daily physical activity and dietary intake during the next week. The third screening visit was conducted 1 week after the second screening visit. During this third visit, participants returned the accelerometer, the pedometer, and the activity and food logs; underwent a modified 7-day recall interview; and received feedback regarding their blood test values and treadmill test results. When the three screening visits were completed and the participants were deemed eligible for participation in the trial, participants were randomized into one of the two treatments, stratified by gender. The groups consisted of a standard CRP and a GMCB program that represented CRP exercise therapy augmented with group-motivated behavior change.

### Description of the Treatments

The procedures for the center-based exercise therapy sessions were identical for both treatments. These procedures were consistent with the established guidelines for cardiac rehabilitation as outlined by the American Association of Cardio-pulmonary and Pulmonary Rehabilitation (AACVPR) (32).

Certified exercise leaders who were trained to deliver the two interventions according to specific protocols led the groups. Their leadership underwent constant evaluation by the study investigators to preserve the treatment fidelity

**CRP.** The CRP treatment arm consisted of 3 months of center-based training performed 3 days/week. Each exercise session involved four phases: (a) a warm-up (5 min), (b) an aerobic stimulus phase (30–35 min), (c) an upper extremity strength training phase (15–20 min), and (d) a cool-down phase that included stretching exercises (5 min). The warm-up phase consisted of slow walking and four calisthenic type exercises: arm circles, shoulder and chest stretch, calf stretch, and hamstring stretch. During the aerobic stimulus phase, participants were instructed to walk at an intensity of 50% to 85% of heart rate derived by the following formula: training heart rate range = [(symptom limited maximum heart rate – resting heart rate) × desired proportion {or percentage/100}] + resting heart rate. Participants were encouraged to walk for the entire 35 min within their training heart rate range; however, individual adjustments were made depending on abilities to meet the exercise goals. Heart rates were taken and recorded after 10, 20, and 35 min of exercise during the aerobic stimulus phase. Participants were instructed to monitor and record their heart rates after 10 and 35 min of exercise. After 20 min of exercise, participants' heart rates and electrocardiogram readings were recorded using a Physio-Control Lifepak9 cardiac monitor defibrillator (Medtronic Physio-Control, Redmond, WA). The upper extremity strength training phase consisted of five resistance exercises using small hand weights designed to increase strength in the muscles of the arms and shoulder girdle. The exercises included overhead dumbbell press, overhead triceps extension, biceps curl, upright row, and side bends. Participants were asked to perform one set of 10 repetitions of each exercise. A cool-down phase consisting of stretching exercises was performed following the upper extremity strength training. After the stretching exercises, participants self-monitored and recorded a final cool-down heart rate. In addition to exercise therapy, weekly educational lectures were given on topics that related to modification of risk factors for cardiovascular disease. These procedures are consistent with the established guidelines for CRP as outlined by the AACVPR (32).

**GMCB.** Recall that the theoretical foundation for the cognitive-behavioral aspect of the GMCB intervention was drawn from social-cognitive theory (20), whereas the group motivational aspect was based on the group dynamics literature (21,22). The GMCB treatment arm included the same forms of exercise as prescribed for the CRP condition, and both groups received the same total number of contact hours over the entire course of the trial. However, during the first 3-month phase of the trial the overall goals, structure, and timing of the GMCB condition differed from the CRP condition. For instance, the goal of the GMCB condition was to gradually wean participants from dependency on the staff and group program toward independent self-regulation of physical activity. During the first 3-month period, there was a process of phased increase in per-

sonal responsibility for exercise among participants in conjunction with a phased decrease in staff, group, and clinic dependency. Participants were challenged to integrate physical activity into their daily lives via planned homework assignments that were individually tailored. These experiences were discussed in subsequent group sessions for purposes of group encouragement, motivation, and support. For the 1st and 2nd months, participants engaged in center-based exercise therapy two times each week. During the 3rd month, center-based training was reduced to one time per week. In each of these months, self-planned home-based activity by the participants provided the additional sessions of exercise for a frequency equivalent to the CRP treatment.

Following each exercise therapy session, participants engaged in a 20- to 25-min period of instruction and discussion regarding learning and using self-regulatory tools in order to maintain long-term physical activity. For instance, during the 1st month, participants were asked to identify their primary motivations for becoming more active. In addition, participants were introduced to the concept of self-monitoring of overall physical activity by using Digi-walkers (New Lifestyles, Inc., Lee's Summit, MO), which measure the number of steps taken. Digi-walker values were recorded on activity logs. In addition, participants were taught how to record the frequency (days per week), intensity (heart rate and rating of perceived exertion), time, and type of exercise on activity logs. Also during this period, individual and group goal setting for exercise were discussed. Participants were instructed on how to set appropriate goals and how to deal with failure to meet goals.

During Month 2, discussion focused on the concept of becoming an "independent exerciser" and how to plan home-based exercise that is safe and effective. Counseling between clinic staff and participants was coupled with peer-initiated solutions on how to maintain an active lifestyle. Throughout this period, strategies were discussed on how to overcome barriers, and lapses in exercise. The importance of group support to promote independent exercise and these solutions and strategies were reinforced during this time.

In Month 3, group discussions focused on the recognition that, as individuals and as a group, participants had reached a stage of rehabilitation in which they could view themselves as "active people." At this stage, discussions focused on how to use environmental cues to facilitate activity goals, develop plans to deal with common barriers, recognize signs of relapse, and how to avoid or deal with relapse. Attention was given to raising awareness of the progress that participants had achieved over the past 3 months, the importance of developing and maintaining their own independent activity programs, and the plans they had developed for the 1st month of independence from center-based activity. In sum, participants prepared themselves for independence and weaning from the rehabilitation group environment.

Months 4 through 9 represented the home-based phase of the trial. During this phase, staff contact with participants in the GMCB condition was less intensive than in the center-based phase of the trial and was accomplished through the combination of booster exercise sessions, phone contacts, newsletters, and participants' mailing their completed monthly mail-back

activity cards to the center. A booster exercise session was held at the center during Months 4, 6, and 9. In addition, participants received two phone calls from the staff during Months 4, 5, and 6, and they received one phone call during Months 7, 8, and 9. The purpose of the booster sessions and the phone calls was to discuss the progress of each participant's exercise program, to identify potential barriers, and to use either the group setting (booster sessions) or individual contact (phone calls) to develop strategies to overcome barriers and lapses. In addition, newsletters were mailed to participants at the end of Months 4 through 9. The newsletters contained educational information regarding cardiovascular disease, exercise, and nutrition, and provided updates on the GMCB participants who were in each specific "wave." In addition, the newsletters contained a blank mail-back activity card with a stamped envelope to be returned to the center. The participants recorded on the mail-back cards their goals and the frequency and duration of exercise for each week of the previous month. As part of the ongoing self-monitoring portion of the GMCB intervention, participants recorded their activity throughout the month and then transferred this information onto the mail-back card. In addition, they recorded their total steps for each week and whether they planned to maintain, decrease, or increase their activity for the next month. Finally, they identified barriers to their activity in the previous month and recorded how they planned to overcome these barriers. Completed cards were then mailed back to the center.

During Months 9 through 12, participants engaged in home-based activity completely independent of contact initiated by the staff. However, participants were told that contact initiated by them was welcome. To summarize, this phase of the trial provided participants with the maximum opportunity to engage in independent exercise and was structured so that the relationship between the participants and staff was collaborative in nature rather than directive.

### Statistical Analyses

Descriptive statistics were calculated for participants who completed the SF-36 at baseline and at least one of the 3- and 12-month visits. The primary analysis was a mixed-model analysis of covariance (ANCOVA) using the intention-to-treat principle with a random effect for participants and a fixed effect for treatment group. We used a random effect for participants to allow for within-subject correlation of the repeated measurements. Analyses were conducted using SAS PROC Mixed, a procedure that used all of the available follow-up information collected at the 3- and 12-month assessments by providing maximum likelihood estimates for missing data. The method enables missing data to be dependent on baseline and other observed data and provides unbiased estimates making a missing-at-random assumption. Covariates included age, gender, visit (3 or 12 months), and the value of the response at baseline as fixed effects. The three-way interaction of baseline level, treatment, and gender and the three two-way interactions were also included. Backward selection (with  $p \leq .15$  for inclusion) was used to reduce the model. If an interaction was included, then all component interactions and main effects were also in-

cluded. The primary results reported use the change from baseline as the response variable. Adjusted means and their standard errors were calculated with the Treatment  $\times$  Time interaction in the models. The adjusted means from these models were used to create the figures. This model was used for the Mental and Physical Health summary scales and for the Physical Function, General Health, and Vitality subscales. For variables where the normality assumption was not justified (Role-Physical, Bodily Pain, Social Functioning, Role-Emotional, and Mental Health), we used the Wilcoxon rank sum test to compare the change from baseline between the treatments at the 3- and 12-month visits. The normality assumption was not justified for these variables because of ceiling effects or extreme discreteness of the data. SAS Version 8.2 was used for analysis. Alpha was set at  $p < .05$  for significance testing.

## RESULTS

### Study Attrition

Nineteen participants were lost to attrition. Nine of these individuals left the study because of personal or family illness. Four individuals left the study because of psychological complications. One participant left the trial because of job demands, and 5 individuals left the study because of noncompliance with the interventions. Overall, 6 participants were lost from the CRP group and 8 participants were lost from the GMCB group after the initiation of the intervention. It should be acknowledged that 5 individuals in the GMCB group left the study after they were randomized but before the intervention began. The loss to GMCB follow-up was due, in part, to a personal health complication or family illness ( $n = 4$ ). In summary, the rate of retention from baseline to 3 months of this study was 83.6%, which is comparable to that reported in other studies of older adults (16). Consistent with the CONSORT statement guidelines for reporting the results of randomized clinical trials (33), a flow diagram depicting the number of eligible participants for the trial, the number randomized to each treatment group, and the number completing each follow-up assessment is provided in Figure 1.

### Adherence to the Intensive Phase of the Intervention

The intensive phase of the intervention involved the first 3-month segment of the trial. Because standard CRP included 3 days of physical activity each week, we compared the frequency with which this goal was met by the men and women in each treatment group. Adherence was expressed as a percentage of the total number of sessions attended during the intensive phase (i.e., first 3 months) of the trial. Using analysis of variance, we found significant main effects for gender,  $F(1, 100) = 6.17, p < .05$ , and treatment,  $F(1, 100) = 15.04, p < .05$ . The interaction term was not significant. Inspection of the means associated with these effects revealed that men ( $M = 88.54\%$ ,  $SE = 2.34$ ) demonstrated significantly better adherence than women ( $M = 80.22\%$ ,  $SE = 2.39$ ). In addition, participants in the GMCB treatment ( $M = 90.88\%$ ,  $SE = 2.65$ ) demonstrated significantly better adherence than participants in the CRP group ( $M = 77.88\%$ ,  $SE = 2.04$ ).

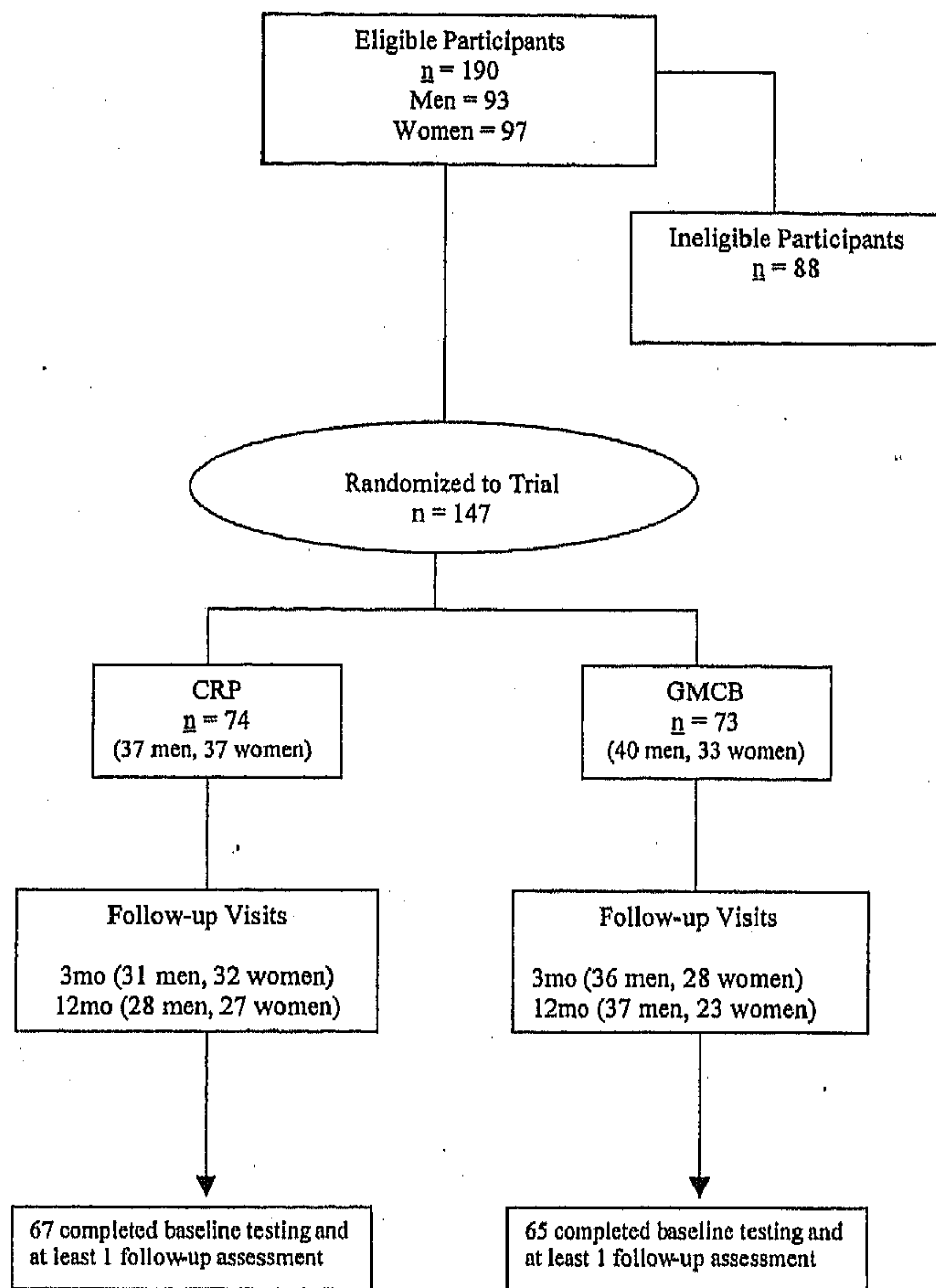


FIGURE 1 Flow chart for the CHAMP trial. CRP = traditional cardiac rehabilitation program; GMCB = group-mediated cognitive-behavioral program; mo = months.

**Outcomes**

The descriptive statistics on the study outcomes for participants in GMCB and CRP treatment conditions across time are presented in Tables 1 and 2. Mixed-model ANCOVAs revealed a number of significant effects. Most notable, however were significant three-way interactions for the Mental Health composite scale and for the Vitality subscale of the SF-36; details of these analyses are presented in the sections that follow.

*Mental Health Composite Scale.* Analysis of change in the Mental Health composite scale yielded significant two-way Gender  $\times$  Treatment,  $F(1, 110) = 15.96, p < .0001$ , and Baseline  $\times$  Gender interactions,  $F(1, 110) = 5.45, p = .0214$ . These interactions were superseded by a significant three-way Baseline  $\times$  Gender  $\times$  Treatment Arm interaction,  $F(1, 110) = 16.60, p < .0001$ . Inspection of the plot illustrating the three-way interaction using adjusted means (see Figure 2) illustrates that GMCB men, CRP men, and GMCB women with the lowest baseline values demonstrated greater improvement in perceived mental health when compared to women in the CRP group.

*Vitality.* Analysis of change in the Vitality subscale produced significant two-way Gender  $\times$  Treatment Arm,  $F(1, 112)$

TABLE 1  
Means and Standard Deviations for the Short Form-36 Composite Physical and Mental Health Summary Scales for Men and Women in the GMCB and CRP Treatment Groups

| Variable                      | Baseline |       | 3-Month |       | 12-Month |       |
|-------------------------------|----------|-------|---------|-------|----------|-------|
|                               | M        | SD    | M       | SD    | M        | SD    |
| Physical Health summary scale |          |       |         |       |          |       |
| GMCB men                      | 43.13    | 8.43  | 44.95   | 9.45  | 43.65    | 10.51 |
| GMCB women                    | 36.64    | 9.27  | 40.55   | 8.98  | 43.20    | 9.95  |
| CRP men                       | 43.46    | 9.47  | 45.32   | 9.22  | 44.64    | 8.99  |
| CRP women                     | 41.93    | 10.65 | 42.68   | 10.17 | 43.09    | 9.18  |
| Mental Health summary scale   |          |       |         |       |          |       |
| GMCB men                      | 52.88    | 9.46  | 56.11   | 6.37  | 55.69    | 6.88  |
| GMCB women                    | 54.94    | 7.27  | 55.74   | 6.33  | 52.98    | 9.08  |
| CRP men                       | 56.02    | 7.60  | 57.15   | 4.43  | 57.32    | 6.42  |
| CRP women                     | 51.50    | 7.74  | 52.84   | 9.88  | 53.26    | 9.53  |

Note. GMCB = group-mediated cognitive-behavioral; CRP = traditional cardiac rehabilitation program.

= 5.86,  $p = .0171$ , and Baseline  $\times$  Treatment Arm,  $F(1, 112) = 4.53, p < .0355$ , interactions. These interactions were superseded by a significant three-way Baseline  $\times$  Gender  $\times$  Treatment Arm interaction,  $F(1, 112) = 5.96, p < .0162$ . Inspection of the plot illustrating the three-way interaction using adjusted means (see Figure 3) illustrates that GMCB men, CRP men, and GMCB women with the lowest baseline values demonstrated greater improvement in vitality when compared to women in the CRP group.

For the remaining models concerning the tests of the other subscales of the SF-36, there were no significant main effects or interactions with treatment arm. However, baseline levels of these subscales were always highly significant predictors of their final levels. Finally, there were no significant differences between the treatment groups for the five subscales where we used the Wilcoxon rank sum test at either 3 or 12 months. In summary, the Mental Health composite scale and the Vitality subscale were sensitive to the differential responsiveness of the older adults in the two arms of the trial.

**DISCUSSION**

Patients' appraisals of their health status have important implications for improvements in various health outcomes (4). Consistent with this position, our findings indicate that specific aspects of HRQL are salient outcomes for cardiac rehabilitation programs. This study examined the effects of two different approaches to cardiac rehabilitation on HRQL among older adults. The treatments compared in this randomized trial were a group-mediated cognitive-behavioral physical activity intervention and a traditional exercise therapy program. Consistent with the results of previous reviews (4,17,27), the results revealed that each physical activity intervention produced improvements in selected indices of HRQL. In addition, we addressed future research recommendations presented in a recent

TABLE 2  
Means and Standard Deviations for the Short Form-36 Subscales for Men and Women in the GMCB and CRP Treatment Groups

|                           | Baseline |       | 3-Month |       | 12-Month |       |
|---------------------------|----------|-------|---------|-------|----------|-------|
|                           | M        | SD    | M       | SD    | M        | SD    |
| <b>Physical Function</b>  |          |       |         |       |          |       |
| GMCB men                  | 71.41    | 20.09 | 76.29   | 21.37 | 74.54    | 23.33 |
| GMCB women                | 55.24    | 20.96 | 65.94   | 16.82 | 67.98    | 17.49 |
| CRP men                   | 72.11    | 18.03 | 73.19   | 20.64 | 73.92    | 20.75 |
| CRP women                 | 64.39    | 21.43 | 67.68   | 21.71 | 67.17    | 20.38 |
| <b>Role-Physical</b>      |          |       |         |       |          |       |
| GMCB men                  | 66.41    | 38.94 | 78.23   | 31.45 | 69.64    | 38.70 |
| GMCB women                | 49.24    | 40.26 | 66.41   | 39.46 | 66.67    | 36.69 |
| CRP men                   | 65.13    | 41.32 | 74.31   | 37.07 | 74.32    | 32.54 |
| CRP women                 | 60.34    | 42.00 | 71.43   | 38.92 | 72.83    | 35.29 |
| <b>Bodily Pain</b>        |          |       |         |       |          |       |
| GMCB men                  | 69.31    | 21.10 | 71.58   | 23.66 | 72.00    | 27.14 |
| GMCB women                | 60.79    | 23.74 | 62.22   | 24.10 | 73.63    | 21.10 |
| CRP men                   | 73.45    | 20.35 | 74.50   | 19.23 | 70.62    | 23.33 |
| CRP women                 | 67.34    | 22.95 | 63.46   | 21.82 | 61.61    | 18.85 |
| <b>General Health</b>     |          |       |         |       |          |       |
| GMCB men                  | 60.34    | 17.79 | 63.29   | 16.56 | 60.86    | 22.12 |
| GMCB women                | 56.70    | 20.21 | 59.34   | 20.05 | 60.19    | 18.24 |
| CRP men                   | 68.18    | 17.26 | 71.47   | 17.75 | 70.08    | 17.50 |
| CRP women                 | 60.55    | 22.88 | 61.43   | 21.98 | 66.00    | 20.32 |
| <b>Vitality</b>           |          |       |         |       |          |       |
| GMCB men                  | 53.75    | 22.29 | 65.48   | 17.86 | 63.87    | 18.00 |
| GMCB women                | 50.05    | 19.83 | 60.21   | 13.33 | 55.19    | 18.68 |
| CRP men                   | 60.13    | 19.36 | 69.03   | 16.73 | 66.62    | 17.16 |
| CRP women                 | 57.24    | 18.40 | 59.46   | 20.74 | 61.09    | 22.56 |
| <b>Social Functioning</b> |          |       |         |       |          |       |
| GMCB men                  | 87.11    | 18.10 | 90.73   | 19.62 | 87.95    | 22.69 |
| GMCB women                | 84.47    | 18.76 | 87.11   | 16.34 | 87.04    | 15.69 |
| CRP men                   | 85.53    | 20.24 | 92.01   | 12.73 | 89.86    | 17.39 |
| CRP women                 | 80.60    | 23.29 | 83.04   | 21.30 | 85.33    | 20.87 |
| <b>Role-Emotional</b>     |          |       |         |       |          |       |
| GMCB men                  | 80.21    | 36.77 | 88.17   | 23.65 | 85.71    | 27.86 |
| GMCB women                | 83.84    | 29.01 | 85.42   | 28.00 | 79.01    | 32.22 |
| CRP men                   | 92.11    | 25.03 | 86.11   | 26.87 | 87.39    | 27.61 |
| CRP women                 | 74.71    | 37.43 | 79.76   | 29.17 | 78.26    | 37.08 |
| <b>Mental Health</b>      |          |       |         |       |          |       |
| GMCB men                  | 79.38    | 14.59 | 84.81   | 10.85 | 84.54    | 9.19  |
| GMCB women                | 78.18    | 13.71 | 81.56   | 11.41 | 79.19    | 14.12 |
| CRP men                   | 84.21    | 13.95 | 86.61   | 8.58  | 88.22    | 10.49 |
| CRP women                 | 74.62    | 13.91 | 77.29   | 14.93 | 77.74    | 17.00 |

Note. GMCB = group-mediated cognitive-behavioral; CRP = traditional cardiac rehabilitation program.

meta-analytic review of HRQL among older adults in the Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) trials (27) by identifying types of older adults most responsive to intervention and by examining the effects of adherence to treatment. In this regard, gender and baseline health status were found to moderate these positive responses to the exercise therapy interventions.

The most distinctive findings were the significant Gender  $\times$  Baseline  $\times$  Treatment interactions obtained for the specific HRQL indices: the Mental Health composite scale and the Vitality subscale. Decomposition of these interactions revealed that CRP men, GMCB men, and GMCB women exhibited more favorable changes in self-reported mental health status and vitality than did CRP women. Also, older adults with lower baseline health status showed greatest improvement. Finally, adherence was found to differ as a function of both treatment group and gender for the intensive phase of the trial. Specifically, men were more adherent than women, and older adults in the GMCB treatment had superior adherence compared to those in the CRP treatment.

### Moderators of Treatment Response

Whereas the significant three-way interactions for composite mental health and vitality underscore the importance of evaluating the influence of gender differences in baseline status on the health outcomes of CRP, they also provide evidence that other factors may contribute to the divergent gender responses to CRP treatment.

The importance of these interactive effects is twofold. First, they suggest that cardiac rehabilitation patients with lower self-perceptions of mental health status and vitality gain the greatest benefit following exercise therapy. Second, although it has been previously documented that men have exhibited more favorable responses to CRP (3,8), these results have been criticized because of the selective sampling and attrition of female participants. This study remedied these problems by (a) ensuring random assignment of genders to treatment, (b) avoiding selective attrition by gender, and (c) taking into account the interaction of initial health status with gender and treatment. The findings indicate that coupling exercise therapy with group-mediated cognitive-behavioral counseling may facilitate improvements in women's perceived mental health status that are comparable to those experienced by men.

Explanations for the interactive responses we obtained require some consideration of previous research. In earlier studies, women have reported higher social inhibition than men on entry into CRP (12). Given the favorable improvement in perceived mental health among the GMCB women, it is plausible that the group-based counseling and social interaction within the GMCB treatment helped reduce the uneasiness reported by many women who enroll in cardiac rehabilitation. The GMCB treatment attempted to foster a lifelong commitment to independent physical activity through the improvement of cognitive-behavioral skills. Group interaction for the purpose of developing independent self-regulation was an integral component of the intervention. Recall that the treatment included setting specific behavioral goals, involvement in group discussions that focused on problem solving and commitment, and sharing achievements and setbacks with other members of the group, as well as training in self-regulatory skills and acquiring social support. Whereas in previous research social inhibition has been found to be particularly salient among women enrolled in CRP (8), it appears that the GMCB intervention may facilitate more

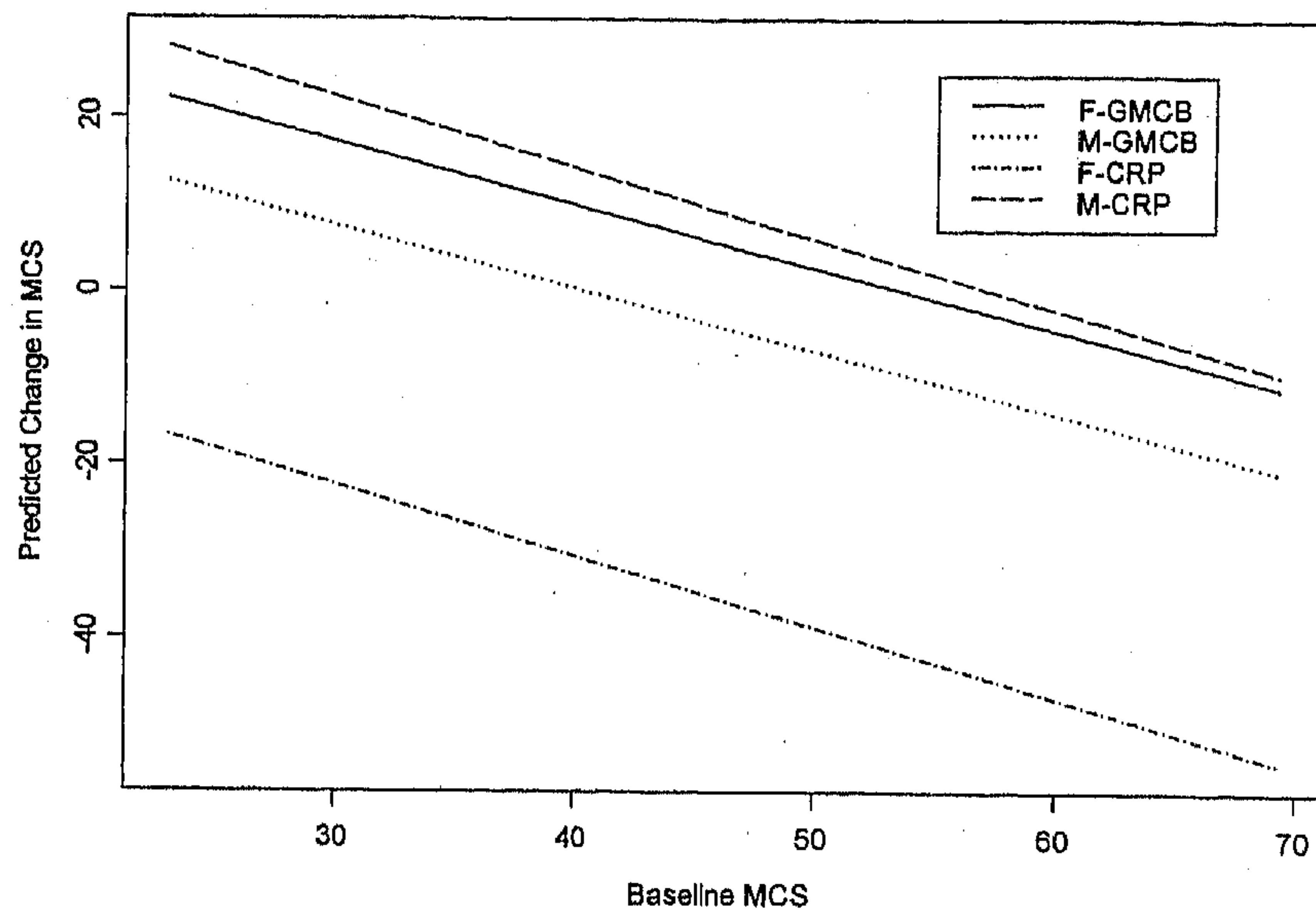


FIGURE 2 Combined effect of gender, treatment, and baseline performance on change in the Mental Health composite summary scale. Test for differences in slopes,  $F(3, 112) = 7.52, p < .0001$ . F = female; M = male; GMCB = group-mediated cognitive-behavioral program; CRP = traditional cardiac rehabilitation program; MCS = Mental Health composite scale.

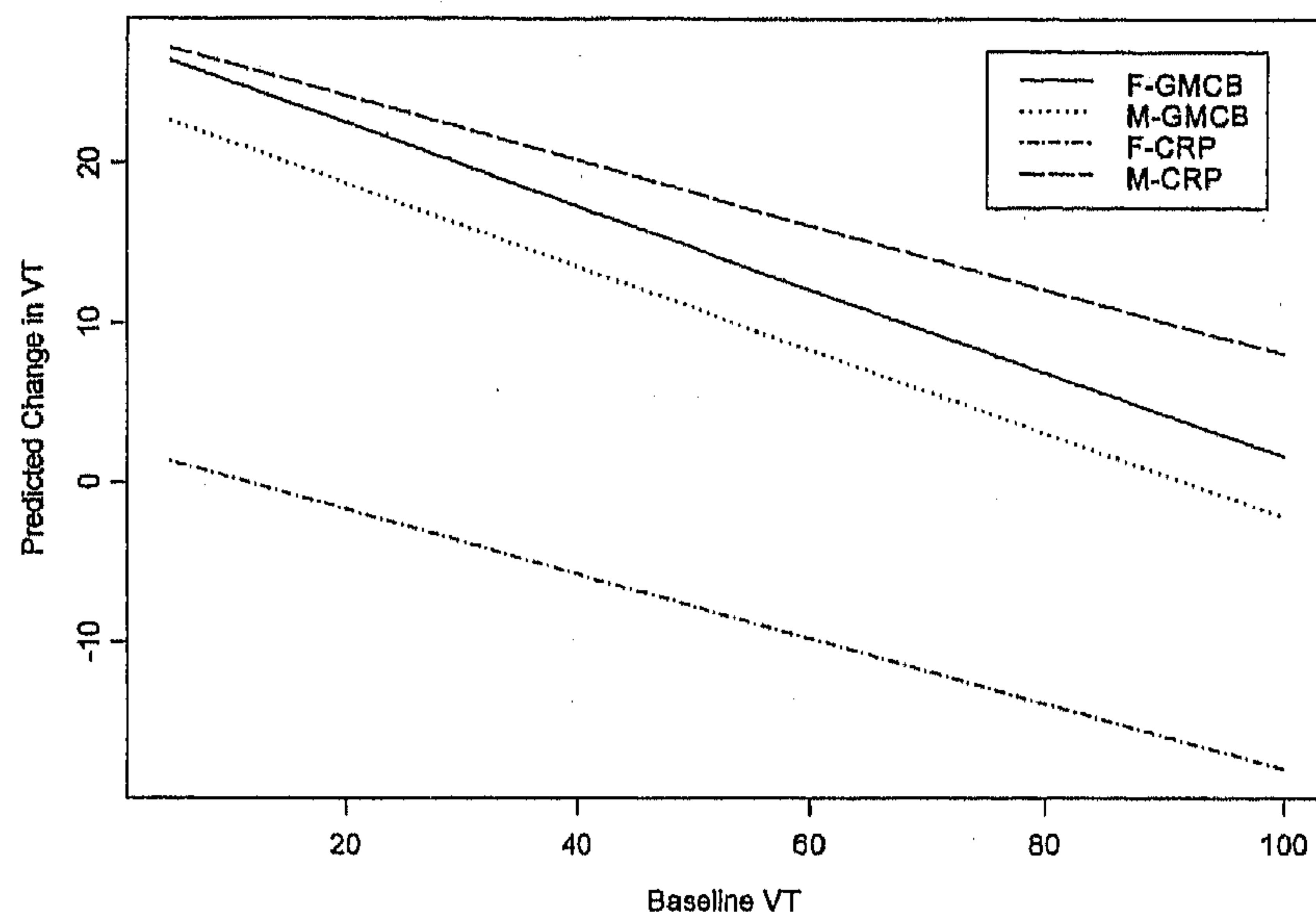


FIGURE 3 Combined effect of gender, treatment, and baseline performance on change in vitality. Test of equality of slopes,  $F(3, 112) = 3.10, p < .0295$ . F = female; M = male; GMCB = group-mediated cognitive-behavioral program; CRP = traditional cardiac rehabilitation program; VT = vitality.

favorable psychosocial adjustment to CRP. However, to test the veracity of this explanation, additional research using a similar intervention, design, and stratification by gender is required.

The sensitivity to change found for the Vitality subscale of the SF-36 is consistent with Thayer's (34) work, which suggests that perceptions of energy are important determinants of mood and quality of life. In this regard, it is important to recognize that many older adults burdened with chronic disease cite fatigue or a lack of energy as a primary motive for sedentary behavior (35). Furthermore, among older adults with CVD, feelings of exhaus-

tion have been associated with greater attrition from cardiac rehabilitation (12) as well as increased risk for myocardial infarction (36). In light of these reports, the elevation in vitality observed in our investigation represents an important finding with significant implications for the delivery of physical activity interventions among older adults with chronic disease. It is quite possible that interventions that produce enhanced perceptions of energy may also promote more favorable changes in perceived health status and compliance with the therapeutic regimen. Thus, monitoring feelings of energy and fatigue during rehabili-

tation and tailoring physical activity programs to specifically target these outcomes through self-regulatory skills training (i.e., as in the GMCB) may enhance compliance among older adults enrolled in CRPs. Nevertheless, this speculation requires more detailed inquiry into the processes accounting for changes in HRQL.

### Adherence

Finally, during the intensive phase of the intervention, the GMCB treatment produced superior adherence to the activity prescription when compared to the traditional CRP program. The findings of better exercise adherence within the GMCB group and the superior improvement in perceived mental health status and vitality observed for GMCB women collectively support the notion that improvements in HRQL among older adults can be enhanced. Augmenting a physical activity intervention with a group-mediated cognitive-behavioral approach that focuses on independent self-regulation of activity appears to be successful in achieving these effects and combines suggestions for intervention made previously in the literature (10,16,17,19).

This study, like most others, is not without limitations. Generalizability of the results to other chronic conditions, settings, and younger adults with CVD would be premature. The results are most generalizable to older men and women participating in certified CRPs that follow AACVPR guidelines. Nonetheless, they do have substantial comparability to the older adults participating in the many clinical CRP approaches offered in North America. As concerns HRQL measurement, we used a recognized generic standard measure (the SF-36) frequently assessed in CRPs because of its apparent generalizability. However, the sensitivity of a generic measure may not be adequate to examine all of the changes in HRQL experienced by participants. Accordingly, we recommend that future studies could benefit from the addition of specific measures of facets of HRQL that would be directly affected by the intervention. Thus, effects not captured by the generic measure would be less likely to go undetected.

An obvious recommendation for the future is that we design more studies to detect the intervention processes related to specific outcome changes. Although we detected changes as a function of the combined influences of the multicomponent GMCB treatment, we cannot specifically identify which individual aspects may have functioned more effectively than others. Answers to such questions require a different study design, as we suggested earlier. The relationship between elevations in feelings of vitality, improvements in HRQL, and adherence to exercise therapy during and following CRP has yet to be adequately explained and warrants further inquiry.

In summary, the results of this study indicate that exercise therapy is a valuable intervention for improving HRQL among older adults who either have CVD or are at high risk for it. Furthermore, these findings support the position that perceived mental health status represents a salient outcome among older

adults enrolled in cardiac rehabilitation and underscore the importance of incorporating both generic and specific measures of HRQL in the design of future studies. It is also evident from this study and other research that the influence of physical activity interventions on psychological well-being and subjective health status are moderated by gender and baseline level of mental health. Therefore, additional investigations of these moderators and their effect on physical activity interventions that include group-mediated cognitive-behavioral counseling are warranted for older adults with chronic disease.

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