The Effects of Exercise on the Quality of Life of Frail Older Adults: A Preplanned Meta-Analysis of the FICSIT Trials

Kenneth B. Schechtman, Ph.D.
Washington University School of Medicine

Marcia G. Ory, Ph.D., M.P.H.
National Institute on Aging, Behavioral and Social Research

The FICSIT Group

ABSTRACT

The Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) was a linked series of randomized clinical trials focused on the benefits of exercise in the frail elderly. This article uses covariate-adjusted preplanned meta-analyses of FICSIT data to evaluate the effect of exercise on quality of life (QOL) outcomes (N = 1,733; age = 73.4 ± 6.1 years). Results indicate that (a) exercise produced a small but significant improvement in the emotional health component of QOL, trended toward an improved social component, and did not effect perceptions of general health; (b) exercise-related joint and muscle stresses did not increase bodily pain; and (c) QOL improvements were independent of changes in physical functioning. We conclude that exercise can improve QOL in the frail elderly but that the magnitude of the improvement is modest in size. The benefits of a meta-analytical approach for documenting efficacy outcomes across different types of interventions are discussed.

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INTRODUCTION

The health benefits of physical activity are well documented in epidemiological research (1). Long-term observational data from the Alameda County Study (2,3) show that leisure time physical activity is associated with reduced morbidity and mortality and better functioning in older adults. Regular exercise has been hypothesized to improve health and well-being through mechanisms that include improved self-efficacy, expanded social networks, attention effects, and direct physiological responses (4,5). Yet, until recently, prevention oriented exercise interventions have not been conducted in older populations that have been assumed to be uninterested in or unable to adopt changed lifestyles (6). These preconceptions are being challenged by recent studies that demonstrate that older people can be successfully recruited and retained in exercise programs, although long-term maintenance of health behaviors still remains an issue (7–9).

Although some intervention studies have shown that exercise may benefit frail older people (10–13), most previous research on exercise interventions has been conducted in healthy younger populations or based on small sample sizes, inadequate controls, or little standardization of outcome assessments. An exception is a set of linked randomized clinical trials, the Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) (14). These trials involved eight clinical sites and were designed to test the effectiveness of several exercise-oriented interventions in the frail elderly. The eight sites recruited more than 2,500 older persons at risk for fall-related injury.

Although FICSIT focused primarily on physiologic and fitness benefits, these trials also examined quality of life (QOL), an outcome category that has been shown to be potentially modifiable by exercise (15) and that has several domains which can be differentially affected by exercise interventions (16). The inclusion of a well-tested and widely used standardized measure makes FICSIT one of the largest controlled studies to assess the benefits of exercise on different domains of QOL in frail older adults.

The purpose of this article is to discuss the effects of exercise in older adults on four QOL scales of the Medical Outcomes Study (MOS) Short Form–36 (SF–36). We were particularly interested in whether the potential QOL benefits of exercise are partially offset by increased bodily pain resulting from the physical burden of the exercise. To address these issues, we employed meta-analysis in a unique context: when raw data were available to compute prespecified site specific covariate-adjusted summary statistics, and when there was no possibility of publication bias (17,18) and selection bias (19,20) because included studies were chosen in advance. Specifically, we performed covariate-adjusted meta-analyses to (a) assess the effect of exercise on the four QOL outcomes, (b) investigate the effects of exercise on QOL measures according to the predominant intervention type (resistance, endurance, flexibility, balance), and (c) examine the association between changes in QOL and physical function.

METHOD

Data discussed herein were collected as part of the National Institute on Aging and National Center of Nursing Research sponsored study, known as FICSIT. FICSIT was a multicenter investigation of exercise-related interventions, with outcomes including functional status, falls, fall-related injuries, and QOL. The selection of FICSIT QOL measures, and issues related to QOL assessment in the elderly, are discussed elsewhere by Kutner et al. (16).

Reprint Address: K. Schechtman, Ph.D., Washington University School of Medicine, Division of Biostatistics, Box 8067, 660 South Euclid Avenue, St. Louis, MO 63110. E-mail: ken@wubios.Wustl.EDU

The eight FICSIT clinics defined their own interventions using site-specific endpoints and evaluations and, aside from the requirement that all participants be elderly, their own eligibility requirements. At the same time, an extensive database, developed jointly by the clinical sites and the Coordinating Center at Washington University in St. Louis, contains data common to all or to several FICSIT sites. Thus, the unique FICSIT design had the flavor of a multicenter clinical trial in that eight studies were linked with a coordinating center and a large common database. Results from the four FICSIT sites that collected QOL data are included in this report. More general findings on physiological mediators and fall outcomes are found elsewhere (21). Details of the four designs, each of which is a randomized exercise trial involving community-dwelling participants, are discussed in other reports (22–25). Table 1 provides summary information about each trial, with Panel A providing general information and Panel B providing the details of the intervention.

Variables and Measures

The four dependent variables were the general health perceptions, emotional health, social functioning, and bodily pain scales of the MOS SF–36 (26–27), in which the pain scale is viewed primarily as an adverse symptom in our analysis. All scores range from 0 to 100. FICSIT began prior to the publication of the final version of the SF–36, so the prepublication version was used. However, because differences between prepublication and final versions are small, they should not affect the interpretation of results. The physical functioning subscale of the MOS was not included because this construct was treated as a covariate in these analyses.

Prospectively defined covariates were age, gender, and gait speed. Gait speed was measured in meters per second using a previously described common protocol (28). Gait speed was selected as an indicator of physical functioning because it correlates well with other physical function measures and with the risk of falling (29), and because it correlates better with self-perceived physical function than any other available physical performance measure (30). To investigate the effect of specific characteristics of the exercise programs on the outcome measures, we present each arm of each intervention according to which of four training components it included (resistance, endurance, flexibility, balance) and according to a subjective assessment of the intensity of the intervention (low, medium, or high intensity).

Intensity of the Intervention

Our meta-analytic results are presented according to a subjective categorization of the intensity of the relevant intervention as high, medium, or low. The primary determinant was the vigor of the prescribed exertion, but the ordering would correlate precisely with a measure of kilocalories burned per week that combined information about the number and duration of the sessions as well as the level of exertion. There was little ambiguity in defining the categories because the Seattle target of 75% of maximal heart rate after 2 months was by far the most vigorous, and the program in Portland that involved brisk walking was clearly the least intense because it was both less vigorous and for fewer minutes per week than in the other sites.

Statistical Analysis of Data

Our primary data analytic tool was a meta-analysis performed separately for each outcome measure. The purpose was to assess the covariate-adjusted combined effect of interventions on poststudy values. The meta-analytic approach is based on the two-stage procedure developed by DerSimonian and Laird (31) and discussed by Fleiss and Gross (32). The first stage generated summary statistics for each treatment arm in each FICSIT site. Within site regression analyses were performed with the poststudy value of the outcome measure as the dependent variable and with covariates and treatment group as predictors. For each treatment arm in each FICSIT site, these analyses yielded adjusted means plus or minus standard errors of the poststudy value of each dependent variable. Control group means were then subtracted from treatment group means, and the difference and associated standard error served as a covariate adjusted measure of the effect of each intervention in each site.

The second stage in this process used the aforementioned adjusted mean differences and standard errors as raw data that generated pooled estimates of the overall effect of interventions on each outcome measure. The pooled estimates were computed using the DerSimonian and Laird meta-analysis procedure and are applied to all nine interventions evaluated in the four FICSIT sites included in this article. We also applied these methods to four overlapping subsets of the nine interventions: those that contained a resistance component ($n = 4$ interventions), a balance component ($n = 4$), an endurance component ($n = 3$), and a flexibility component ($n = 4$).

All data were analyzed using SAS (33–34). Chi-square tests and a one-way analysis of variance tested the equality of means and proportions across sites. Because the intensity measure was subjective and could not include the component of intensity that reflects participant compliance, we had no predefined analytic strategy for dealing with this variable. Instead, a graphical presentation of the impact of each intervention is presented according to the level of intensity. Subjective evaluation of these graphs provided no obvious trends, so no formal statistical analysis of the intensity variable was performed.

RESULTS

A total of 1,733 participants from four FICSIT sites are discussed in this article. Mean age (± *SD*) was 73.4 ± 6.1 years, and 55.6% of participants were women. Table 2 contains a detailed description, by site and treatment arm, of baseline characteristics of the sample. As a reflection of the different entry criteria across sites, Table 2 reports significant between site differences in six of the seven tabulated variables.

Table 3 contains site and intervention-specific information about the covariate-adjusted effect of the individual interventions. The table describes each intervention according to whether it contains a resistance, endurance, flexibility, or balance component. Reported mean values are the adjusted postintervention values of each outcome measure. They were

TABLE 1
Characteristics of the Four Included FICSIT Trials

Panel A: General Characteristics of Trial

Site No. and Location	*Intervention (Details in Panel B)*	*N*	*Eligibility Criteria*	*Primary Outcomes*
Site 1: Portland, OR (7)	Control group versus endurance exercise group. Modify environmental risks at home to reduce falls.	1,323 in two groups	At least age 65; community dwelling; ambulatory; at least one fall in last year, a near fall in last month, or at least age 75	Falls and fall-related injuries
Site 3: Seattle, WA (23)	Modified 2 × 2 factorial design using resistance and endurance training. Reduced endurance exercise time in group receiving both interventions.	100 in four groups	Age 68–85, community dwelling, ambulatory, no severe cognitive impairment, no participation in vigorous exercise, moderate gait and balance impairments	Strength, aerobic capacity, gait,and balance
Site 5: Atlanta, GA (24)	Three groups: Control group meets once a week for education session; interventions groups are a static balance exercise group using a balance platform and a dynamic balance group using Tai Chi	200 in three groups	At least age 70, community dwelling, ambulatory, no major debilitating illness	Balance, range of motion, activities of daily living, instrumental activities of daily living
Site 8: Farmington, CT (25)	2 × 2 factorial design with balance and resistance training	110 in four groups	At least age 75, community dwelling, ambulatory, no cognitive impairment or terminal illness	Balance on balance platform, gait, functional mobility

Panel B: General Characteristics of Interventions

Site No.	*Type of Intervention*	*Method*	*Frequency of Sessions*	*Session Length*	*Duration of Trial*
1	Endurance component[a]	Large group (one/week), unsupervised vigorous walking (3–5/week) at home	4–6/week total	30 min in group and 15 min at home	4 months
1	Flexibility component[a]	Small group	11 sessions	30 min	4 months
1	Education component[a]	Small group	11 sessions	30 min	4 months
3	Endurance + flexibility	Small group	3/week	1 hr	6 months
3	Resistance + flexibility	Small group	3/week	1 hr	6 months
3	Endurance + resistance + flexibility	Small group	3/week	1 hr	6 months
5	Balance	Individual in lab	1/week	50 min	15 weeks
5	Tai Chi	Small group (1/week), unsupervised (1/week)	2/week	1 hr	15 weeks
8	Balance	Individual	3/week	45 min	13 weeks
8	Resistance	Small group	3/week	45 min	13 weeks
8	Balance + resistance	Individual + small group	3/week	90 min	13 weeks

Note. All trials are randomized. FICSIT = Frailty and Injuries: Cooperative Studies of Intervention Techniques.
[a]The three components at Site 1 are each part of the intervention for the only intervention group at that site. For all other sites, the number of tabulated groups corresponds to the number of intervention groups at the site.

TABLE 2
Baseline Characteristics by FICSIT Site and Treatment Group

	Covariates			*Outcome Measures*			
Site and Treatment Arm	*Age*	*% Female*	*Baseline Gait Speed*	*Baseline MOS General Health*	*Baseline MOS Emotional Health*	*Baseline MOS Pain Score*	*Baseline MOS Social Scale*
All participants[a]	73.4 ± 6.1	55.6	0.99 ± 0.2	69.4 ± 18.8	77.0 ± 33.8	69.9 ± 23.4	86.4 ± 19.7
Portland[b]	73.4 ± 6.1	53.3	0.92 ± 0.2	67.6 ± 19.2	76.2 ± 34.8	67.0 ± 23.8	85.5 ± 20.2
Control[c]	72.3 ± 6.3	52.6	0.93 ± 0.2	67.1 ± 19.4	76.3 ± 34.3	66.7 ± 23.7	84.7 ± 20.6
Individualized[d]	72.5 ± 5.9	54.0	0.91 ± 0.2	68.1 ± 19.1	76.0 ± 35.3	67.3 ± 23.9	86.4 ± 19.7
Seattle[e]	75.2 ± 4.8	51.0	1.32 ± 0.2	75.6 ± 14.4	79.3 ± 30.3	76.8 ± 20.4	87.9 ± 18.1
Control[f]	76.4 ± 4.9	52.0	1.23 ± 0.2	77.7 ± 12.9	73.3 ± 34.7	76.4 ± 17.1	89.3 ± 15.9
Resistance[f]	73.8 ± 4.1	52.0	1.35 ± 0.2	75.8 ± 11.1	86.7 ± 28.9	74.7 ± 20.7	81.3 ± 24.6
Endurance[f]	75.4 ± 5.1	52.0	1.34 ± 0.2	78.5 ± 17.7	78.7 ± 27.0	79.6 ± 23.3	89.8 ± 15.7
Resistance and endurance[f]	75.2 ± 4.7	48.0	1.35 ± 0.2	70.6 ± 14.7	78.7 ± 30.2	76.4 ± 21.1	91.1 ± 13.6
Atlanta[g]	75.7 ± 4.7	80.5	1.16 ± 0.2	74.7 ± 17.2	78.3 ± 31.3	79.6 ± 18.9	90.1 ± 16.6
Control[h]	74.9 ± 4.1	84.4	1.19 ± 0.2	72.6 ± 17.8	74.5 ± 36.5	80.2 ± 17.0	87.7 ± 19.5
Balance[h]	75.8 ± 5.1	76.6	1.15 ± 0.2	76.9 ± 16.2	76.6 ± 31.2	79.0 ± 19.5	91.1 ± 16.5
Tai Chi[i]	76.4 ± 4.9	80.6	1.15 ± 0.2	74.7 ± 17.5	83.3 ± 25.6	79.6 ± 20.1	91.4 ± 13.5
Farmington[j]	79.3 ± 3.9	41.8	1.09 ± 0.2	75.4 ± 15.8	83.2 ± 28.0	82.1 ± 17.4	89.6 ± 19.9
Control[k]	80.1 ± 4.5	40.7	1.07 ± 0.2	75.5 ± 14.0	82.1 ± 28.6	80.8 ± 15.6	90.2 ± 17.9
Resistance[l]	79.8 ± 4.0	39.3	1.05 ± 0.2	73.7 ± 15.3	85.3 ± 25.6	81.3 ± 21.9	88.9 ± 24.0
Balance[l]	78.4 ± 2.8	42.9	1.12 ± 0.2	76.4 ± 16.0	84.0 ± 29.8	85.6 ± 15.4	86.0 ± 23.6
Resistance and balance[k]	79.0 ± 4.1	44.4	1.10 ± 0.2	76.0 ± 18.3	81.3 ± 29.0	80.4 ± 16.8	93.8 ± 12.0
p value comparing sites[m]	< .0001	< .0001	< .0001	< .0001	.170	< .0001	.005

Note. FICSIT = Frailty and Injuries: Cooperative Studies of Intervention Techniques; MOS = Medical Outcomes Study.
[a]N = 1,733. [b]n= 1,323. [c]n = 662. [d]n = 661. [e]n = 100. [f]n = 25. [g]n = 200. [h]n = 64. [i]n = 72. [j]n = 110. [k]n = 27. [l]n = 28. [m]p values generated using analysis of variance and, for gender, a chi-square test.

generated by a linear regression in which the dependent variable was the poststudy value of the outcome measure and the independent variables were age, gender, baseline gait speed, the baseline value of the relevant outcome measure, and the treatment group to which the patient was assigned. Reported *p* values are adjusted for covariates, with each representing a test of the null hypothesis that the postintervention adjusted mean value of the outcome measure in the control group equals the corresponding mean in the relevant intervention group. Because postintervention outcome data were missing for some participants, sample sizes in Table 3 are somewhat reduced.

Figures 1 through 4 report the results of the meta-analyses, one figure per outcome. Each graph contains information about the difference between the covariate-adjusted final value of the outcome in the control group and the corresponding adjusted value in the relevant intervention group. Graphed values are means and 95% confidence bounds, with positive values indicating that the intervention was associated with improved QOL.

The top nine bars in each figure present means and confidence bounds that compare control groups with individual interventions in each site. They are divided into three groups according to the intensity of the intervention. The final five bars in each figure report the meta-analytic results. Because all interventions involved exercise, the pooled estimate labeled Exercise in each figure reflects a meta-analysis of all nine interventions. This is the primary, predefined hypothesis test. The specific interventions that generate the pooled estimates of resistance, balance, endurance, and flexibility can be determined from the Type of Exercise column of Table 3. Table 4 provides covariate-adjusted measures of the between group differences associated with each meta analysis summarized in Figures 1 through 4. Confidence bounds and *p* values associated with these effect sizes are also contained in Table 4.

The Effect of Interventions on the General Health Perceptions Scale

Figure 1 and the first results column of Tables 3 and 4 summarize the effect of FICSIT on the general health scale of the MOS. Table 3 indicates that with one exception, none of the adjusted within site evaluations of the effect of specific interventions on general health was significant. The exception was that in Site 8 (Farmington), the combined resistance and balance intervention was associated with improved general health (p = .021). However, the meta-analyses in Figure 1 indicate that none of the five intervention categories showed even a trend toward significance, with the smallest p value at .300.

TABLE 3
Effect of FICSIT Interventions on the General Health, Emotional Health, Pain, and Social Subscales of the MOS

		General Health Subscale		*Emotional Subscale*		*Pain Subscale*		*Social Subscale*	
FICSIT Site	*Treatment Group*	*Adjusted M ± SE*	*p*	*Adjusted M ± SE*	*p*	*Adjusted M ± SE*	*p*	*Adjusted M ± SE*	*p*
Site 1: Portland,OR[a]	1. Control	69.0 ± 0.5		77.2 ± 1.1		69.7 ± 0.8		85.7 ± 0.7	
	2. Individual-ized (endur + flex)	68.7 ± 0.5	.667	80.9 ± 1.2	.029	70.2 ± 0.8	.673	87.4 ± 0.7	.060
		R^2 = .551		R^2 = .217		R^2 = .339		R^2 = .310	
Site 3: Seattle, WA[b]	1. Control	75.9 ± 2.1		79.3 ± 5.9		78.4 ± 3.6		90.2 ± 3.9	
	2. Resist + flex	76.9 ± 2.3	.757	8 8.7 ± 6.4	.289	79.3 ± 3.8	.869	90.5 ± 4.2	.958
	3. Endur + flex	77.4 ± 2.2	.624	83.8 ± 6.2	.599	77.7 ± 3.8	.893	88.9 ± 4.0	.818
	4. Resist + endur + flex	75.0 ± 2.1	.756	79.5 ± 5.8	.982	76.7 ± 3.5	.731	85.2 ± 3.8	.353
		R^2 = .565		R^2 = .124		R^2 = .334		R^2 = .073	
Site 5: Atlanta, GA[c]	1. Control	74.9 ± 1.4		71.3 ± 3.7		76.6 ± 2.1		85.3 ± 2.6	
	2. Static balance with platform	73.1 ± 1.4	.360	82.3 ± 3.8	.039	78.9 ± 2.1	.442	90.5 ± 2.7	.164
	3. Tai Chi (dynamic balance)	74.8 ± 1.3	.966	80.6 ± 3.5	.073	77.8 ± 1.9	.680	84.1 ± 2.4	.738
		R^2 = .683		R^2 = .257		R^2 = .424		R^2 = .189	
Site 8: Farmington, CT[d]	1. Control	74.6 ± 2.3		84.2 ± 5.7		74.2 ± 3.9		91.3 ± 4.0	
	2. Resistance	75.1 ± 2.3	.872	83.2 ± 5.7	.899	72.0 ± 3.9	.687	86.0 ± 4.0	.355
	3. Balance	74.4 ± 2.3	.952	68.9 ± 5.8	.066	73.6 ± 4.0	.913	85.5 ± 4.2	.320
	4. Resistance + balance	82.3 ± 2.3	.021	85.7 ± 6.0	.854	82.4 ± 4.0	.150	86.5 ± 4.2	.408
		R^2 = .519		R^2 = .223		R^2 = .395		R^2 = .109	

Note. Least square means are adjusted for age, gender, baseline gait speed, and baseline score on the relevant subscale in within site analysis of variance models that use the posttreatment score on the relevant subscale as the dependent variable. For each subscale, *p* values compare each treatment arm with the control arm in the same site. FICSIT = Frailty and Injuries: Cooperative Studies of Intervention Techniques; MOS = Medical Outcomes Study.

[a]*n* = 1,218. [b]*n* = 90. [c]*n* = 175. [d]*n* = 91.

The Effect of Interventions on the Emotional Health Scale

Figure 2 and the second results column of Tables 3 and 4 summarize the effect of FICSIT interventions on the emotional health scale. Table 3 indicates that after adjusting for covariates, the final emotional health score at Site 1 (Portland) was significantly greater (i.e., an improvement) in the intervention group (80.9 ± 1.2, p = .029) than in the control group (77.2 ± 1.1). In Site 5 (Atlanta), the adjusted final score was greater in the balance group (82.3 ± 3.8, p = .039) than in the control group (71.3 ± 3.7). Also in Atlanta, the emotional health score in the Tai Chi group (80.6 ± 3.5) was almost significantly greater (p = .073) than in the control group. Finally, Table 3 demonstrates that in Site 8 (Farmington), the adjusted final emotional health score in the balance group (68.9 ± 5.8) was almost significantly less than the score in the control group (84.2 ± 5.7, p = .066).

The meta-analyses presented in Figure 2 indicate that for three of the five intervention categories, the pooled adjusted final emotional health score was significantly greater in the intervention than in the control group. Specifically, Table 4 indicates that the adjusted effect of all interventions combined was to increase the emotional health score by 3.97 ± 2.0 (p = .043). In addition, endurance exercise programs were associated with a significant increase (after subtracting off the control group change) in the emotional health score of 3.59 ± 1.6 (p = .027), and flexibility programs were associated with a greater final emotional health score than control programs (3.78 ± 1.6, p = .018). Due to the anomalous negative result in Farmington (Site 8), there was significant heterogeneity (p = .041) with respect to the balance

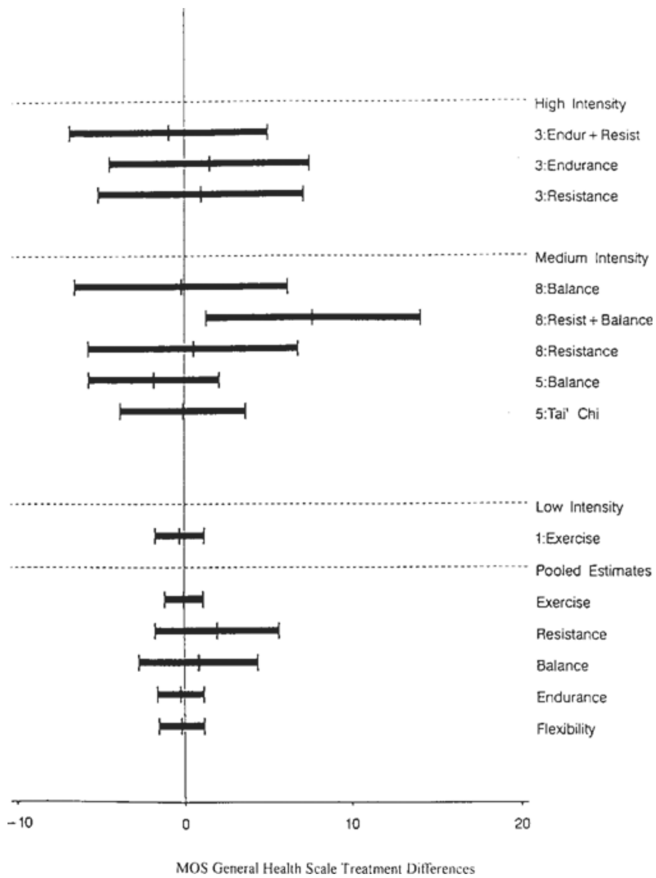

FIGURE 1 Effect of exercise interventions on the general health scale of the Medical Outcomes Study Short Form–36. The top nine bars contain point estimates and 95% confidence bounds for individual estimates ordered by intensity. The final five bars contain meta-analytic results for all nine interventions and separately for each of four exercise categories (which evaluate, respectively, four, four, three, and four interventions). The horizontal axis measures pre- to postintervention changes in raw scores. The numbers preceding the labels of the type of exercise refer to FICSIT sites: 1 = Portland, 3 = Seattle, 5 = Atlanta, and 8 = Farmington.

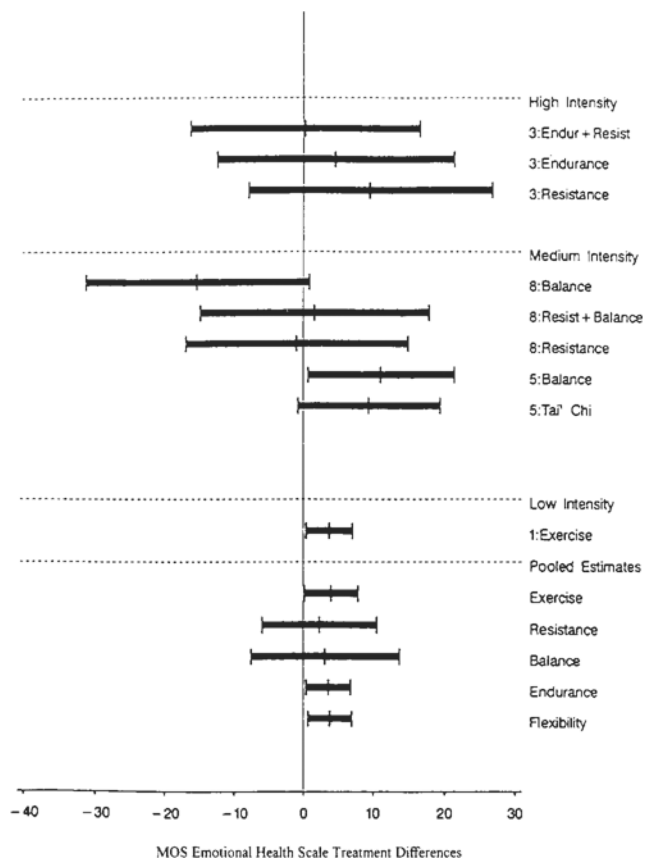

FIGURE 2 Effect of exercise interventions on the emotional health scale of the Medical Outcomes Study Short Form–36. The top nine bars contain point estimates and 95% confidence bounds for individual estimates ordered by their intensity. The final five bars contain meta-analytic results for all nine interventions and separately for each of four exercise categories (which evaluate, respectively, four, four, three, and four interventions). The horizontal axis measures pre- to postintervention changes in raw scores. The numbers preceding the labels of the type of exercise refer to FICSIT sites: 1 = Portland, 3 = Seattle, 5 = Atlanta, and 8 = Farmington.

intervention. There was no evidence of heterogeneity with respect to any of the other four meta-analyses.

Because there were significant changes in the emotional health scale, we evaluated factors associated with changes in the scale, with a particular focus on whether they were associated with changes in gait speed. There was almost no correlation (.021) between changes in gait speed and changes in the emotional health scale ($p = .433$). This lack of correlation was independent of treatment group assignment. When the meta-analyses presented in Figure 2 were repeated with change in gait speed replacing baseline gait speed as a covariate, the results were almost identical to those in the figure. In particular, the same pattern of significant pooled results for all interventions combined and for the endurance and flexibility exercises only was repeated. To further assess changes in the emotional health scale, we note that there was no association between changes in this scale and age (–.006, $p = .810$) or gender ($p = .914$ by t test).

The Effect of Interventions on the Pain Scale

Figure 3 and the third results column of Tables 3 and 4 summarize the effect of interventions on the MOS pain scale. Table 3 indicates that none of the adjusted within site evaluations approached significance. Moreover, the meta-analyses at the bottom of Figure 3 indicate that none of the five intervention categories showed a significant difference between treatment and

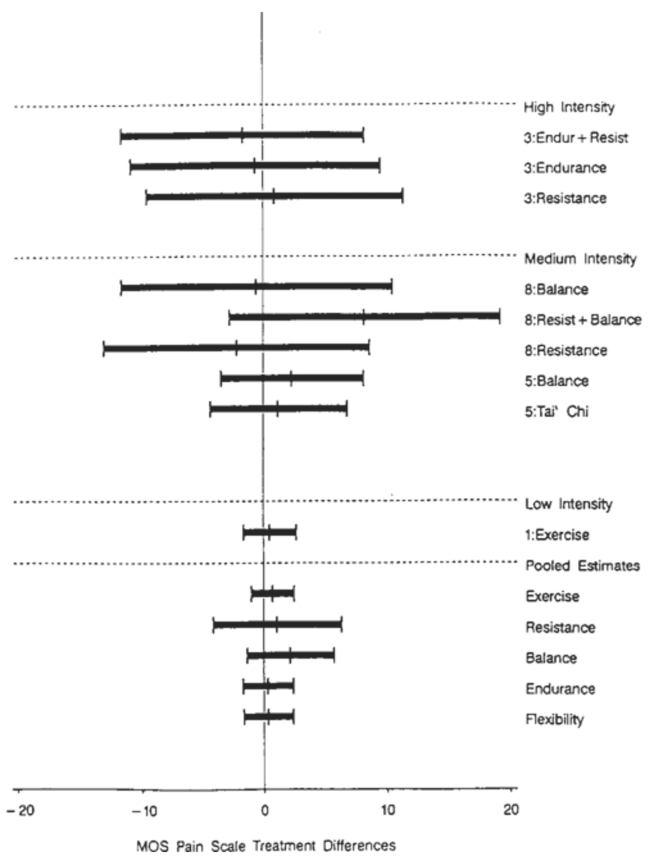

FIGURE 3 Effect of exercise interventions on the pain scale of the Medical Outcomes Study Short Form–36. The top nine bars contain point estimates and 95% confidence bounds for individual estimates ordered by their intensity. The final five bars contain meta-analytic results for all interventions and separately for each of four exercise categories (which evaluate, respectively, four, four, three, and four interventions). The horizontal axis measures pre- to postintervention changes in the raw scores. The numbers preceding the labels of the type of exercise refer to FICSIT sites: 1 = Portland, 3 = Seattle, 5 = Atlanta, and 8 = Farmington.

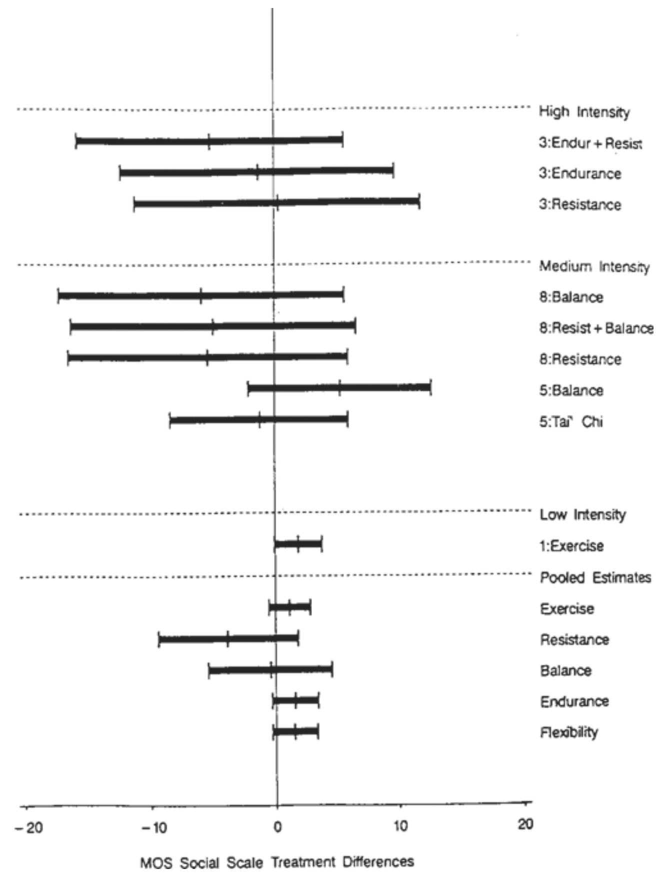

FIGURE 4 Effect of exercise interventions on the social scale of the Medical Outcomes Study Short Form–36. The top nine bars contain point estimates and 95% confidence bounds for individual estimates ordered by their intensity. The final five bars contain meta-analytic results for all nine interventions and separately for each of four exercise categories (which evaluate, respectively, four, four, three, and four interventions). The horizontal axis measures pre- to postintervention changes in raw scores. The numbers preceding the labels of the type of exercise refer to FICSIT sites: 1 = Portland, 3 = Seattle, 5 = Atlanta, and 8 = Farmington.

control. The smallest of the five p values is shown in Table 4 to be .239.

The Effect of Interventions on the Social Scale

Figure 4 and the final results column of Tables 3 and 4 summarize the effect of the FICSIT interventions on the social scale. Table 3 indicates that none of these adjusted within site evaluations was significant. However, there was a clear trend in Portland (Site 1) where the intervention was almost significantly associated with a greater final adjusted social scale score (87.4 ± 0.68, p = .060) than the control group (85.7 ± 0.68). Although there was a suggested effect in Portland, the other sites did not add to the trend and none of the meta-analyses in Figure 4 was significant. The endurance (p = .103) and flexibility (p = .106) exercise programs came closest (see Table 4). There was no suggestion of heterogeneity in any of these meta-analyses.

Because there were suggested changes in the social scale, we evaluated factors associated with these changes more closely. As a consequence of the large sample size, the small correlation between changes in gait speed and changes in the social scale (.052) was nearly significant (p = .055). However, when the meta-analyses presented in Figure 4 were repeated with the change in gait speed replacing baseline gait speed as a covariate, results were almost identical to those in the figure. There was no correlation between changes in the social scale and either age or gender.

TABLE 4
Effect Sizes and Significance Levels Associated With Results of Meta-Analyses

Type of Intervention in Meta-Analysis	*No. of Interventions in Analysis*	*Subscale*			
		General Health	*Emotional*	*Pain*	*Social*
Exercise (all interventions)	9	–0.05 ± 0.6 (–1.2, 1.1)	3.97 ± 2.0 (0.1, 7.8)	0.71 ± 0.9 (–1.0, 2.5)	1.10 ± 0.8 (–0.6, 2.8)
p		.937	.043	.427	.192
Resistance	4	1.96 ± 1.9 (–1.7, 5.7)	2.28 ± 4.2 (–5.9, 10.5)	1.07 ± 2.7 (–4.2, 6.3)	–3.79 ± 2.8 (–9.4, 1.8)
p		.300	.586	.690	.182
Balance	4	0.08 ± 1.8 (–2.7, 4.4)	3.07 ± 5.4 (–7.5, 13.7)	2.15 ± 1.8 (–1.4, 5.7)	–0.43 ± 2.5 (–5.4, 4.5)
p		.648	.570	.239	.865
Endurance	3	–0.25 ± 0.7 (–1.6, 1.1)	3.59 ± 1.6(0.4, 6.8)	0.32 ± 1.1 (–1.8, 2.4)	1.53 ± 0.9 (–0.3, 3.4)
p		.724	.027	.762	.103
Flexibility	4	–0.19 ± 0.7 (–1.5, 1.2)	3.78 ± 1.6 (0.6, 6.9)	0.35 ± 1.0 (–1.7, 2.4)	1.50 ± 0.9 (–0.3, 3.3)
p		.781	.018	.741	.106

Note. Entries are $M \pm SE$ of the covariate adjusted change in the outcome measure generated by the specific meta-analysis. Numbers in parentheses are 95% confidence bounds on the covariate adjusted differences. *p* values test the null hypothesis that mean differences are zero.

DISCUSSION

Although the literature on effects of exercise on QOL domains measured by the SF–36 is extensive, intervention results have been inconsistent. McAuley (35) reviewed 23 studies that evaluated the association between exercise and psychological well-being in people of all ages and concluded that 69% were suggestive of positive associations. The results are equally inconsistent in older populations. In a randomized study of 357 older adults, for example, King, Taylor, and Haskell (36) found that exercise reduced anxiety, depressive symptoms, and perceived stress. Although other intervention studies (37–38) have provided similar evidence of a positive association between exercise and measures of psychological well-being in older adults, studies finding no positive differences have been equally common (12,39–41).

One reason for the inconsistent results noted in previous studies may be diversity in the intensity, duration, and other aspects of the exercise programs themselves. Although the epidemiological literature suggests a dose response effect with additional health benefits being achieved through greater amounts of physical activity (1), exercise intensity did not seem to be a major factor in our analysis.

Alternatively, it is possible that differences in outcome measures are responsible, with the MOS not being as sensitive as more detailed measures of anxiety or depression. It is also possible that participants recruited into studies may be at a high level of psychological well-being at the beginning of the study, thus making it more difficult to detect improvements on generic QOL scales. Based on the FICSIT experience, we would recommend that future studies incorporate more detailed psychological assessment measures if QOL is a major outcome variable of interest.

Finally, the problem may lie in the fact that intention to treat analysis may minimize overall intervention effects if compliance to prescribed interventions is low or if study participants in control groups increase activities on their own. Studies examining QOL effects in those who adopted and maintained a new level of physical activity suggest more positive outcomes (42). Other recent studies are indicating that particular intervention strategies may be more effective in different populations and that future intervention efforts should be better tailored to participant's functional levels and preferences (43).

A major concern regarding vigorous exercise in older adults is the risk of injury and pain (44). Figure 3 demonstrates that there was no trend toward exercise-induced increases in pain, either in the individual FICSIT sites or in the meta-analyses. This result suggests that none of the exercise programs created chronic muscle or joint pain, or other injuries, that were sufficient to be noticed above the general background of pain and discomfort experienced by these elderly participants. Because FICSIT participants were elderly individuals with many potential sources of pain (e.g., 64% of our sample reported having arthritis), and because none of the interventions was focused specifically on any of those sources, we are not surprised that pain was not reduced. On the contrary, one may reasonably expect an increase in pain in a frail elderly population subjected to the repeated stress of vigorous and frequent exercising. We view the absence of such an increase as an important positive finding, although recent findings demonstrating that flexibility and stretching types of exercises can reduce pain in sedentary older adults are quite intriguing (45).

There was a significant improvement in the emotional health score that essentially translates into perceptions of less interference in work and other daily activities due to emotional problems. This finding is consistent with the general conclusion from the 1996 Surgeon General's Report on Physical Activity and Health (1). That report documented the potential of physical activity for enhancing psychological well-being by improving mood, relieving depression, and providing a personal sense of accomplishment. Although not directly tested in this meta-analysis, FICSIT interventions may have increased self-efficacy and the sense of mastery that help to provide focus and meaning to one's life. It is noteworthy also that the changes we observed were not correlated with changes in gait speed and that they were maintained after adjusting for such changes. Thus, our data suggest that the impact of exercise on self-perceived emotional health cannot be explained by improved physical functioning in these participants, at least as assessed by gait speed.

The general health scale scores in the combined resistance and balance group in the Farmington site improved significantly following the intervention. However, no other intervention showed a trend toward an improvement, and all meta-analyses of this measure demonstrated changes that were clustered around zero. The lack of a response in this domain suggests, as one may expect, that the FICSIT interventions had limited ability to broadly affect perceived health. Indeed, respondents who scored poorly on this parameter generally had the burden of one or more chronic conditions that the interventions were not designed to affect.

There was a nonsignificant trend toward endurance and flexibility exercises having a beneficial effect on factors that are associated with social functioning. Figure 4 indicates that the suggested benefit was small in magnitude and that the effect results entirely from Portland where the site-specific analysis demonstrated that the intervention was associated with a nearly significant improvement in the social scale ($p = .060$). As distinct from other FICSIT sites, Portland conducted a group intervention emphasizing social reinforcement, the implication is that any impact of exercise on social functioning may be mediated more by the social nature of the intervention than by enhanced mobility and self-confidence resulting from the exercises themselves.

The decision to use meta-analysis in this article was prospective and based on several considerations. First, publication bias (17,18) and selection bias (19,20) are common problems in many meta-analyses, with substantial evidence showing that research with positive results is more likely to be published than research with negative findings (17,18). Thus, literature-based meta-analyses tend to be biased in favor of treatment. Additional problems related to the selection of articles can occur when researchers are aware of the results of articles being considered for inclusion, when time has changed the standard of care, and when large variability in the quality of selected articles means that meta-analytic conclusions reflect research quality as much as treatment efficacy. Because FICSIT preselected the data to be analyzed and provided central oversight of research, these problems are either nonexistent or limited.

A second benefit of meta-analysis in this context is that most such analyses combine findings from studies that differ in sample and intervention characteristics and in outcome measures. Although FICSIT participants and interventions varied across sites, outcome measures were prospectively defined using a common protocol. Moreover, we were not restricted to comparing aggregate values only. Thus, unlike the standard meta-analysis, we adjusted for between-site differences using covariates with common definitions.

A final benefit of the meta-analytic approach is that it was simpler than the alternative option of pooling across sites and evaluating covariate by site interactions. Indeed, an appropriate pooled analysis would include three dummy variables to represent the four sites along with factors reflecting the statistical interactions between dummy variables and covariates (12 interactions in all). Interpreting these results would be far more complex that the meta-analytic results summarized in the figures and would not yield the simple intervention-specific summaries that are provided by these graphs and by Table 3.

Limitations

Because FICSIT was not designed to compare exercise programs across sites, our analyses provide limited information about the type of exercise program that is most likely to improve QOL. Although we categorize interventions according to their predominant characteristics, those distinctions do not reflect the intensity of the exercise, compliance with the program, or other potentially predictive characteristics of specific interventions. Although precise compliance figures are not available for the four sites, study investigators reported relatively high group attendance levels (e.g., in the 70% and higher range during the course of the active intervention). Nevertheless, because we do not have precise compliance data and because our subjective intensity measure did not prove useful, we are unable to make the basic assertion that there is a dose–response relation in the effects we have observed. We would expect such a relation, but we do not have the data to prove it.

A further limitation in our results is that the overlapping components of the intervention characteristics mean that the characteristic-specific meta-analyses are not independent of one another. Thus, although the final four bars in Figure 4 suggests that the modest trend toward exercise having a positive impact on the social subscale can be explained by the endurance and flexibility components, there is overlap in the component-specific analyses so that these conclusions should be interpreted cautiously. Also, because FICSIT participants came from disparate sources and because participant selection was not population based, we must be cautious in generalizing to other populations. Finally, we were careful in this study to prospectively define only four primary analyses: one covariate-adjusted meta-analysis for each outcome measure. For this reason, multiple comparisons are a minor issue as they relate to the primary hypotheses. However, there were numerous secondary analyses, which implies the need for caution in interpreting the associated p values unless they are substantially below .05.

SUMMARY AND CONCLUSIONS

The marked contrast between FICSIT and other investigations is highlighted by the fact that most previous studies in this area employed younger and healthier populations and used either nonrandomized designs or lacked control groups altogether. Moreover, most have had small sample sizes and limited statistical power—facts that may largely explain the inconsistent published results. The results of this study suggest that exercise can improve QOL in at least one important domain without causing an increase in pain. At the same time, because the magnitude of the effects are limited and because the confidence bounds in the figures are narrow, this large study of 1,733 randomized participants suggests strongly that the QOL benefits of these exercise interventions in frail elderly adults are modest in size. Finally, the observed effects appear to be independent of improvements in physical functioning at least as assessed by gait speed.

As a next research step, we recommend additional studies with designs focused on identifying the type of older adults who can be expected to achieve the greatest QOL benefits from various exercise interventions. In addition, we also recommend that future studies incorporate more sensitive measures of QOL in their assessment batteries to ascertain intervention impacts more precisely and that future analyses examine the effects of adherence to the prescribed exercise regimens.

The FICSIT model of linking distinct clinical studies with a coordinating center and a common database has facilitated the successful implementation of preplanned meta-analyses that have several methodological advantages. Thus, the FICSIT model has provided the sample size benefits of a common efficacy analysis while yielding site specific information about locally defined interventions. Both the FICSIT study design and the data-analytic approach deserve careful consideration as a potential model for future multicenter investigations.

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APPENDIX

The FICSIT Group consists of:

Division of Biostatistics, Washington University School of Medicine (U01 AG09098)

J. Philip Miller, A.B.
Michael A. Province, Ph.D.
Kenneth B. Schechtman, Ph.D.
Cynthia L. Arfken, Ph.D.
Jane E. Rossiter-Fornoff, D. Phil

Center for Health Research, Kaiser Permanente Northwest Region (U01 AG09089)

Mark C. Hornbrook, Ph.D.
Victor J. Stevens, Ph.D.
Darlene J. Wingfield, M.P.A., P.T.
Merwyn R. Greenlick, Ph.D.

Program on Aging, Yale University School of Medicine (U01 AG09087)

Mary E. Tinetti, M.D.
Dorothy I. Baker, Ph.D., R.N.C.
Elizabeth B. Claus, Ph.D.
Ralph I. Horwitz, M.D.

Department of Health Sciences, University of Washington (U01 AG09095)

David M. Buchner, M.D., M.P.H.
Edward H. Wagner, M.D., M.P.H.
Barbara J. de Lateur, M.D.
M. Elaine Cress, Ph.D.
Robert Price, M.M.S.E.
Itmar B. Abrass, M.D.
Peter Esselman, M.D.
Tony Marguerita, M.D.

Geriatric Research, Education, and Clinical Center Audie L. Murphy Veterans Hospital (U01 AG09117)

Cynthia D. Mulrow, M.D.
Meghan B. Gerety, M.D.
John E. Cornell, Ph.D.
Louis A. DeNino, Ph.D.
Deanna Kanten, R.N.

Department of Rehabilitation Medicine
Emory University School of Medicine
(U01 AG09124)

Steven L. Wolf, Ph.D. FAPTA
Nancy G. Kutner, Ph.D.
Robert C. Green, M.D.
Elizabeth McNeely, Ph.D.
Carol Coogler, P.T., DSc.

Hebrew Rehabilitation Center for Aged
Harvard Medical School
USDA Human Nutrition Research Center on Aging
(U01 AG09078)

Maria A. Fiatarone, M.D.
Evelyn F O'Neill, C.T.R.S
Nancy Doyle Ryan, Diet T.
Karen M. Clements, M.P.H.
Lewis A. Lipsitz, M.D.
Joseph J. Kehayias, Ph.D.
Susan B. Roberts, Ph.D.
William J. Evans, Ph.D.

University of Iowa
Iowa State University (U01 AG09123)

Robert Wallace, M.D.
Jo Ellen Ross, M.A.
Jeffrey C. Huston, Ph.D.
Carolyn J. Kundel, Ph.D.
Michael S. Selberg, B.S.

Department of Neurology,
University of Connecticut Health Center
(U01 AG09096)

Leslie I. Wolfson, M.D.
Robert H. Whipple, M.A.
Paula M. Amerman, R.N., M.S.N.
James O. Judge, M.D.
Carol A. Derby, Ph.D.
Mary B. King, M.D.

NIA/NCNR

Evan Hadley, M.D.
Ashlesha Tamboli, M.D., Ph.D.
Marcia G. Ory, Ph.D., M.P.H.
Sharlene Weiss, Ph.D., R.N.

Centers for Disease Control and Prevention

Richard W. Satin, M.D.