lower for the intervention than for the control group. Although this difference was not statistically significant, it corresponds with an estimated 0.4 life-years gained. From the British Doctors study it is possible to estimate that an intervention that yielded an increased cessation rate at the 12-month follow-up of 30% (39% vs 9%) in smokers with the age distribution represented in this study would be expected to yield approximately 0.8 life-years. The Table also shows lower hazard ratios for many specific causes of death in the intervention group compared with the control group, though none were statistically significant at conventional levels. As might be expected, the largest putative effect size was for lung cancer.

Comment. Although this study had low power to detect a long-term effect on mortality of the size predicted from the British Doctors study, to our knowledge, these data provide the best estimate of such an intervention to date. This estimated gain of 0.4 life-years was approximately half what might be expected from the British Doctors cohort study. In addition to the low sample size, several factors may have militated against showing an effect of the kind predicted. First, there was no biochemical verification of abstinence, so at least some of the “effect” may have resulted from misreporting by smokers in the intervention group who did not want to admit that they were not able to stop. Second, brief advice without pharmacological support tends to lead to cessation in lighter, less nicotine-dependent smokers, with heavier smokers requiring more support. These light smokers would have been exposed to less-than-average risk from their smoking.

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Online-Only Material: The eTable is available at http://www.archinternmed.com.


Improvement of Quality of Life With Supervised Exercise Training in Subjects With Type 2 Diabetes Mellitus

In the recent Italian Diabetes and Exercise Study (IDES), we showed that a strategy combining a prescribed and supervised mixed training program with structured exercise counseling is more effective than counseling alone in improving physical fitness, hemoglobin A1c level and other modifiable cardiovascular risk factors, and coronary heart disease 10-year risk scores in a large cohort of sedentary subjects with type 2 diabetes mellitus. In addition, subjects participating in the supervised sessions performed a higher volume of physical activity (PA) compared with the control group.

However, long-term patient compliance with exercise recommendations is largely dependent on changes in quality of life (QoL) associated with training. Unfortunately, although increased PA is expected to improve QoL and most epidemiological studies have demonstrated an association between exercise and QoL in the general population, the very few intervention trials investigating the impact of structured exercise counseling or supervised training on physical and mental health and well-being in diabetic subjects have provided inconclusive results.
We report herein data on the effect of supervised mixed exercise training on top of structured exercise counseling compared with counseling alone on QoL-related measures in subjects with type 2 diabetes participating in the IDES.

**Methods.** The design and methods of this multicenter randomized controlled trial have been detailed elsewhere (eAppendix; http://www.archinternmed.com). Sedentary patients with type 2 diabetes and metabolic syndrome (606 of 691 eligible patients) were enrolled in 22 outpatient diabetes clinics throughout Italy between October 1, 2005, and March 31, 2006, and randomized by center, age, and diabetes treatment to twice-a-week supervised training plus exercise counseling (EXE group) vs counseling alone (CON group) for 12 months.

The training program for the EXE group consisted of 150 min/wk in 2 supervised sessions of progressive mixed (aerobic and resistance) training. Subjects from both groups received a structured individualized counseling aimed at achieving the currently recommended amount of PA.

Prespecified secondary outcomes included health-related QoL, as assessed by the 36-Item Short Form Health Survey (SF-36) health survey, previously validated in subjects with type 2 diabetes. In addition to the 8 domains included in the instrument, physical and mental component summary measures were also computed and normalized to a mean (SD) population of 50 (10).

Mean changes in SF-36 measures (end of study−baseline) were compared between groups by analysis of covariance, with score changes as dependent variables, study arm as factor, and baseline score as a covariate. Because even small between-group differences could reach statistical significance owing to the large number of patients evaluated, we also estimated effect size, which is the difference in score between groups divided by the pooled standard deviation of the score at baseline. The generally accepted benchmarks are 0.20 for a small effect size, 0.50 for a moderate effect size, and 0.80 for a large effect size.

### Results

Among study completers, baseline and end-of-study SF-36 questionnaires were available and fully evaluable for 260 patients in the CON group (94.5%) and 278 patients in the EXE group (96.5%). Baseline patient characteristics were similar in the 2 groups.

At baseline, SF-36 scores did not significantly differ between study groups, except for a significantly higher score in the energy/vitality domain in the EXE vs CON group (P = .03, Table). After 12 months of follow-up, QoL markedly improved in all the areas investigated except physical functioning in the EXE group, while all scores worsened in the CON group. This translated into marked between-group differences for all SF-36 scores, the relevance of which is further documented by effect sizes, approaching or exceeding the 0.80 value for physical health measures (0.90 for physical component summary) and largely exceeding the value of 0.50 for all mental health measures (0.61 for mental component summary) (Table).

### Comment

Results of the IDES show for the first time to our knowledge that supervised mixed exercise training on top of counseling significantly improves both physical and mental QoL scores. This finding is consistent with previous reports in the general population showing an association between exercise and QoL. Moreover, it is consistent with a previous small-sized trial in 51 patients with type 2 diabetes and also with a large randomized controlled trial conducted in sedentary postmenopausal women with elevated systolic blood pressure. Toobert et al also reported a significant effect on QoL of a lifestyle intervention including a mixed self-directed PA program in postmenopausal women with type 2 diabetes; however, significance was driven solely by an improvement of a diabetes-specific measure of QoL, whereas the physical and mental health scores of the 12-item Medical Outcomes Study (MOS-12), a brief version of the SF-36, were unchanged. Finally, our data are only in part consistent with a recent study from Reid et al who found that resistance exercise was better than aerobic or no exercise for improving physical health in

### Table. SF-36 Scores at Baseline and End-of-Study According to Study Arm

<table>
<thead>
<tr>
<th>SF-36 Dimension</th>
<th>CON Baseline</th>
<th>END-OF-STUDY</th>
<th>EXE Baseline</th>
<th>END-OF-STUDY</th>
<th>P Value&lt;sup&gt;a&lt;/sup&gt;</th>
<th>BETWEEN GROUPS</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mean Difference (95% CI)&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>75.6 (21.4)</td>
<td>62.9 (24.9)</td>
<td>77.7 (19.6)</td>
<td>77.6 (18.6)</td>
<td>.33</td>
<td>14.4 (10.8-18.0)</td>
<td>0.70</td>
</tr>
<tr>
<td>Role limitations due to physical problems</td>
<td>69.2 (36.9)</td>
<td>52.1 (41.4)</td>
<td>69.1 (36.8)</td>
<td>80.4 (24.7)</td>
<td>.92</td>
<td>30.1 (23.2-37.0)</td>
<td>0.82</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>67.3 (25.8)</td>
<td>55.0 (26.0)</td>
<td>67.0 (24.9)</td>
<td>74.6 (21.9)</td>
<td>.97</td>
<td>20.1 (15.3-24.8)</td>
<td>0.79</td>
</tr>
<tr>
<td>General health perception</td>
<td>52.9 (22.8)</td>
<td>43.3 (24.9)</td>
<td>56.1 (22.9)</td>
<td>64.9 (21.0)</td>
<td>.07</td>
<td>18.6 (14.1-23.0)</td>
<td>0.81</td>
</tr>
<tr>
<td>Energy/vitality</td>
<td>58.4 (20.2)</td>
<td>52.3 (21.1)</td>
<td>62.0 (19.5)</td>
<td>69.4 (15.3)</td>
<td>.03</td>
<td>12.6 (9.0-16.2)</td>
<td>0.63</td>
</tr>
<tr>
<td>Social functioning</td>
<td>69.0 (23.8)</td>
<td>56.8 (26.9)</td>
<td>72.1 (22.1)</td>
<td>75.0 (21.9)</td>
<td>.16</td>
<td>15.4 (10.8-19.9)</td>
<td>0.67</td>
</tr>
<tr>
<td>Role limitations due to emotional problems</td>
<td>67.0 (36.2)</td>
<td>53.7 (35.1)</td>
<td>69.9 (32.7)</td>
<td>76.1 (26.5)</td>
<td>.55</td>
<td>20.2 (13.5-26.9)</td>
<td>0.59</td>
</tr>
<tr>
<td>Mental health</td>
<td>63.0 (22.0)</td>
<td>53.6 (22.4)</td>
<td>65.7 (20.8)</td>
<td>70.7 (16.9)</td>
<td>.23</td>
<td>14.4 (10.6-18.3)</td>
<td>0.67</td>
</tr>
<tr>
<td>Summary physical component score</td>
<td>45.9 (9.1)</td>
<td>40.6 (10.5)</td>
<td>46.1 (8.8)</td>
<td>48.5 (8.0)</td>
<td>.91</td>
<td>8.0 (6.1-10.0)</td>
<td>0.90</td>
</tr>
<tr>
<td>Summary mental component score</td>
<td>44.7 (11.2)</td>
<td>41.1 (11.1)</td>
<td>46.3 (10.1)</td>
<td>49.2 (8.7)</td>
<td>.13</td>
<td>6.5 (4.5-8.4)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Abbreviations: CON, control group; EXE, training plus exercise counseling group; SF-36, 36-Item Short Form Health Survey.

<sup>a</sup> Adjusted for baseline value. Mean changes in quality of life scores (end of study − baseline) are compared between groups by analysis of covariance, with score changes as dependent variables, study arm as factor, and baseline score as a covariate.
subjects with type 2 diabetes status, whereas no exercise was superior to resistance and combined exercise for improving mental health status. The authors claimed insufficient statistical power and/or the effect of fatigue to explain the lack of improvement in the physical component summary measures with mixed training and attributed to a “reversion to the mean” phenomenon the improvement in the mental component summary measures in the control group, starting with a lower mean score at baseline than the exercise intervention groups.

A possible limitation of this study, in addition to intrinsic limitation of the SF-36 survey, is the unblinded design, though blinding is not feasible in clinical trials using behavioral interventions. Strengths of this study are that it was multicenter, thus less dependent on local factors, and of larger size and longer duration than other exercise intervention trials in patients with type 2 diabetes, including those assessing QoL and well-being measures.2-4

In conclusion, this large trial shows that the health benefits induced by supervised mixed exercise training on top of counseling include a significant improvement of physical and mental health-related QoL measures. Thus, this intervention strategy may be effective for promoting permanent lifestyle changes in subjects with sedentary habits, such as patients with type 2 diabetes.

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