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Effect of a Low-Impact Exercise Program on Bone Mineral Density in Crohn's Disease: A Randomized Controlled Trial

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Background & Aims: Physical exercise increases bone mineral density (BMD) in healthy young adults and slows the rate of bone loss in later life. The aim of this randomized controlled trial was to investigate the effect of exercise on BMD in patients with Crohn's disease. _Methods:_ A total of 117 patients with Crohn's disease were randomized to a control group or a low-impact exercise program of increasing intensity. BMD (g/cm^2) was measured at baseline and 12 months at the hip and spine (L2–L4) by dual energy x-ray absorptiometry. _Results:_ Nonsignificant gains in BMD occurred at the hip and spine in the exercise group compared with controls ($P > 0.05$). In fully compliant patients, BMD increased by 3.54% (7.95%) at the femoral neck, 2.97% (7.7%) at the spine, 4.1% (10.26%) at Ward's triangle, and 7.77% (8.2%) at the greater trochanter. Compared with controls, gain in BMD at the greater trochanter was statistically significant (difference in means, 4.67; 95% confidence interval, 0.86–8.48; $P = 0.02$). Increases in BMD were significantly related to the number of exercise sessions completed (femoral neck: $r = 0.28$; 95% confidence interval, 0.10–0.45; $P = 0.04$). _Conclusions:_ Progressive low-impact exercise is a potentially effective method of increasing BMD in Crohn's disease. If sustained, the increases in BMD may reduce the risk of osteoporotic fracture.

Osteoporosis is a common complication of inflammatory bowel disease, and people with Crohn's disease are at particular risk.[1–4] Low bone mineral density (BMD) is associated with increased risk of fracture, and disabling vertebral crush fractures have been reported even in young people with Crohn's disease.[1,5] Measures to prevent and treat osteoporosis in this high-risk group have not yet been well established.

Physical activity is an important determinant of bone health. Gravitational forces or muscle pull as a result of exercise produce strain within the axial skeleton, which is osteogenic, leading to bone formation.[6] Epidemiological studies and prospective intervention trials show that exercise can increase BMD in young adults[7–9] and can slow the rate of bone loss in later life.[10] Bone gain as a result of exercise can also occur in postmenopausal women and in elderly people with established osteoporosis.[11,12] In addition to increasing bone density, physical activity can modify other risk factors for fracture.[13] Improvements in balance and muscle strength reduced the risk of falls, and the improved flexibility and coordination minimize the risk of fall-induced fractures.[14–16] To our knowledge, no trials of the effect of exercise on BMD in patients with Crohn's disease have been performed.

The aim of this randomized controlled study was to evaluate the effects of a 1-year low-impact exercise training program on BMD in patients with Crohn's disease. The program was home based to achieve maximum compliance and consisted of site-specific low-impact exercises of increasing intensity.

Materials and Methods

Subjects

Patients with Crohn's disease were recruited from a database of inflammatory bowel disease cases held in Leicestershire. The diagnosis of Crohn's disease had been confirmed by histological, endoscopic, radiological, and clinical criteria.[17] Invitations were mailed to 400 patients with Crohn's disease, 230 of whom expressed an initial interest in participating. Each respondent was then contacted by telephone, and the study was explained in more detail. The following exclusion criteria were applied: age less than 18 or greater than 65 years, current pregnancy, a history of ankylosing spondylitis, a concurrent medical condition leading to low bone density (renal disease, liver disease, hypogonadism, parathyroid disorders, or untreated thyroid disease), intake of medication known to affect bone density (hormone replacement therapy, bisphosphonates, vitamin D, fluoride, calcium, or calcitonin), or unwillingness

Abbreviations used in this paper: CI, confidence interval; BMD, bone mineral density; MET, metabolic equivalent unit.

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to accept randomization. The first 120 eligible respondents were enrolled in the study.

All patients were assessed at baseline and at 1 year by a single investigator (R.J.R.). Details of the Crohn's disease were obtained from hospital records, and previous and current medications were recorded; cumulative steroid dose was estimated from hospital records and expressed in grams of prednisolone. Hormonal status in women was assessed by menstrual history. Height and weight were recorded, and the body mass index was calculated. Disease activity was estimated using a Simple Disease Activity Score.[18] Three patients were excluded from the study after randomization. In 1 patient, the diagnosis had not been adequately established, 1 had ankylosing spondylitis, and 1 was pregnant.

The protocol was approved by the Leicestershire Ethical Committee, and all subjects gave informed written consent.

Study Design

Patients were randomly assigned into control group (n = 57) and exercise group (n = 60) by stratified block randomization.[19] Men, women younger than 47 years, and women older than 47 years were randomized as individual groups to ensure similar age, sex, and postmenopausal status in both groups. The success of randomization was confirmed by checking the mean age, weight, BMD at the femoral neck, and dietary calcium intake in the groups. Baseline characteristics of subjects are shown in Table 1.

BMD

BMD (g/cm^2) was measured at baseline and at 12 months at the hip (femoral neck, Ward's triangle, and greater trochanter) and lumbar spine (L2–L4) by dual energy x-ray absorptiometry (Lunar DPX, Lunar software version 3.1; Lunar Radiation Corp., Madison, WI). All measurements were performed by a single trained operator; the coefficient of variation of dual x-ray absorptiometry was 0.49% at the femoral neck, 2.14% at Ward's triangle, 1.7% at the greater trochanter, and 0.5% at the lumbar spine.

Table 1. Baseline Characteristics of 117 Patients With Crohn's Disease Randomized to Control or Low-Impact Exercise Group

	Exercise group (n = 60)	Control group (n = 57)
Age	40.1 (12.6)	41.2 (14.1)
Sex (M/F)	26/34	22/35
Current steroid use	11/49	12/45
Duration of disease (*yr*)	9.7 (7.8)	9.4 (8.3)
Disease activity	1.6 (1.7)	1.4 (2.0)
Height (*m*)	1.69 (0.09)	1.66 (0.08)
Weight (*kg*)	68.2 (14.0)	66.5 (12.3)
BMI (*kg/m*^{2})	23.2 (5.6)	23.7 (4.7)
Cumulative steroid (*g*)	11.7 (17.2)	8.0 (10.2)
BMD neck (*g/cm*^{2})	0.942 (0.137)	0.961 (0.139)
BMD spine (*g/cm*^{2})	1.176 (0.205)	1.191 (0.137)
Dietary calcium (*mg*)	1054 (273)	1065 (292)
Total energy (*kcal*)	2308 (748)	2143 (647)

NOTE. At baseline there were no significant differences between the two groups. Results are presented as mean (SD).
BMI, body mass index.

Habitual Physical Activity Levels

To control for changes in lifestyle outside the exercise program, habitual physical activity was assessed at baseline and on completion of the study by a structured interview based on the Allied Dunbar National Fitness Survey by a single interviewer.[20] Individuals were classified into one of seven activity categories based on ranges of energy expenditure during the previous week.[21,22] Very light activity (mean weekly energy expenditure, 1.5–2.0 metabolic equivalent unit [MET]) was classified as activity level zero, and a very active individual (mean weekly expenditure, ≥8.0 MET) was classified as activity level 6. All subjects were requested to maintain their habitual physical activity patterns during the study.

Dietary Intake

Dietary intake of calcium, phosphorus, protein, and total energy was assessed by a validated semiquantitative food frequency questionnaire (DIET Q).[23] No dietary advice was provided, and subjects were requested not to make changes to their usual diet during the study period. The self-administered questionnaire was completed before and after the program to control for changes in diet during the study.

Low-Impact Exercise Program

The emphasis of the exercise program was to dynamically load the axial skeleton at the hip and lumbar spine sites using home-based, low-impact exercises. At baseline, subjects in the exercise group attended a series of induction meetings during which the correct exercise techniques were demonstrated and a supporting resource package was provided.

Each exercise session involved a 5-minute warm-up consisting of general whole body pulse-raising and mobility-promoting activities, followed by preparatory stretching of muscles being worked during the main session. A 5-minute period of pulse-lowering activity and stretching was performed after the exercises were completed. The main section of the home-based program was comprised of 12 core floor-based *low-impact* exercises. Exercises were focused on the hip and lumbar region, consisting of dynamic muscular conditioning of the major muscle groups of the trunk and legs including quadriceps, hamstrings, gluteals, erector spinae, and muscles of the anterior abdominal wall. Subjects were asked to exercise at least twice a week, with a minimum of 10 sessions per month considered necessary for full compliance. Additional meetings were held at 1, 3, and 9 months to provide motivation and support for exercising individuals and to supervise the increase in training intensity. Intensity of exercise was increased by developing the core exercises, increasing the number of repetitions of each exercise, advancing body positions to increase resistance to movement (lever principles), and using resistive tubing or free weights. The program was intentionally flexible to allow individuals of different fitness levels to reach an exercise overload effect.

Assessment of Compliance

Compliance and progress with the exercise program were monitored through completion of individual self-report exercise diaries. Training diaries were returned monthly, and compliance was formally assessed at 3 and 12 months. Analysis of compliance was based on subjects performing a minimum of 10 exercise sessions per month over the 1-year intervention. Complete compliance to the program included subjects progressing the exercise intensity by using the resistance tubing.

Statistical Analysis

The number of patients required in each arm of the trial was calculated on the basis of a mean baseline BMD of 0.80 g/cm^2 with a standard deviation of 0.09 g/cm^2, and that the minimal clinically significant difference in terms of percentage change from baseline was 5%. To detect such a difference at the 5% significance level with 80% power, 52 patients were required in each group.

Results are presented as mean (SD). Changes during the 12 months were calculated and compared between groups using Student's unpaired *t* tests with 95% confidence intervals (CIs). The Mann–Whitney *U* test was used when the data were not normally distributed. Correlations between continuous variables that might have influenced the response to exercise and change in BMD were assessed using Pearson's correlation coefficients together with 95% CIs. Multiple regression analysis was used to allow for possible confounding factors. Two-tailed significance tests were used in all the statistical analysis. The Statistical Package for Social Sciences (SPSS Inc., Chicago, IL) was used for the analysis.

Results

One hundred seven patients (91.5%) completed the study, 53 (88%) in the training group and 54 (95%) in the control group. Reasons for withdrawal from the study are shown in Figure 1. There was no significant difference between groups in the number of patients taking corticosteroids during the study (control, 18 [34%]; training, 18 [33%]), and mean cumulative steroid dose was similar in control and exercise groups (701 mg [1687] vs. 779 mg [1343]; difference in means, 78 mg; 95% CI, −507 to 663; $P = 0.79$). Disease activity scores on completion of the study were similar in control (1.3 [1.6]) and exercise groups (1.5 [1.7]; difference in means, 0.3; 95% CI, −0.35 to 0.93; $P = 0.37$), and the change in disease activity from baseline did not differ significantly between the two groups (exercise, −0.02 [1.9]; control, −0.14 [2.6]; difference in means, 0.12; 95% CI, −0.74 to 0.99; $P = 0.78$). Nine patients (17%) in the training group and 6 (11%) in the control group had been hospitalized during the study; 3 (6%) in the training group and 1 (2%) in the control group had undergone surgery. The training group had taken a mean of 20 days (56) off work as a result of Crohn's disease during the study compared with 6 days (15) in the control group (difference in means, 14 days; 95% CI, −1 to 30; $P = 0.07$). No patient reported any serious adverse effects of exercise.

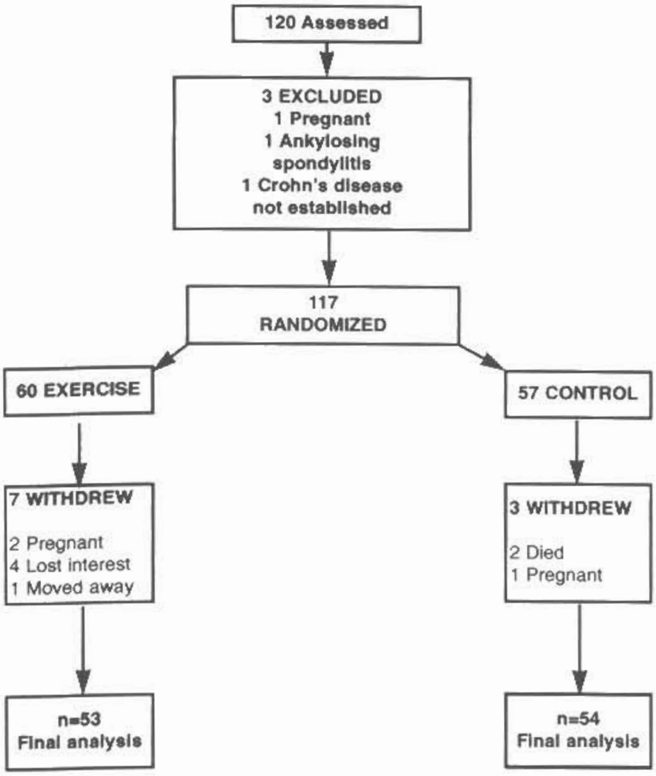

Figure 1. Reasons for withdrawal from a study on the effect of a low-impact exercise on BMD in patients with Crohn's disease.

After 3 months, the mean number of sessions completed was 20 (SD, 14). The reported training compliance defined as the percentage of completed exercise sessions was 62% (37%). At 12 months, the mean number of completed sessions was 70 (58), with reported compliance of 52% (40%). Habitual activity levels did not change significantly in control or training groups during the study period. Levels of habitual activity at baseline and on completion of the study are shown in Table 2. Dietary intake of calcium, protein, and total energy did not alter significantly in control or training groups during the study period. Weight (+0.55 kg [3.4] vs +0.4 kg [4.2]; difference in means, 0.15; 95% CI, −1.6 to 1.3; $P = 0.83$) and body mass index (+0.52 m/kg^2 [2.8] vs. +0.88 m/kg^2 [4.1]; difference in means, 0.36; 95% CI, −0.99 to 1.72; $P = 0.59$) increased in the control group compared with trainers, but the differences were not statistically significant.

The percentage change in BMD over the 12-month period in the training and control groups is shown in Table 3. BMD increased at all measured sites in the

Table 2. Levels of Habitual Physical Activity in Exercise and Control Groups at Baseline and After 1 Year

	Baseline	After 1 year
Exercise group		
Activity level 0 (1.5–2.0 MET)	7 (13.2%)	2 (3.8%)
Activity level 1 (2.0–3.5 MET)	28 (52.8%)	25 (47.2%)
Activity level 2 (3.5–5.0 MET)	9 (17.0%)	16 (30.2%)
Activity level 3 (5.0–6.0 MET)	8 (15.1%)	7 (13.2%)
Activity level 4 (6.0–7.0 MET)	1 (1.9%)	3 (5.7%)
Control group		
Activity level 0 (1.5–2.0 MET)	3 (5.6%)	3 (5.6%)
Activity level 1 (2.0–3.5 MET)	19 (35.2%)	17 (31.5%)
Activity level 2 (3.5–5.0 MET)	15 (27.8%)	20 (37.0%)
Activity level 3 (5.0–6.0 MET)	13 (24.1%)	10 (18.5%)
Activity level 4 (6.0–7.0 MET)	2 (3.7%)	3 (5.6%)
Activity level 5 (7.0–8.0 MET)	2 (3.7%)	1 (1.9%)

NOTE. Habitual physical activity (i.e., energy expenditure outside the exercise program) did not change significantly in either the exercise or control group.

training group compared with controls. However, these differences did not reach statistical significance when analyzed on an intention-to-treat basis. On subgroup analysis, there was no significant sex by group interaction at the spine ($P = 0.11$) or hip (femoral neck, $P = 0.27$; trochanter, $P = 0.05$; Ward's triangle, $P = 0.12$).

Fourteen patients (9 men and 3 postmenopausal women) completed more than 120 sessions and used the resistance band (i.e., reported full compliance with the program). Baseline characteristics of fully compliant patients were not significantly different from those of the control group or subjects in the training group who did not fully comply. Their mean age was 45.7 years (12.2 years; range, 28–65); 11 (79%) had previous bowel resection, 3 were taking oral steroids, and 13 (93%) had used steroids previously. Before taking part in the study, 6 (43%) took no regular recreational activity. During the study, 4 patients (29%) received oral steroids. Their BMD increased by 3.54% (7.95%) at the femoral neck, 2.97% (7.7%) at the lumbar spine, 4.1% (10.26%) at Ward's triangle, and 7.7% (8.2%) at the greater trochanter. The gain in BMD at the greater trochanter was statistically significant compared with the control group (difference in means, 4.67; 95% CI, 0.86–8.48; $P = 0.02$) (Table 4).

Increase in BMD at both the hip and spine was positively associated with the number of exercise sessions completed and the number of repetitions of each exercise. At 3 months, the associations were statistically significant at the femoral neck (number of sessions: $r = 0.35$; 95% CI, 0.17–0.51; $P = 0.01$; number of repetitions: $r = 0.32$; 95% CI, 0.14–0.48; $P = 0.02$). At 12 months, the total number of sessions completed was significantly associated with increased BMD at the femoral neck ($r = 0.28$; 95% CI, 0.10–0.45; $P = 0.04$). The association remained significant ($P < 0.05$) after allowing for change in body weight, steroid use, habitual exercise, and change in dietary calcium or total energy by multivariate analysis. Changes in BMD during the study were not significantly related to any baseline characteristic including habitual exercise, age, sex, menstrual status, diet, disease activity, or baseline BMD. Cumulative steroid dose during the study was not significantly associated with changes in hip or spine BMD in either control (femoral neck: $r = 0.13$; 95% CI, −0.14 to 0.38; $P = 0.60$; spine: $r = -0.04$; 95% CI, −0.30 to 0.23; $P = 0.87$) or exercise group (femoral neck: $r = -0.26$; 95% CI, −0.50 to 0.01; $P = 0.31$; spine: $r = 0.05$; 95% CI, −0.22 to 0.32; $P = 0.85$).

Discussion

To our knowledge, this study is the largest prospective randomized controlled trial of low-impact exercise, and is the first to study exercise in patients with inflammatory bowel disease. Our results show that a 12-month low-impact exercise program may have a positive effect on BMD at the hip and spine in patients with Crohn's disease. Gains in BMD occurred at all

Table 3. Percentage Change in BMD After 1 Year of Low-Impact Exercise in 107 Patients With Crohn's Disease

	Exercise	Control	% Diff (95% CI)	*P* value
Femoral neck	+1.05 (5.99)	+0.55 (3.52)	0.5 (−1.39 to 2.39)	0.60
Lumbar spine	+1.53 (5.5)	+0.76 (3.2)	0.77 (−0.97 to 2.51)	0.38
Trochanter	+3.96 (8.55)	+3.1 (5.83)	0.86 (−1.95 to 3.65)	0.55
Ward's triangle	+1.26 (8.24)	−0.87 (5.96)	2.13 (−1.41 to 4.1)	0.34

NOTE. BMD increased at all measured sites in the exercise group compared with controls, but the changes did not reach statistical significance.

Table 4. Changes in Bone Density in Patients Who Were Fully Compliant With a Progressive Low-Impact Exercise Program Compared With Nonexercising Controls

	Compliers (n = 14)	Control (n = 57)	% Diff (95% CI)	*P* value
Femoral neck	+3.54 (7.95)	+0.55 (3.52)	2.99 (−7.67, 1.68)	0.19
Lumbar spine	+2.97 (7.70)	+0.76 (3.2)	2.21 (−6.74, 2.30)	0.30
Trochanter	+7.77% (8.2)	+3.1 (5.83)	4.67 (0.86 to 8.48)	0.02
Ward's triangle	4.1% (10.26)	−0.87 (5.96)	4.15 (−10.25, 1.95)	0.17

NOTE. In patients who fully complied with the exercise program, gains in BMD were seen at all four measured sites. The increase was statistically significant at the trochanter.

measured sites in the training group and were positively related to the amount of exercise performed. The increases were independent of changes in other potential confounding variables such as steroid dose, body weight, and diet. Statistically significant gains in BMD were seen at the greater trochanter in patients who were able to fully comply with the exercise program.

The optimum frequency and type of exercise required to increase BMD have not yet been established, but in women the greatest gains in BMD have been reported from dynamic exercise interventions producing large strains on the skeleton.[10] High-impact exercises such as jumping are particularly effective,[24,25] with statistically significant gains in bone mass also resulting from weight training.[26] However, a low-impact program was chosen for our study because it could be performed readily at home without special equipment or supervision and was unlikely to lead to training injuries or fracture in patients with established osteoporosis. The exercises were site specific for the hip and lumbar spine, with body positions and additional resistive devices used in intensive bouts of exercise to produce strain and osteogenic stimulus in these areas. Home-based activity, moderate intensity of exercise, and self-monitored training diaries are factors leading to high compliance with exercise.[27] More than 90% of patients completed our study, but overall compliance with the exercise program was disappointing and less than that reported in other large intervention studies using supervised exercise regimens.[25] However, this is the first exercise intervention study to target people with chronic ill health; given the relapsing and remitting nature of Crohn's disease, the poor compliance can be explained. Many patients had acute relapse of their symptoms during the study, and illness was commonly cited as a reason for not exercising regularly. Poor compliance with the exercises undoubtedly contributed to the failure of the study to produce an overall significant difference between the groups; however, the independent relation of increased BMD and number of exercise sessions confirm the "training effect." This is supported by the 3%–7.8% increases in BMD found in patients who were fully compliant (Table 4).

There are a number of other possible reasons why this study failed to show a significant overall benefit of exercise. Bone loss in Crohn's disease results from many factors including corticosteroid use, malabsorption, sex hormone deficiency, and persistent disease activity.[1,2,28,29] Although resistance training can partially reverse steroid-induced bone loss,[30] the osteogenic effect of exercise is modest and perhaps insufficient to counteract the many factors leading to osteoporosis in Crohn's disease. Furthermore, patients included in our study were heterogeneous in terms of age, sex, menstrual status, disease severity, baseline bone mineral density, and habitual physical activity level, which might have diluted any beneficial training effect. In addition, the power analysis based on a 5% difference in BMD over 12 months was overly optimistic. In particular, at the planning stage we did not expect the compliance to be so poor, and therefore the power calculation did not take compliance into consideration. Assuming average compliance with the exercise program of only 50%, then the target difference on which the power calculation should have been be based was 2.5%, i.e., requiring four times as many subjects. Future studies need to take account of anticipated limited compliance, and considerably larger sample sizes are required.

Aerobic exercise can have a major impact on gut motility and blood flow, leading to troublesome gastrointestinal symptoms.[31] It has been suggested that even low-intensity exercise may have a detrimental effect on disease activity in patients with Crohn's disease.[32] However, in this study, no important side effects were reported by patients in the training group and exercise had no significant adverse effect on disease activity. Disease activity was similar in the two groups during the study, as evidenced by similar use of steroids, need for surgery, and hospitalization during the study period. However, there was no significant association between these parameters and change in bone density in either group.

Very few studies have addressed prevention and treatment of bone loss in patients with inflammatory bowel disease. Hormone replacement therapy is effective in postmenopausal women with inflammatory bowel disease, increasing bone density at the radius and lumbar spine by 1.42% and 2.60%, respectively, over a 12-month period.[33] However, the optimum treatment in men and premenopausal women is not established, with studies of calcium and vitamin D supplementation producing conflicting results. Bernstein et al.[34] concluded that over a 1-year period calcium and vitamin D supplementation conferred no significant benefit to bone density in inflammatory bowel disease. In a larger study of patients with Crohn's disease using higher doses of vitamin D, Vogelsang et al.[35] reported a significant decrease in BMD in controls but maintenance of bone density in patients who received the supplement.

In view of our results, we conclude that prescription of a home-based, low-impact exercise program is feasible in patients with Crohn's disease and is a potentially effective method of increasing BMD. The exercises were simple to perform by people of varying levels of fitness and required only minimal instruction, supervision, and monitoring. Although the changes in BMD were small, the increases seem to be related to the amount of exercise performed and independent of all other potential confounding variables. Future studies should address methods of increasing uptake and compliance with exercise in this high-risk group and study the effect of more intense modes of exercise training.

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