

## Effect of a yearlong, moderate-intensity exercise intervention on the occurrence and severity of menopause symptoms in postmenopausal women

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### ABSTRACT

**Objective:** To evaluate the effect of moderate-intensity exercise on the occurrence and severity of menopause symptoms.

**Design:** A yearlong, randomized, clinical trial, conducted in Seattle, WA, with 173 overweight, postmenopausal women not taking hormone therapy in the previous 6 months. The intervention was a moderate-intensity exercise intervention (n = 87) versus stretching control group (n = 86). Using logistic regression, odds ratios comparing exercise with controls were calculated at 3, 6, 9, and 12 months for menopause symptoms and their severity.

**Results:** There was a significant increase in hot flash severity and decreased risk of memory problems in exercisers versus controls over 12 months, although the numbers affected were small. No other significant changes in symptoms were observed.

**Conclusions:** Exercise does not seem to decrease the risk of having menopause symptoms in overweight, postmenopausal women not taking hormone therapy and may increase the severity of some symptoms in a small number of women.

**Key Words:** Postmenopausal – Hot flashes – Memory problems – Exercise – Randomized clinical trial.

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Menopause symptoms can cause discomfort and may negatively impact quality of life for women undergoing menopause. Hormone therapy (HT) has been shown to be effective in alleviating hot flashes and night sweats.<sup>1-3</sup> Yet some women may be reluctant to use hormone therapy because of potential adverse effects.<sup>4-6</sup> Several reviews focusing on the management of menopause symptoms propose exercise as an alternative form of treatment for these symptoms, but there are no clinical trial data to support this.<sup>7-9</sup>

However, observational studies have shown that increased adiposity is associated with an increase in estrogen and decrease in sex hormone binding globulin (SHBG) levels in postmenopausal women.<sup>10-12</sup> Regular exercise should lower adiposity and, in turn, decrease estrogen levels. This decrease in circulating estrogen levels could increase the severity of menopause symptoms.<sup>13</sup>

No randomized trials have evaluated the direct impact of exercise alone on menopause symptoms. However, a few observational studies have examined the association between physical activity and menopause symptoms. One study of pre- and postmenopausal women noted that women who exercised at least twice a week for 30 minutes ( $n = 101$ ) had more positive moods and less somatic symptoms than sedentary women ( $n = 119$ ).<sup>14</sup> A study of 793 postmenopausal women observed that highly physically active women were at a decreased risk for hot flashes compared with physically inactive women ( $RR = 0.26$ ).<sup>15</sup> An additional study comparing 82 women with regular hot flashes (at least once a day) to 89 controls with few menopause symptoms noted no difference in physical activity level between the two groups.<sup>16</sup> A combined diet and exercise intervention as a randomized-controlled trial showed no significant differences in the prevalence of hot flashes between 246 intervention and 263 control women after 5 years.<sup>17</sup>

The aim of the present study was to examine the effect of a moderate-intensity exercise intervention on five menopause symptoms (hot flashes, night sweats, memory problems, depressive feelings, and sleep problems) in overweight, previously sedentary, postmenopausal women not using HT.

## METHODS

The study was a randomized clinical trial comparing the effect of a yearlong, moderate-intensity exercise intervention versus stretching control group on body fat and circulating sex hormone concentrations.<sup>18</sup> The exercise intervention was designed to test the effect of a combined exercise program: an initial (3-mo) closely monitored exercise program at an exercise facility, followed by a longer (9-mo) home-based program.

### Study participants

The study population consisted of 173 postmenopausal women ( $n = 87$  exercisers, 86 stretching controls) recruited from the greater Seattle area who were aged 50-75, not taking hormone therapy (HT), non-smokers, and sedentary at baseline [ $< 60$  min/week of moderate-to-vigorous intensity recreational activity and a maximal oxygen consumption ( $VO_{2max}$ )  $< 25.0$  mL/kg/min]. Women were recruited through a combination of mass mailings and media placements.<sup>19</sup> All participants had to have a baseline body mass index (BMI)  $\geq 25.0$  or between 24.0 and 25.0 with percent body fat  $> 33.0$  to be eligible for the study. After eligibility was determined, we randomly assigned women

to either the exercise intervention ( $n = 87$ ) or control group ( $n = 86$ ). Randomization was performed by random number generation; group assignment was placed in a sealed envelope, which was opened by the study coordinator at the time of randomization. Randomization was stratified by BMI ( $< 27.5$  vs  $\geq 27.5$ ) to ensure equal numbers of heavier and lighter women in each study group. Informed consent was obtained following requirements of the Fred Hutchinson Cancer Research Center Institutional Review Board.

### Exercise intervention

The exercise intervention consisted of at least 45 minutes of moderate-intensity exercise, 5 days per week (goal of 225 min per week) for 12 months. During the first 3 months, participants attended 3 sessions per week at the facility, and exercised 2 additional days per week at home. During months 4 through 12, participants attended at least 1 session per week at the facility and exercised the remaining 4 days per week on their own (participants were allowed to exercise additional days at the facility if they chose). Facility-based exercise sessions consisted of treadmill walking and stationary bicycling. A variety of home exercises were suggested and encouraged, including walking, aerobics, and bicycling. Adherence was tracked via daily activity logs of all sports or recreational activities performed. Average duration (min/week) of moderate-intensity activity was used as a measure of adherence.

Women randomized to the control group were invited to attend once-weekly 45-minute stretching sessions for the entire year and were asked not to change other exercise habits during the study. All exercise and control participants were asked to continue to eat their usual diet during the yearlong study. Caloric intake was monitored using a 120-item self-administered food-frequency questionnaire at baseline, 3, and 12 months.<sup>20</sup>

### Baseline, 3-, 6-, 9-, and 12-month follow-up measures

Information on menopause symptoms and their severity was collected at baseline, 3, 6, 9, and 12 months using a self-administered questionnaire. This questionnaire was a modified version of a questionnaire used by the Women's Health Initiative to determine the occurrence and severity of menopause symptoms.<sup>21</sup> The symptoms were selected from a list of menopause symptoms used in the Postmenopausal Estrogen/Progestin Interventions Trial,<sup>2</sup> which was based on published literature.<sup>22</sup> At baseline, participants were asked if they experienced each of the following symp-

toms in the last month: hot flashes; memory loss, forgetfulness or difficulty concentrating; depression; night or day sweats, or cold sweats; and trouble sleeping or awakening too early. If the woman reported having the symptoms, she was then asked to rate the usual severity of the symptom as mild, moderate, or severe. At 3, 6, 9, and 12 months, participants were asked if they experienced each symptom within the last 3 months and, if yes, to rate the usual severity as mild, moderate, or severe.

Reproductive and medical history data were collected at baseline, 3, 6, 9, and 12 months via a self-administered questionnaire. A dual-energy x-ray absorptiometry (DXA) scan was conducted at baseline and 12 months to determine body fat and lean body mass. Maximal oxygen consumption (VO<sub>2</sub>max) was determined at baseline and 12 months via a maximal-graded treadmill test; heart rate and oxygen consumption were monitored by an automated metabolic cart (Medgraphics, MN).

**Statistical analysis**

Generalized estimating equations were used to conduct all analyses to account for repeated measures over time using ordinary logistic regression.<sup>23</sup> Odds ratios and 95% CIs were calculated comparing intervention women to controls for the existence (yes/no) and severity (moderate/severe vs mild/none), separately, of each menopause symptom at 3, 6, 9, and 12 months. These analyses were intent-to-treat and unadjusted for covariates. Two control women were excluded from the analyses because they took some form of HT after randomization.

Stratified analyses were conducted to explore differential intervention effects by time since menopause (≤ 5 vs > 5 years) among exercisers and controls. We also examined whether changes in percent body fat (decreased percent body fat vs no change or increased percent body fat), levels of adherence to the intervention (< 165 min, 166-215 min, and > 215 min per week), or changes in VO<sub>2</sub>max from baseline to 12 months (< 1%, 1% to < 10%, ≥ 10%) modified the intervention effect among exercisers only. As these secondary analyses included only exercisers and were not intent-to-treat, adjustment variables included baseline symptoms or baseline severity, ethnicity (non-Hispanic white vs other), history of oral contraceptive use (yes/no), history of herbal hormone use (yes/no), number of years since menopause (continuous; not included in the analysis stratified by years since menopause), marital status (married/living with partner, divorced/separated,

**TABLE 1.** Baseline characteristics of exercisers and controls

	Exercisers (n = 87)		Controls (n = 86)	
	Mean	(SD)	Mean	(SD)
Age	60.7	(6.6)	60.6	(6.7)
Height (cm)	163.2	(7.2)	163.3	(6.6)
Weight (kg)	81.3	(14.0)	81.7	(12.1)
Body mass index (kg/m <sup>2</sup> )	30.5	(4.1)	30.6	(3.8)
Percent body fat <sup>a</sup>	47.5	(4.8)	47.4	(4.6)
	n	(%)	n	(%)
Ethnicity				
Non-Hispanic White	74	(86.2)	75	(87.2)
Other	12	(13.8)	11	(12.8)
Marital status				
Married/living with partner	46	(52.9)	52	(60.5)
Divorced/separated	23	(26.4)	21	(24.4)
Widowed	10	(11.5)	9	(10.5)
Never married	8	(9.2)	4	(4.6)
≤ 5 y past menopause	23	(27.4)	25	(30.5)
Ever took estrogen	35	(40.2)	38	(44.2)
Ever used oral contraceptives	51	(58.6)	55	(63.9)
Ever took herbal hormones	6	(6.9)	6	(7.1)
Had a hysterectomy	13	(14.9)	18	(20.9)

There were no statistically significant differences between exercisers and controls for any characteristics. Numbers may not add up to totals due to missing values.

<sup>a</sup>Percent body fat measured using DXA scan

widowed, never married), and hysterectomy status (yes/no).

**RESULTS**

No significant baseline differences were noted between exercisers and controls for various demographic characteristics (Table 1). The majority of both exercisers and controls were non-Hispanic white, married, and had never taken any form of HT before randomization. The average age was 61 years and the mean BMI of the population at baseline was 31 kg/m<sup>2</sup>. On average, during the 12 months, women randomized to the exercise group participated in moderate-intensity sports/recreational activity 3.7 days/week (74% of the prescribed frequency of 5 days/week) for 171 min/week (76% of the prescribed duration of 225 min/week). Six exercisers “dropped out” of the intervention after 3 months; however, all were included in the analyses. Exercisers lost, on average, 1.3 kg (95% CI, -2.0, -0.5) in weight, 1.4 kg (95%CI, -2.0, -0.8) total body fat, and gained 12.7% (95% CI, 8.8-14.6) in maximal oxygen consumption.<sup>24</sup>

Approximately 54% of all women reported having at least one menopause symptom within the month before randomization (Table 2). A greater proportion of control women reported having at least one menopause symptom at baseline than exercisers (P = 0.03); how-

**TABLE 2.** Odds ratios for having menopause symptoms comparing intervention and control subjects at 3, 6, 9, and 12 mo

Menopause symptom	Exercisers n (%)	Controls n (%)	Symptom occurrence OR (95% CI)	P for trend
Any symptom				
Baseline	40 (46.0)	54 (62.8)	—	0.79
3 mo	59 (67.8)	58 (69.1)	0.9 (0.5, 1.8)	
6 mo	54 (65.1)	60 (74.1)	0.6 (0.3, 1.2)	
9 mo	51 (63.8)	55 (68.8)	0.8 (0.4, 1.5)	
12 mo	56 (68.3)	59 (68.6)	1.0 (0.5, 1.9)	
Hot flashes				
Baseline	15 (17.2)	19 (22.6)	—	0.69
3 mo	28 (32.2)	26 (31.7)	1.0 (0.5, 2.0)	
6 mo	23 (27.7)	30 (38.0)	0.6 (0.3, 1.2)	
9 mo	23 (28.8)	24 (30.8)	0.9 (0.5, 1.8)	
12 mo	23 (28.1)	28 (33.3)	0.8 (0.4, 1.5)	
Memory problems				
Baseline	28 (32.2)	33 (39.3)	—	0.17
3 mo	35 (40.2)	31 (37.8)	1.1 (0.6, 2.1)	
6 mo	30 (36.1)	41 (51.9)	0.5 (0.3, 1.0)	
9 mo	27 (33.8)	32 (41.3)	0.7 (0.4, 1.4)	
12 mo	29 (35.4)	39 (46.4)	0.6 (0.3, 1.2)	
Depressive feelings				
Baseline	13 (14.9)	13 (15.5)	—	0.89
3 mo	23 (26.4)	25 (30.5)	0.8 (0.4, 1.6)	
6 mo	24 (28.9)	21 (26.6)	1.1 (0.6, 2.2)	
9 mo	22 (27.5)	19 (24.4)	1.2 (0.6, 2.4)	
12 mo	20 (24.4)	25 (29.8)	0.8 (0.4, 1.5)	
Night sweats				
Baseline	6 (6.9)	13 (15.5)	—	0.95
3 mo	20 (23.0)	17 (20.7)	1.1 (0.5, 2.4)	
6 mo	14 (16.9)	20 (25.3)	0.6 (0.3, 1.3)	
9 mo	15 (18.8)	15 (19.2)	1.0 (0.4, 2.2)	
12 mo	15 (18.3)	15 (17.9)	1.0 (0.5, 2.3)	
Sleep problems				
Baseline	23 (26.4)	30 (35.7)	—	0.35
3 mo	36 (41.4)	37 (45.1)	0.9 (0.5, 1.6)	
6 mo	32 (38.6)	34 (43.0)	0.8 (0.4, 1.6)	
9 mo	31 (38.8)	36 (46.2)	0.7 (0.4, 1.4)	
12 mo	30 (36.6)	40 (47.6)	0.6 (0.3, 1.2)	

ever, the differences for individual symptoms were not statistically significant. The proportion of women with symptoms did not change consistently at each time point during the intervention. Among women with no menopause symptoms at baseline, there were no statistically significant differences between the proportion of exercisers and controls who later experienced symptoms at 3, 6, 9, or 12 months (data not shown). We found no statistically significant associations between exercise and the occurrence of any menopause symptoms. Although not significant, there was some suggestion of a decrease in memory problems over time for exercisers compared with controls ( $P$  for trend = 0.17).

The proportion of women who reported moderate or severe symptoms did not change consistently over time in exercisers or controls (Table 3). Few women experienced severe/moderate menopause symptoms; therefore, the CIs for the odds ratios are large and cross unity. There was a nonsignificant increase in the risk of

moderate/severe versus mild/no hot flashes at 12 months in exercisers compared with controls [odds ratio (OR) = 2.8; 95% CI, 0.8-9.3]. Exercisers had a greater risk of moderate/severe hot flashes than controls over time, although this degree of severity affected few women ( $P$  for trend = 0.02).

When the results were stratified by time since menopause ( $\leq 5$  years vs  $> 5$  years,  $n = 48$  and  $118$ , respectively), exercisers who had experienced menopause more recently had a statistically significant decreased risk for the occurrence of memory problems by 6 months into the intervention compared with controls (OR at 6 mo = 0.2; 95% CI, 0.08-0.6). The risk of memory problems was also significantly decreased among exercisers compared with controls at 9 (OR = 0.3; 95% CI, 0.1-0.9), and 12 months (OR = 0.2; 95% CI, 0.08-0.7). No substantial differences were noted in the risk estimates of all other menopause symptoms.

**TABLE 3.** Odds ratios for moderate/severe menopause symptoms versus mild/no symptoms, comparing 87 intervention and 86 control participants at 3, 6, 9, and 12 months

Menopause symptom	Exercisers n (%)	Controls n (%)	Symptom severity <sup>a</sup> OR (95% CI)	P for trend
Hot flashes				
Baseline	11 (12.6)	10 (11.9)	—	0.02
3 mo	8 (9.2)	7 (8.5)	1.1 (0.4, 3.1)	
6 mo	4 (4.9)	8 (10.1)	0.5 (0.1, 1.6)	
9 mo	8 (10.0)	4 (5.1)	2.1 (0.6, 7.2)	
12 mo	10 (12.2)	4 (4.8)	2.8 (0.8, 9.3)	
Memory problems				
Baseline	7 (8.1)	6 (7.1)	—	0.06
3 mo	8 (9.2)	2 (2.4)	4.1 (0.8, 19.8)	
6 mo	8 (9.6)	4 (5.1)	2.0 (0.6, 7.0)	
9 mo	6 (7.5)	4 (5.1)	1.5 (0.4, 5.6)	
12 mo	5 (6.1)	4 (4.8)	1.3 (0.3, 5.0)	
Depressive feelings				
Baseline	5 (5.8)	3 (3.6)	—	0.24
3 mo	5 (5.8)	6 (7.3)	0.8 (0.2, 2.6)	
6 mo	6 (7.2)	5 (6.3)	1.2 (0.3, 4.0)	
9 mo	7 (8.8)	3 (3.9)	2.4 (0.6, 9.7)	
12 mo	6 (7.4)	4 (4.8)	1.6 (0.4, 5.9)	
Night sweats				
Baseline	4 (4.6)	5 (6.0)	—	0.48
3 mo	5 (5.8)	5 (6.1)	0.9 (0.3, 3.4)	
6 mo	4 (4.8)	8 (10.1)	0.4 (0.1, 1.6)	
9 mo	3 (3.8)	5 (6.4)	0.6 (0.1, 2.5)	
12 mo	5 (6.1)	3 (3.6)	1.7 (0.4, 7.6)	
Sleep problems				
Baseline	10 (11.5)	9 (10.7)	—	0.31
3 mo	11 (12.6)	8 (9.7)	1.3 (0.5, 3.5)	
6 mo	7 (8.4)	12 (15.2)	0.5 (0.2, 1.4)	
9 mo	10 (12.5)	15 (19.2)	0.6 (0.3, 1.4)	
12 mo	8 (9.8)	11 (13.1)	0.7 (0.3, 1.9)	

<sup>a</sup>Odds ratios represent the risk of having moderate or severe symptoms versus mild symptoms or no symptoms for exercisers compared with controls.

When the results among exercisers were stratified by adherence to the intervention, increased adherence was not associated with the occurrence of menopause symptoms or increasing severity (data not shown). Neither changes in percent body fat nor changes in fitness among exercisers from baseline to 12 months modified the intervention effect in a consistent direction (data not shown).

**DISCUSSION**

This study examined the effects of a yearlong, moderate-intensity, exercise program on self-reported occurrence of menopause symptoms and their severity in women not taking HT. This is the first study to examine such associations using data from a randomized, controlled trial testing exercise as the only behavioral intervention. We observed suggestions of an increased risk of moderate/severe hot flashes at 12 months in exercisers compared with controls and decreased risk of memory problems after 3 months of exercise; however, we did not observe a statistically significant decrease in the occurrence or severity of any other

menopause symptoms in exercisers compared with controls.

The proportion of women who experienced menopause symptoms in our study was similar to the proportions of premenopausal women who reported hot flashes in the behavioral diet and exercise intervention by Boraz et al.<sup>17</sup> In that trial, 21% of intervention women (n = 246) and controls (n = 263) reported hot flashes at baseline, increasing to 29.8% at the end of 54 months, with no significant differences between intervention and control participants. Observational studies report a much higher prevalence, with approximately 50% to 85% of study participants reporting hot flashes.<sup>25–27</sup> Our study participants were restricted to overweight women who may have had fewer hot flashes than the general population due to greater amounts of estrogen production in peripheral tissues. The mean age of study participants was 60.7 years, which may be past the peak incidence of hot flashes for most women. In addition, this study only evaluated the occurrence of menopause symptoms for one month before baseline, whereas other studies have evaluated the

occurrence of menopause symptoms at any time before baseline.

Our results are similar to those of Boraz et al, who found no difference in the occurrence of hot flashes in premenopausal women after a diet and exercise intervention compared with controls.<sup>17</sup> Additionally, a case-control study among postmenopausal women in which participants reported regular hot flashes or night sweats at least once a day, observed no significant differences in the amount of vigorous recreational physical activity (at least 6 MET-hours [metabolic equivalents] between 82 cases and 89 controls (OR = 1.03; 95% CI, 0.91, 1.10).<sup>16</sup> Data from another study (n = 793) showed that only 5% of highly physically active postmenopausal women experienced hot flashes compared with 14% to 16% of sedentary women—a difference that was not explained by BMI or HT use.<sup>15</sup> However, that study was observational and used a retrospective assessment of physical activity.

Although decreases in circulating estrogen levels may be one reason that we saw a trend of increasing hot flash severity associated with exercise, other biological mechanisms exist that may help explain this association. Exercise has been shown to increase core body temperature, which in turn may trigger hot flashes in women with a narrower thermoneutral zone.<sup>28</sup> Increased adiposity may also raise core body temperature, thus increasing the occurrence of hot flashes in overweight women.<sup>29</sup> In fact, one cross-sectional study actually found an increased risk for moderate/severe hot flashes among women with a BMI greater than 30 kg/m<sup>2</sup> compared with women with a BMI less than 24.9 kg/m.<sup>2,30</sup>

The major strength of our study is that it was a randomized clinical trial. Adherence to the intervention was excellent, with minimal attrition from either the intervention or control group. Additionally, no women in this study were taking HT during the intervention period (other than the two women deleted from this analysis). Lastly, because both exercisers and controls in our study were able to interact with other women in their same treatment arm, it is unlikely that socialization had any differential impact on our results, even if socialization does have an effect on the reporting of menopause symptoms.

Although this study demonstrated little benefit or adverse affect of exercise in postmenopausal women, caution should be taken when interpreting the results. Women were excluded from the study if they currently had menopause symptoms severe enough that they would likely opt to take HT within the yearlong intervention. Thus, the results may not apply to women cur-

rently experiencing severe menopause symptoms or to women presenting for clinical management of menopause symptoms. We only enrolled currently sedentary, overweight women who were not taking HT to maximize the results for the primary aims of the intervention: body mass and sex hormone levels. The effect of exercise on menopause symptoms may be different for leaner women or women taking estrogen. Yet in light of an increasing trend for women to opt not to take HT,<sup>31</sup> these results may be more clinically relevant. In addition, the body mass profile of our participants reflects more than 60% of the population of American adult women.<sup>32</sup> Regarding the differences in total body fat and total weight lost in exercisers (1.4 vs 1.3 kg, respectively), the average total body fat could have been greater than the average total weight lost because the exercisers may have gained muscle mass.

We also observed that the proportion of controls that reported having menopause symptoms at baseline was greater than the proportion of intervention participants, a difference that occurred by chance. Since this was a randomized clinical trial, we did not adjust for baseline symptoms in this intent-to-treat analysis. When we did adjust for baseline symptoms, we found that the risk estimates were similar to the primary analysis (data not shown); however, none of the adjusted odds ratios were statistically significant. In addition, the overall prevalence of menopause symptoms for both groups was still similar to that of the general population.<sup>17,25-27</sup>

The baseline questionnaire asked women about the occurrence of menopause symptoms in the past month, whereas the follow-up questionnaires asked about the occurrence of menopause symptoms in the past 3 months. This may explain the increases in the proportion of women experiencing menopause symptoms from baseline to 3 months. However, telescoping bias (recalling events or behaviors as occurring during a more recent time period than when the behavior actually occurred) may have influenced symptom reporting on the baseline questionnaire, suggesting that the difference in the questionnaires had a minimal effect on our results.<sup>33-36</sup>

In conclusion, these data suggest that in a small number of women, a moderate-intensity exercise intervention may increase the prevalence or severity of some menopause symptoms, and it may reduce self-assessed memory problems. However, these data do not support exercise as a method to reduce the occurrence of hot flashes or night sweats, two symptoms that affect many postmenopausal women and will especially impact women who opt not to take HT because of concerns about adverse effects.<sup>6</sup> It is not clear what steps might

be taken for women who experience increased hot flashes or night sweats during an exercise program, although several alternatives to HT have been suggested for postmenopausal women in general.<sup>37</sup>

### CONCLUSIONS

Exercise did not seem to substantially increase the risk of having menopause symptoms in this population of overweight, postmenopausal women. In addition, the risk of severe symptoms (specifically hot flashes) was only increased in a very small number of women. Women who decide to take up an exercise program should do so in consultation with their primary physician, but should not be deterred due to the thought that their menopause symptoms might increase in occurrence or severity.

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