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Effects of a six-month walking intervention on depression in inactive post-menopausal women: a randomized controlled trial


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Effects of a six-month walking intervention on depression in inactive post-menopausal women: a randomized controlled trial


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Objectives: Physical inactivity and advanced age are associated with risk of depressive disorders. Physical activity can reduce depressive symptoms in older subjects with depressive disorders. We investigated whether a walking intervention program may decrease the occurrence of depressive symptoms in inactive post-menopausal women without depression.

Method: A total of 121 participants aged 57–75 years were randomly assigned to a six-month moderate intensity walking intervention (three times a week, 40 minutes per session, supervised and home-based) or to a control group (waiting list). Inactivity was assessed using the Physical Activity Questionnaire for the Elderly. Depression levels were measured pre- and post-intervention with the Beck depression inventory (BDI). Several baseline measures were considered as possible predictors of post-intervention BDI score.

Results: Participants in the walking intervention showed a significant decrease in depression as compared with controls. Baseline cognitive-BDI subscore, subjective health status, body mass index and adherence were post-intervention BDI score predictors.

Conclusion: A six-month, three-session per week, moderate intensity walking intervention with a minimal 50% adherence rate reduces depression in post-menopausal women at risk for depression due to physical inactivity. This type of walking intervention could be considered as a widely accessible prevention strategy to prevent depressive symptoms in post-menopausal women at risk of depression.

Keywords: post-menopausal women; walking; exercise; depressive disorders; predictors; physical activity

Introduction

In its global burden of disease report based on disability and mortality estimates, the World Health Organization reports that major depressive disorders (MDD) will become the second most important public health issue by the year 2020 (Munoz, Beardslee, & Leykin, 2012). Specifically, older adults are well identified as a high-risk population for depression (Sutin et al., 2013). Depressive disorders, whatever their severity, are associated with significant excess mortality after myocardial infarction and stroke, as well as cancer, and are the major risk factors for suicide in old age (Reynolds et al., 2012). A high depression score is associated with increased risk of incident myocardial infarction, diabetes (Balasubramanian et al., 2011; Byers et al., 2012), as well as osteoporosis and fracture (Wu, Liu, Gallegos-Orozco, & Hentz, 2010; Yirmiya & Bab, 2009). Furthermore, a score above 15 on the Center for Epidemiologic Studies Depression Scale (CES-D) was significantly associated with a risk of long-term incident diabetes in a Women’s Health Initiative cohort (Ma et al., 2011). Among adults aged 60 and above, a longitudinal increase in Geriatric Depression Scale score is associated with a decline in functional ability, even with an initial low to moderate depression score (Nyunt, Lim, Yap, & Ng, 2012). Moreover, a low CES-D score predicts an increase in instrumental activities of daily living limitations (Hybels, Pieper, & Blazer, 2009). Depressive adults aged 65 years or more, even with a low score on the CES-D, are more likely to experience major depression over a 12-year follow-up period, especially if they are women (Andreescu, Chang, Mulsant, & Ganguli, 2008).


Among the factors associated with the emergence of depressive disorders (e.g. disability, social isolation, neuroticism, lower education), physical inactivity (PI) is well identified and modifiable (Mammen & Faulkner, 2013). PI is defined as less than 150 minutes of moderate-intensity physical activity (PA) or 60 minutes of vigorous-intensity PA per week (Lee et al., 2012). PI has been identified as a factor for depressive disorders in several national-scale population-based prospective studies in both middle-aged (Brown, Ford, Burton, Marshall, & Dobson, 2005) and older adults (Lindwall, Larsman, & Hagger, 2011; Mammen & Faulkner, 2013; Strawbridge,
Deleger, Roberts, & Kaplan, 2002), even after adjustment for possible confounders including smoking or alcohol consumption. Specifically, a 10-year prospective study including older women showed that walking for more than 40 minutes per day decreased the risk of MDD by 17% (Lucas et al., 2011). In this perspective, obtaining further evidence of the effectiveness of health prevention strategies on inactive post-menopausal women seems necessary.

PA may therefore significantly help lower depression symptoms in post-menopausal women. Indeed, previous meta-analyses suggested that PA was effective in reducing depression symptoms in adults with depressive disorders (Bridle, Spanjers, Patel, Atherton, & Lamb, 2012; Cooney et al., 2013). Based on these results, UK-National Institute for Health and Care Excellence (UK NICE) guidelines recommend structured PA programs for adults with persistent subthreshold depressive symptoms. In this case, PA should be supervised and consist of three sessions of 45–60 minutes per week for a period of at least 10–14 weeks (National Institute for Health and Clinical Excellence, 2009). A favorite among post-menopausal women (Daley et al., 2011), walking involves little or no financial cost and minimal risk of adverse effects (Robertson, Robertson, Jepson, & Maxwell, 2012); it is thus particularly relevant. Furthermore, among adults with depressive disorders, walking interventions have yielded promising results on depression (Robertson et al., 2012).

However, evidence that PA may prevent depression in older subjects without depressive disorders is lacking. To the best of our knowledge, only one pilot study, conducted on a sample of post-menopausal women without depressive disorders (n = 17), has shown that an exercise program (six weeks, five sessions per week) could significantly improve the subjects’ depression subscores on the Hospital Anxiety Depression Scale (Asbury, Chandrauangphen, & Collins, 2006).

Ancillary analyses in randomized-control trials (RCTs) have identified baseline high outcome expectations, social support, quality of life and low self-reported anxiety (Herman et al., 2002), strength gains and training intensity (Singh, Clements, & Fiatarone, 1997; Singh et al., 2005) as predictors or correlates of a decrease in the depression score after an exercise intervention among the elderly with minor depression or MDD (Herman et al., 2002; Singh et al., 1997, 2005). The above have also been identified as predictors of the decrease in the depression score on the Hamilton Depression Rating Scale (HDRS). Among adults without depressive disorders, age (>40 years), poor sleep quality and alcohol consumption (>6 drinks per week) were negatively associated with HDRS score after an exercise intervention (Leppämäki, Haukka, Lönnqvist, & Partonen, 2004).

Thus, a selective preventive intervention according to the Institute of Medicine (1994) based on walking should particularly target inactive post-menopausal women (who are particularly at high risk of incident MDD; Robertson et al., 2012).

We therefore conducted an RCT to investigate whether a six-month walking intervention may lower depression symptoms in inactive post-menopausal women without depressive disorders, and to identify the baseline predictors of the post-intervention depression score.

**Method**

**Design**

This study used a prospective, randomized, control-group design. Participants in both groups were assessed at inclusion and at the end of the program. This study was approved by the Committee for Protection of Human Subjects (CPP Sud-Méditerranée III, number: 2008.07.04) and registered with ClinicalTrials.gov, number NCT02094144. All participants provided written informed consent.

**Participants**

Community-dwelling women were recruited during public meetings held between January 2008 and September 2010, aimed at promoting PA among post-menopausal women. Candidates completed the Physical Activity Questionnaire for the Elderly (PAQE). Eligible participants were asked to provide a certificate of non-contraindication to perform the six-minute walk test (6MWT). After inclusion criteria were checked, participants were randomly assigned to either a waiting list involving no practical intervention (control group) or to a six-month standardized walking program.

**Eligibility criteria**

Candidates were included if they (1) scored less than 9.4 on the PAQE questionnaire, (2) achieved a six-minute walking distance under 5% of the normative 6MWT (based on Troosters’ reference equation, i.e., $218 + [(5.14 \times \text{height}) − (5.32 \times \text{age})] − [(1.8 \times \text{height}) + (51.31 \times \text{sex})]$) and (3) were aged between 55 and 76 years. Women who (1) were unable to complete self-administered questionnaires in French, (2) were diagnosed with any of the following conditions: rheumatoid arthritis, osteoarthritis, ischemic heart disease, previous joint replacement surgery or cerebrovascular disease affecting lower limb function, malignant tumors, or (3) experienced pain or used medication known to alter physical performance (e.g. corticosteroids, estrogens, statins, or anti-estrogen drugs) were excluded from the study.

**Randomization**

After a baseline assessment, participants were randomized using a computer-generated list of random numbers. The study manager subsequently informed participants of their group allocation. Participants were unaware of their group allocation until they had completed all of their pre-intervention assessment.
**Intervention**

A (physical training) walking program called Acti’march® was implemented by properly qualified exercise trainers. Participants were required to attend two outdoor supervised walking sessions (40 minutes per session) and one non-supervised session per week for six months. Walking intensity was tailored to each subject according to her capabilities. It was based on the theoretical maximum heart rate (HR) of the subject, as given by the formula for the inactive elderly, $HR_{\text{max}} = (208 - 0.7) \times (age)$ (Tanaka, Monahan, & Seals, 2001), which establishes the maximum HR an individual can achieve before experiencing severe exercise stress issues. Training usually starts at 40% of the working HR (difference between maximum HR and resting HR); training intensity is gradually increased to finally reach 75% of the working HR. The values obtained during the initial visit were considered reference values for each subject. Participants wore HR monitors (Polar Electro, Inc., Woodbury, NY) during their exercise sessions. Each participant received a logbook to record sessions performed at home.

**Measures**

**Primary outcome**

The primary outcome was the change in the depression score level assessed with the Beck Depression Inventory (BDI) at six months. The objective was to measure the impact of the walking intervention (Beck, Steer, & Carbin, 1988; Cathébras, Mosnier, Lévy, Bouchou, & Rouset, 1994). The BDI is a self-reported measure of depression consisting of 21 items, including self-dislike, suicidal ideation, insomnia and sadness. The items are summed (0–63 range), with higher scores indicating greater depression levels. The BDI contains cognitive (e.g. pessimism, worthlessness) and physical (e.g. fatigue and loss of energy) subscales. It has proved sensitive to exercise-induced changes in healthy adults (Stein & Motta, 1992) and in patients with MDD (Babyak et al., 2000).

**Secondary outcomes**

To investigate the predictors of the post-intervention depression scores, we measured baseline parameters and the subjects’ adherence to the intervention program.

**Socio-demographic measures**

Age, education level and marital status data were collected, as were medical information including smoking status, history of depression and fracture, age of menopause, and drug history (antidepressants, anxiolytics).

**Anthropometric measures**

Body mass index (BMI) was calculated based on objective measures of weight and height. Calf circumference was measured on the dominant leg in a sitting position with the knee and ankle at a right angle and the foot resting on the floor. Calf circumference was measured using flexible metal tape on the dominant side of the body. Subjects were asked to stand erect with their weight evenly distributed on both feet and legs slightly apart. The circumference measure was taken 10 cm above the apex of the patella in extension and without contraction.

**Functional characteristics**

The 6MWT was administered according to the American Thoracic Society (2002) guidelines in an indoor corridor. Two cones, placed 30 m apart from each other, indicated the length of the walkway. The subjects were instructed to walk back and forth around the cones for six minutes, without running or jogging. Participants were comfortable clothes and shoes. Standardized encouragements were provided at recommended intervals (ATS, 2002). Maximum grip strength and isometric maximum knee extension strength were measured after a warm-up session, as previously described (Blain et al., 2010). Scores consisted in the mean of three maximum trials.

**Physical activity**

PA (including household activities, sports and leisure activities) was assessed using the PAQE (Voorrips, Ravelli, Dongelmans, Deurenberg, & Van Staveren, 1991). The activities of walking outdoors, biking and doing heavy housework were summed to obtain a PA score (0–3 range). Respondents who did not engage in any activity were given zero points; those who engaged in all three received three points. Healthy subjects with scores below 9.4 were classified as having low PA (Serres, Gautier, Varray, & Préfaut, 1998).

**Subjective measures**

Subjective health status was assessed with the following item: compared to the people of the same age, do you consider your health as better than theirs (1), equal to theirs (2), or worse than theirs (3)? The Tampa Scale for Kinesiophobia is a 17-item questionnaire which assesses the fear of (re)injury due to movement (Swinkels-Meewisse, Swinkels, Verbeek, Vlaeyen, & Oostendorp, 2003). The subjects were asked to rate the degree to which they agreed with each of the 17 statements. Their ratings were summed to obtain a total score; higher values reflect greater fear of (re)injury (French, France, Vigneau, French, & Evans, 2007).

**Adherence**

The adherence rate to the walking intervention was calculated with the data recorded in the logbooks. The supervised and self-reported home-based walking sessions were then pooled to obtain the adherence rate.
Data analysis

Several statistical tests (independent t-test, \(x^2\) test and Mann–Whitney test) were used to compare the baseline characteristics of women in both groups. Our objective was to identify baseline covariates which could differentiate the groups despite the randomized-controlled design of the study. The BDI score change between the baseline value and the value recorded at the end of the six-month walking program was evaluated using an analysis of covariance (ANCOVA), with a term for treatment and the baseline depression score as a covariate. The baseline variables which differed significantly from one group to another were also considered as covariates. Based on the ANCOVA model, the 95% confidence interval (CI) for the adjusted mean change from baseline was computed for each group and for the difference between the groups. The magnitude of the statistically significant group differences, as analyzed by the ANCOVAs, was calculated using partial eta-squared [intervention effect sum of squares (SS) divided by error SS plus intervention SS]. This measure of effect size is small at .01, medium at .09 and large at .25. The primary analysis of study outcomes focused on the ‘completer’ sample (Cohen, 1988). Data were analyzed according to the intention-to-treat (ITT) principle. To minimize type I errors and loss of power, endpoint analyses according to the imputation of the mean of the other group principle were performed for missing values at six months (Unnebrink & Windeler, 2001).

To identify the factors associated with the BDI score at the end of the walking intervention, we first analyzed all the baseline and adherence variables using Pearson r correlations. Second, variables which showed statistically significant or borderline significant (\(p < .05\)) univariate associations with BDI scores were included in a backward multivariate regression analysis with a pre-specified limit requirement of a subject-to-variable ratio of at least 5:1 (i.e. no more than 12 predictor variables; Tabachnick & Fidell, 1989). For all the statistical tests, SPSS 16 (SPSS Inc, Chicago, IL) was used, and \(p\) less than .05 was considered statistically significant.

Results

Figure 1 displays the participant flow throughout the study. We assessed 580 participants for eligibility and randomly assigned 121 participants to two groups (intervention group and control group).

Sample characteristics

Table 1 displays the characteristics of the subjects (women aged 57–75 years). At baseline, participants
from both the groups showed similar characteristics except for BMI ($p < .01$), calf circumference ($p < .01$) and thigh circumference ($p < .05$), which were significantly higher in the control group. The adherence rate to the walking intervention was 53.8%.

**Primary outcome**

The effect of the walking intervention on the depression scores was studied using an ANCOVA of post-intervention BDI scores, based on pre-intervention values and initial difference (i.e. weight, BMI, calf circumference, thigh circumference) as the covariate. Adjusted mean BDI score was significantly lower for the walking group than for the control group ($M_{Wd} = 10.52, SD = 7.8, p = .015$) with the size effect $\eta^2 = .05$. The mean difference was $M = 2.77, SD = 1.12, 95\% CI [.55, -.99].$

### Table 1. Baseline characteristics of trial participants by study group.

<table>
<thead>
<tr>
<th></th>
<th>Walking ($n = 61$)</th>
<th>Control ($n = 60$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>65.46 4.37</td>
<td>65.5 4.03</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary school, high school</td>
<td>22 36.1</td>
<td>16 26.7</td>
</tr>
<tr>
<td>College degree or higher</td>
<td>39 63.9</td>
<td>44 73.3</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced, single, widowed</td>
<td>24 39.3</td>
<td>32 53.3</td>
</tr>
<tr>
<td>Couple</td>
<td>37 60.7</td>
<td>28 46.7</td>
</tr>
<tr>
<td>Age at menopause</td>
<td>47.95 9.41</td>
<td>49.27 9.60</td>
</tr>
<tr>
<td>Antecedent of fracture</td>
<td>19 31.1</td>
<td>21 65</td>
</tr>
<tr>
<td>Menopause before 50 years</td>
<td>38 62.3</td>
<td>30 50</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Former smoker</td>
<td>16 26.2</td>
<td>17 28.3</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>45 73.8</td>
<td>43 71.7</td>
</tr>
<tr>
<td>Antidepressant use</td>
<td>3 4.9</td>
<td>2 3.3</td>
</tr>
<tr>
<td>Anxiolytic use</td>
<td>1 1.6</td>
<td>3 5.0</td>
</tr>
<tr>
<td>Weight (kg)**$^*$</td>
<td>64.13 12.05</td>
<td>70.05 11.56</td>
</tr>
<tr>
<td>BMI**$^*$</td>
<td>24.68 4.34</td>
<td>26.530 4.27</td>
</tr>
<tr>
<td>Calf circumference (cm)**$^*$</td>
<td>34.58 2.73</td>
<td>36.46 2.69</td>
</tr>
<tr>
<td>Thigh circumference (cm)**$^*$</td>
<td>46.02 5.81</td>
<td>47.62 5.10</td>
</tr>
<tr>
<td>Handgrip strength (Nm)</td>
<td>22.03 6.40</td>
<td>22.67 5.77</td>
</tr>
<tr>
<td>6MWT (m)</td>
<td>461.39 50.32</td>
<td>459.71 63.05</td>
</tr>
<tr>
<td>60 PCdoExt</td>
<td>86.03 19.96</td>
<td>86.23 24.54</td>
</tr>
<tr>
<td>TSK</td>
<td>34.36 7.80</td>
<td>36.93 7.87</td>
</tr>
<tr>
<td>Health perception</td>
<td>1.79 0.55</td>
<td>1.78 0.58</td>
</tr>
<tr>
<td>BDI</td>
<td>12.31 9.12</td>
<td>11.32 7.65</td>
</tr>
</tbody>
</table>

Note: BMI = Body mass index; BDI = Beck depression inventory; 60 PCdoExt = Dominant leg extension peak torque at 60°/s; TSK = Tampa Scale for Kinesiophobia.

$^*$Wilcoxon–Mann–Whitney tests.

$p < .05$. $^*p < .001.$

**Secondary outcomes**

We found statistically significant univariate associations between post-intervention BDI score and baseline cognitive-BDI subscore ($r = .71, p = .00$), physical-BDI subscore ($r = .54; p = .00$), subjective health status ($r = .32, p = .01$), kinesiophobia ($r = .30, p = .02$), thigh circumference ($r = .50, p = .00$), adherence to the program ($r = -.30, p = .03$), PAQE score, dominant leg flexion peak torque (CoPCdoFI), BMI, education range between $p < .10$ and .20. All these variables were included in the backward multivariate regression.

In that multivariate model, the baseline cognitive-BDI subscore ($\beta = .65, p = .00$), subjective health status ($\beta = .28; p = .003$), BMI ($\beta = -.182, p = .04$) and adherence rate ($\beta = -.22; p = .01$) were significant and independent predictors of post-intervention BDI score, explaining 62.3% ($p < .001$) of the variance in BDI.
Discussion

This RCT showed that a moderate-intensity, six-month walking intervention comprising three sessions of 40 minutes per week decreased BDI score levels in inactive post-menopausal women without depressive disorders. To our knowledge, this is the first study to evidence this effect.

Beyond the known positive effects of walking interventions on body weight, percent body fat, resting diastolic blood pressure, femoral bone mineral density and persistent mobility disability (Ma, Wu, & He, 2013; Magistro, Liubicich, Candela, & Ciairano, 2013; Murphy, Nevill, Murtagh, & Holder, 2007; Pahor et al., 2014), our results are of particular significance for inactive post-menopausal women. Indeed, this population subgroup is at a high risk for depression, which is known to cause numerous adverse effects increasing the risk of diabetes or fracture (Ma, Chiang, Yen, Huang, & Tsai, 2011; Wu et al., 2010).

Additionally, our data helps solidify the notion that walking should be recommended at both secondary (National Institute for Health and Clinical Excellence, 2009) and primary levels of prevention of depressive disorders in inactive post-menopausal women. In our study, the women who benefited the most from the effects of the intervention were those whose baseline adiposity was high and subjective health status was low; these factors are known to significantly increase the risk of incident depressive disorders (Arve et al., 2012; Pan et al., 2012). Additionally, the subjects who benefited the most were also those whose adherence to the intervention was high independently of baseline BDI and other possible confounders. Taken together, these results substantively contribute to the argument that, when performed at moderate intensity, regularly and for a period at least of six months, walking may help prevent depression in post-menopausal women.

Among different types of PA (e.g. biking, running), walking seems particularly adequate for inactive post-menopausal women. Indeed, in a study conducted on 1693 post-menopausal women, Daley et al. (2011) underlined that walking was the PA preferred by most women (96.5%), regardless of their health status or BMI. In our RCT, all subjects finished the six-month program, and adherence to the sessions reached 53.8%, confirming that a program combining biweekly supervised sessions and weekly home-based sessions was well received by inactive post-menopausal women and easily integrated into their daily life.

Several mechanisms could explain the antidepressant effects of exercise (Bernard et al., 2013): the exercise self-esteem and efficacy model, self-efficacy, response styles theory, the brain-derived neurotrophic factor hypothesis (BDNF) and the serotonin hypothesis. In particular, BDNF and self-efficacy are likely to have been involved in our study. A significantly higher BDNF response to aerobic exercise training has been identified in the elderly (Coelho et al., 2013). Among women >50 years with or without MDD, exercise leads to a significant upregulation and transient normalization of BDNF serum levels (Laske et al., 2010). Self-efficacy could also explain our results partially: a gradual increase in self-efficacy during an exercise intervention is associated with the improved ability to fight depression (Chu, Buckworth, Kirby, & Emery, 2009; White, Kendrick, & Yardley, 2009). Therefore, similarly to the three major sources of self-efficacy (mastery experience, vicarious experience and perceived physiological or affective states; Ashford, Edmunds, & French, 2010), gradual walking intensity, group practice and repeated HR measurements could be conceptualized.

The main strength of this study is its randomized-controlled design and its ITT analysis. Another strength is the variety of baseline parameters measured to identify post-intervention BDI score predictors, in a relatively large sample of well-characterized, healthy post-menopausal women of a wide age range.

Several limitations must be also considered. First, the walking intervention was designed with specific intensity, frequency and length parameters. Therefore, the results are not transferable to other types of physical activity programs. Second, despite randomization, a few imbalances were found with regard to patient characteristics. Nevertheless, these factors were controlled in the statistical analysis. Moreover, the fact that the women in the intervention group exhibited higher adiposity rates than those of the control group may have undermined the impact of the program — indeed, as shown above, adiposity is a predictor of the positive effect of a walking program on depressive symptoms. Third, our sample consisted of inactive post-menopausal white women; therefore, our results cannot be extrapolated to women with other characteristics, especially of other ethnic backgrounds, and in whom depression may have different features (Kripke et al., 2004). Fourth, the history of depression (MDD or minor depression) was not assessed, although this factor could modify our results. Fifth, the validity of this study’s primary result might be questioned on the basis of a potential contamination effect, which could have been induced by the ease with which walking is performed, the assessment instruments (e.g. 6MWT) and a recruitment strategy effect (i.e. the extent to which the control group performed self-motivated walking; Courneya et al., 2004).

In conclusion, this study shows that a six-month, three-session per week, moderate-intensity walking intervention with a minimal 50% adherence rate reduces depression in post-menopausal women who are at risk for depression due to PI. Consequently, this type of walking intervention could be considered as a widely accessible prevention strategy to prevent depressive symptoms in post-menopausal women at risk of depression, especially those whose inactivity is associated with high adiposity and decreased subjective health status. Further studies should attempt to design large scale and multi-center RCTs to explore the impact of a similar walking intervention on long term MDD incidence. Future research should therefore investigate the psychobiological mechanisms by which moderate intensity walking may prevent depression in post-menopausal women with or at risk of depression.


