

BMJ Open Long-term effect of physical activity on health-related quality of life among menopausal women: a 4-year follow-up study to a randomised controlled trial

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ABSTRACT

Objectives: The aim of the study was to explore the long-term effects of physical activity intervention on quality of life (QoL) 4 years after an original randomised controlled trial (RCT).

Design: Cohort study after an RCT.

Setting: 95 of the 159 women from the original RCT participated in weight, height and waist circumference measurements, performed the UKK 2 km Walk Test and completed the SF-36 Health Survey questionnaire. Multilevel mixed regression models were performed in order to compare the original and current group in an RCT setting.

Participants: There were 159 participants in the original RCT; 2.5 years later, 102 of the women responded to a questionnaire and 4-year after the trial, there were 95 respondents. The inclusion criteria in the original RCT were: being symptomatic, experiencing daily hot flushes, age between 40 and 63 years, not using hormone therapy now or in the past 3 months, sedentary lifestyle and having last menstruated 3–36 months earlier.

Main outcome measure: Health-related QoL as measured with the SF-36 instrument.

Results: Women in the intervention group had a significantly higher probability of improved physical functioning (OR 1.41; 95% CI 1.00 to 1.99) as compared with women in the control group. In addition, women in the intervention group had higher odds of good role functioning (OR 1.21; 95% CI 0.88 to 1.67), physical health (OR 1.33; 95% CI 0.96 to 1.84) and general health (OR 1.14; 95% CI 0.81 to 1.62), relative to women in the control group, although the differences did not reach statistical significance.

Conclusions: Women in the intervention group showed positive long-term effects on physical and mental dimensions of QoL after 4 years.

Trial registration number: ISRCTN54690027.

INTRODUCTION

Many physiological and psychological signs and symptoms occur in the lives of

Strengths and limitations of this study

- The core strengths of the study are its prospective study design and repeated assessments of physical activity behaviour at several time points after intervention.
- Our study underlines the importance of physical activity during menopausal transition.
- The response rate (59.7%) was low and women with an adverse lifestyle were more likely to be found among non-responders.

middle-aged women.¹ A positive association between physical activity (PA) and quality of life (QoL) has been explored in many studies.^{2–7} PA has been associated with lower rates of cognitive and physical decline among postmenopausal women.⁸ In addition, PA appears to have positive effects on work ability, both short and long terms.⁹ Hormone therapy (HRT) is widely used as treatment for menopause symptoms, even though exercise has been deemed an alternative option for alleviating their symptoms and improving QoL in midlife.^{1–10} In an 8-year follow-up study, PA has been found to be a significant factor among menopausal women who had stable weight or were highly educated.⁴ Increasing one's level of PA during menopausal transition and the postmenopausal period or at least maintaining the recommended level has also been suggested to reduce various psychological symptoms.¹¹

We previously reported results from our menopausal health and PA intervention randomised controlled trial (RCT)^{6–12} examining aerobic training, and improved menopausal and health-related QoL among menopausal women. Women in the intervention group showed significantly larger decrease in the frequency of night-time hot flushes. These

findings were based on information collected through mobile phone diaries. Additionally, the diaries pointed to better sleep quality among women in the intervention group as compared to those in the control group.⁷ We also reported that the 6-month exercise intervention had effects on work ability 2½ years after the RCT.⁹

The aim of the follow-up study reported here was to explore the long-term effects of the PA intervention on QoL 4 years after the RCT.

MATERIALS AND METHODS

The study population consisted of a sample of women who participated in a follow-up 4 years after the beginning of the trial, which was in 2009.⁶ The intervention study in 2009 was a RCT (ISRCTN54690027, <http://www.controlled-trials.com/>) in which the women were randomised into an intervention and a control group. Criteria for inclusion in the intervention study were: being symptomatic, experiencing daily hot flushes, age between 40 and 63 years, not using HRT now or in the past 3 months, having a sedentary lifestyle (with aerobic training under twice a week) and having last menstruated 3–36 months earlier. Women who were physically active (exercising two or more times a week, at least 30 min at a time); whose body mass index (BMI) was above 35 kg/m²; or who had coronary heart disease, orthopaedic or other diseases preventing them from exercising, were excluded from the study. Further, women who were using medication influencing heart rate, or using β -blockers, were excluded, since they would have biased the results pertaining to heart rate. Menopausal status was verified via assay of plasma follicle-stimulating hormone (FSH exceeding 30 IU/L). Before the trial began, daytime and night-time hot flushes were recorded in a 2-week diary, with the women instructed to record a sensation of warmth, with or without concomitant sweating, as a hot flush, and the daily frequency of hot flushes before the intervention was estimated. During the intervention, the number of hot flushes, both daytime and night-time, was calculated. In total, 159 women participated in the study, and the duration of the intervention was 6 months.⁶

The women in the intervention group engaged in aerobic training four times a week, with 50 min of exercise each time. They were instructed to exercise at a level of about 64–80% of maximal heart rate, whereas the women in the control group were instructed to keep their PA habits unchanged. In the intervention group, at least two PA sessions had to consist of walking or Nordic walking, while the other sessions could include walking, Nordic walking, skiing, jogging, cycling, swimming, aerobics and/or gymnastics. The intervention primarily included walking because earlier trials showed it to have favourable effects on health among menopausal and postmenopausal women.¹³ Information on hot flushes and aerobic training was collected via mobile phone questionnaires twice a day. Responses were automatically

transferred to digital format via 3G technology.¹⁴ The SF-36 Health Survey questionnaire was used to measure health-related QoL. This questionnaire has been validated in Finland¹⁵ and is known to be a reliable measure of QoL. It is composed of 36 items, addressing eight dimensions of QoL: physical functioning, physical role limitations, bodily pain, general health, vitality, social functioning, emotional role limitations and mental health.⁶ The scores for each of the eight dimensions were transformed linearly to a scale ranging from 0 (maximal impairment) to 100 (best QoL).⁶

The first follow-up questionnaire was posted to the participants 2½ years after the intervention began, and 102 of the 159 women responded. Results from this follow-up questionnaire have been reported in earlier work.⁹

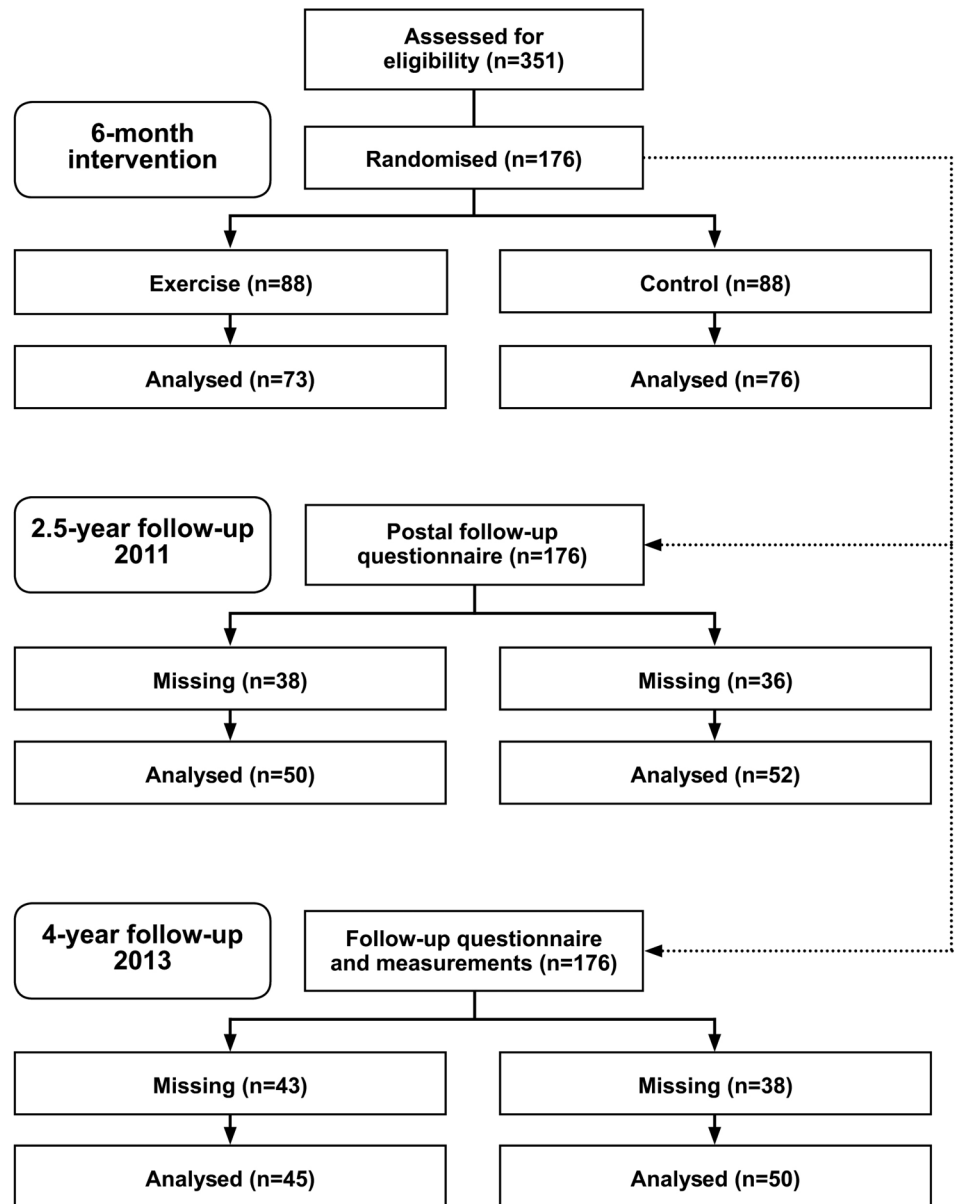
Four years after the beginning of the trial, the participants (n=159) were asked to take part in the second follow-up study. After this request, 95 of the women responded to the questionnaire and participated in the measurements. All the participants gave written consent. Weight, height and waist circumference were measured with lightweight clothing by staff of the UKK Institute, and the UKK 2 km Walk Test was performed.¹⁶ The participants completed the SF-36 Health Survey questionnaire on health-related QoL, at home.¹⁵ In addition, they carried a Hookie accelerometer for a week, in order to measure their daily PA. Also, the women were asked to take notes, in a 1 week diary, about the type and intensity of their PA, and to note the exercise time. Specific questions related to accelerometer use and the UKK 2-km Walk Test will be reported on in a separate article. In addition, the participants were asked to use a 1 week diary to note the number of daytime and night-time hot flushes experienced, the time they fell asleep and woke up, and their judgement of their sleep quality. A flow chart of the participants' data is shown in [figure 1](#).

STATISTICAL ANALYSIS

The characteristics of the study population are described best in terms of means and SEMs, or frequencies and percentages ([table 1](#)).

Multilevel mixed effects logistic regression models were constructed to account for the within-subject correlation between four time points. The odds model was used for analysis of the association between the outcomes both on the physical dimensions (physical functioning; role functioning, physical; freedom from pain; and physical health) and on the psychological dimensions (role functioning; emotional; vitality; emotional well-being; social functioning; general health; and mental health) over time and between the intervention versus the control group. Multilevel linear regression models could not be used, because the distributions of SF-36 variables were skewed or discrete. Since the conditions necessary for the use of multilevel ordinal logistic

Figure 1 Participant flow chart.



regression models were not met, these models could not be used either.

The multilevel model for dichotomous outcome y_{ij} at time i for person j can be expressed as

$$\text{logit}\{\text{Pr}(y_{ij} = 1 | x_{ij}, \zeta_j)\} = \beta_1 + \beta_2 x_{2j} + \beta_3 x_{3ij} + \beta_4 x_{2j} x_{3ij} + \zeta_j,$$

where x_{2j} represents group, x_{3ij} represents time, $\mathbf{x}_{ij} = (x_{2j}, x_{3ij})'$ is a vector containing both covariates, and ζ_j is a person-specific random intercept. This model allows for a difference between groups at baseline β_2 , and linear changes in the log odds of outcome over time with slope β_3 in the control group and slope $\beta_3 + \beta_4$ in the intervention group. Therefore, β_4 , the difference in the rate of improvement (on the log odds scale) between groups, can be viewed as changing over time between groups.¹⁷ Also second-order and third-order functions of time were included in the model, for testing of whether

a model with a non-linear effect improved the fit. A likelihood-ratio test was used for models' comparison, to identify the model fitting best. The parameter estimates were presented as ORs with 95% CIs.

The proportions for the physical and mental dimensions of QoL by time are shown in figures 1 and 2. The outcomes of QoL dimensions were classified in two categories according to medians. Proportions of women having higher or equal score than median are shown in figures. Higher score defines more favourable health state. The Wilson score method without continuity correction:

$$\frac{(2np + z^2 \pm z\sqrt{(z^2 + 4npq)})}{2(n + z^2)},$$

where n denotes the sample size, p is a single proportion, $q=1-p$ and z denotes the standard normal deviate

associated with a two-tailed probability α , was used to calculate the 95% CIs for the proportions in figures 1 and 2.¹⁸

The significance of all tests was determined to be at a p value <0.05, and data analyses were performed with Stata Statistical Software, Release 12 (from StataCorp LP, College Station, Texas, USA).

In these models, we used all available responses from women even if they had not responded to all points of data collection. As sensitivity analyses, we performed multilevel mixed effects logistic regression models also for women who responded to all four time points (N=75). We also analysed the results by using only the second follow-up (without 2.5 years follow-up).

RESULTS

Most of the participants (68%) were employed or part-time workers (9%) when the intervention began. Over the course of the 4 years, 7–20% of the women were in part-time employment.

The women participating in the 4-year follow-up were, on average, 58 years of age, and their mean BMI was 26–27 kg/m². In the follow-up, no significant change in BMI was observed. The proportion of women using HRT was higher at the 4-year follow-up point than before the intervention. In the follow-up, no significant differences were observed in use of blood pressure and cholesterol medication. Use of headache medicine and other painkillers, sedatives and sleeping pills, and antidepressants, decreased within the intervention group and also among those in the control group. The intervention and the follow-up showed increased use of vitamins and mineral preparations in the intervention group (from 55.1% to 68.9%) while in the control group their use declined (from 51.9% to 34.0%); these results are presented in table 1.

The women in the intervention group had a greater likelihood of improvement on the various QoL dimensions from baseline to the end of 4-year follow-up. Overall, the results show that women in the intervention group sustained their improved QoL more often than women in the control group did. Figures 2 and 3 show the proportions observed for the physical and mental dimensions of QoL.

With the follow-up measurements, we found that women in the intervention group displayed an improvement in physical functioning (OR 1.41; 95% CI 1.00 to 1.99) when compared with the control group. However, no significant differences were observed between groups for the other variables, as is indicated by table 2. Results for mental dimensions of QoL did not reach statistical significance (shown in table 3).

The women who did not participate in the 2½-year and 4-year follow-up studies (N=47, 28.1%) were younger at baseline (53.0 years, in contrast to 54.5 years), they had a higher BMI (28.0, in contrast to 26.3) and they were

Table 1 Characteristics (mean and SEM or frequency and percentage) of all participants

| | Baseline | | End of intervention | | 2½ Years | | 4 Years | |
|---|-------------|-------------|---------------------|-------------|-----------|-----------|-----------|-------------|
| | INT | CON | INT | CON | INT | CON | INT | CON |
| N | 78 | 81 | 75 | 80 | 50 | 52 | 45 | 50 |
| Age, mean (SEM) | 54.4 (0.42) | 54.1 (0.41) | 25.2 (0.53) | 26.2 (0.62) | 50 | 52 | 45 | 26.6 (0.79) |
| BMI, mean (SEM) | 26.4 (0.45) | 27.2 (0.50) | 5 (6.7) | 2 (2.5) | 10 (20.4) | 12 (24.5) | 14 (31.1) | 8 (16.0) |
| Use of medicine in the past 7 days | | | 12 (18.8) | 12 (17.9) | 13 (26.5) | 16 (32.7) | 10 (22.2) | 11 (22.0) |
| Hormone replacement therapy, N (%) | 2 (2.6) | 1 (2.8) | 32 (50.0) | 38 (56.7) | 25 (51.0) | 29 (59.2) | 14 (31.1) | 14 (28.0) |
| Blood pressure and cholesterol medicine, N (%) | 16 (20.5) | 12 (14.8) | 39 (60.9) | 36 (53.7) | 28 (57.1) | 32 (65.3) | 31 (68.9) | 17 (34.0) |
| Headache medicine and other painkillers, sedatives and sleeping pills, and antidepressants, N (%) | 43 (55.1) | 33 (40.7) | 42 (51.9) | 42 (51.9) | 28 (57.1) | 32 (65.3) | 31 (68.9) | 17 (34.0) |
| Vitamin and mineral supplements, N (%) | 43 (55.1) | 42 (51.9) | 39 (60.9) | 36 (53.7) | 28 (57.1) | 32 (65.3) | 31 (68.9) | 17 (34.0) |

BMI, body mass index; CON, control; INT, intervention.

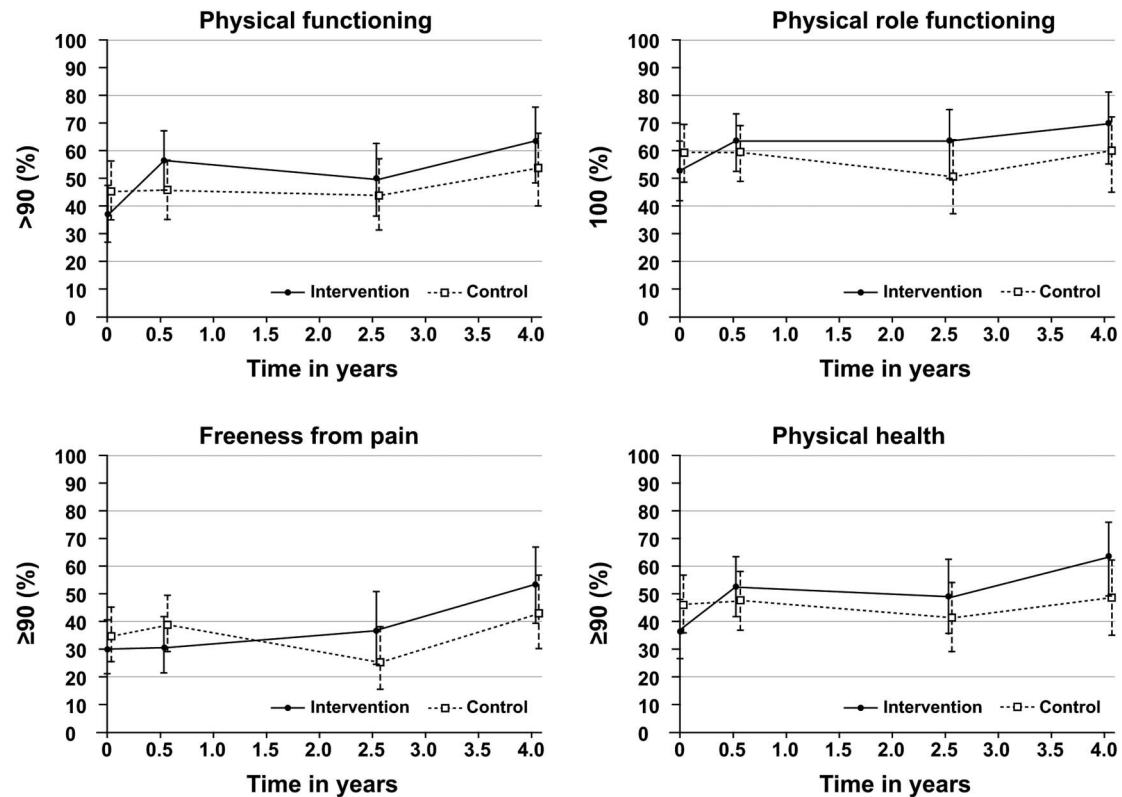


Figure 2 Proportions for the physical dimensions of quality of life (QoL) by time. Outcomes of QoL dimensions were classified into two categories according to medians. Proportions of women having higher or equal score than median are shown. Higher score defines more favourable health state.

regular smokers more often (27.3%, in contrast to 12.0%) than the women who participated in the follow-up study.

As sensitivity analyses, we performed multilevel mixed effects logistic regression models also for women who responded to all four time points (N=75). When these women with non-missing responses were taken in the analyses, intervention women had significantly higher probability of improved mental health functioning (OR 1.96; 95% CI 1.13 to 3.40) as compared with control women (not shown in the figures or tables). Results from the models including only 4-year follow-up responses without 2.5 year responses were similar to the results in the current tables and figures.

DISCUSSION

The physical exercise intervention may have long-term positive effects on health-related QoL among the group of menopausal women experiencing daily symptoms of menopause. Women in the intervention group had a higher probability of improvement in physical functioning dimension of QoL from baseline to the end of 4-year follow-up. Among a subsample of women who responded to both follow-up studies, significant results between the groups were found between mental health dimensions. Overall, the results show that women in the intervention group sustained their improved QoL on

both physical-health and mental-health dimensions more often than did women in the control group.

Findings from previous studies have shown that getting physical exercise is correlated with lower estimates of the perceived severity of symptoms and that exercise moderates the psychological symptoms associated with menopause.^{19 20} Our study is in line with these findings both in physical and mental dimensions. A report on an 8-year population-based follow-up study from Finland⁴ states that motivation to increase one's PA during menopausal transition might be an explanatory factor connected with improved QoL. According to that follow-up study, women whose PA increased or remained stable, had a higher probability of improved QoL than women whose PA decreased.⁴ Elavsky¹⁹ found, in a longitudinal study of middle-aged women, that PA was associated with self-worth and by this mechanism improved QoL. Furthermore, Stojanovska *et al*¹ recently published a review of the role of PA in reducing symptoms of menopause. They considered both somatic and psychological dimensions. On the basis of their review, physical exercise has been proposed as an alternative to HRT, for improving the QoL of menopausal women.

Our study has its limitations, in the response rate (59.7%) and the fact that women with an adverse lifestyle were more likely to be found among non-responders. All initial participants were included in the analyses, even if they did not participate to the end of

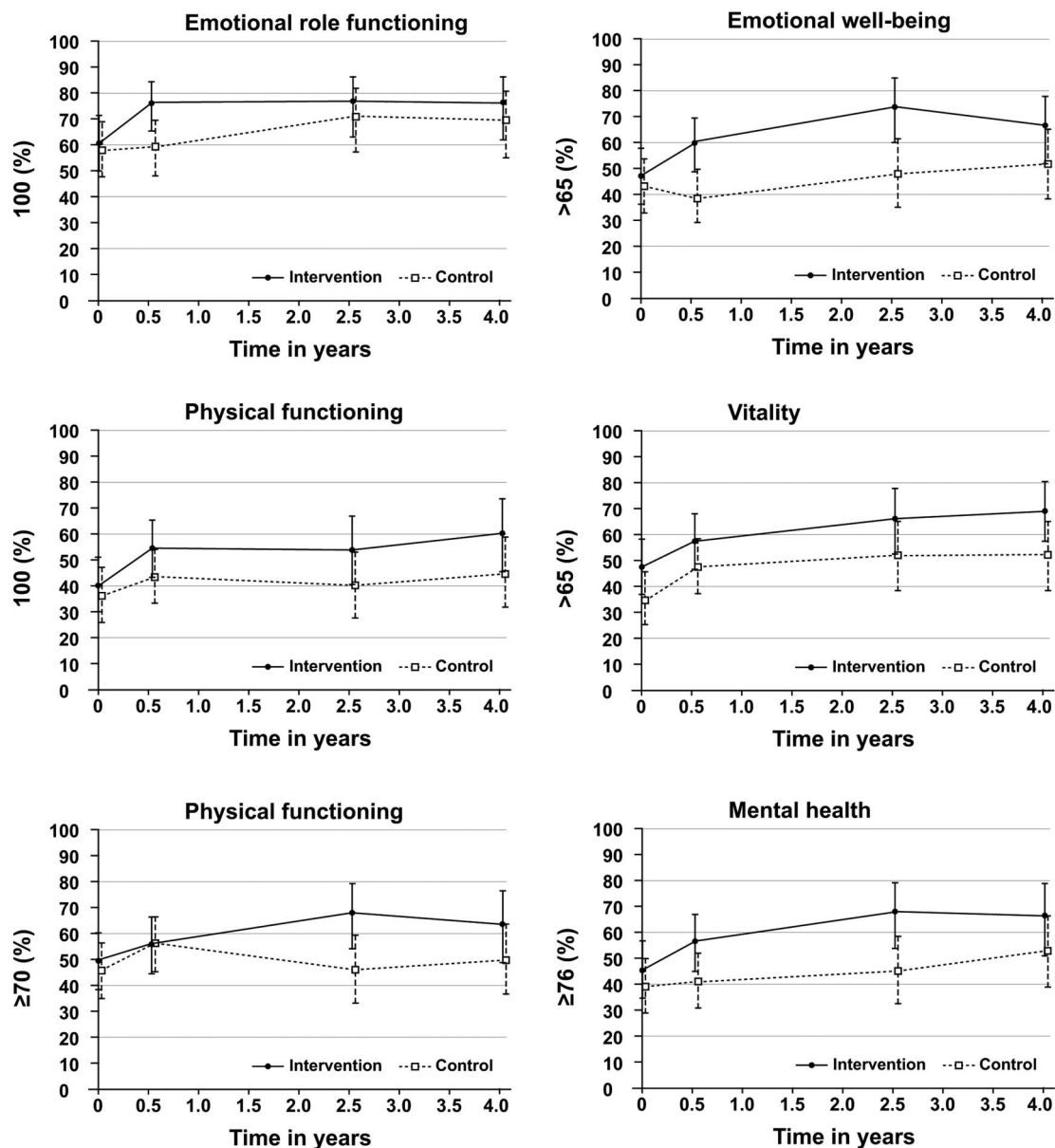


Figure 3 Proportions for mental dimensions of quality of life (QoL) by time. Outcomes of QoL dimensions were classified into two categories according to medians. Proportions of women having higher or equal score than median are shown. Higher score defines more favourable health state.

the intervention or the 2.5-year follow-up study. The results of the study showed a tendency towards increased QoL, although there were no statistically significant

differences for any cores on the physical and mental dimensions of QoL between the groups. Our findings are similar to those from a large multiethnic volunteer

Table 2 Multilevel mixed effects logistic regression, ORs and 95% CIs of physical dimensions of QoL

| | Physical functioning | Physical role functioning | Freeness from pain | Physical health |
|----------------------------------|----------------------|---------------------------|---------------------|---------------------|
| N | 159 | 159 | 159 | 159 |
| Group _{baseline} | 0.52 (0.17 to 1.61) | 0.84 (0.33 to 2.12) | 0.58 (0.22 to 1.54) | 0.72 (0.28 to 1.81) |
| Time | 1.03 (0.10 to 11.1) | 0.93 (0.75 to 1.17) | 1.07 (0.85 to 1.34) | 0.97 (0.77 to 1.22) |
| Group \times time | 44.7 (1.45 to 1374)* | 1.21 (0.88 to 1.67) | 1.25 (0.90 to 1.73) | 1.33 (0.96 to 1.84) |
| Time ² | 0.86 (0.19 to 3.82) | | | |
| Group \times time ² | 0.11 (0.01 to 0.91)* | | | |
| Time ³ | 1.04 (0.82 to 1.32) | | | |
| Group \times time ³ | 1.41 (1.00 to 1.99)* | | | |

*p<0.05.

Table 3 Multilevel mixed effects logistic regression, ORs and 95% CIs of mental dimensions of QoL

| | Emotional role functioning | Vitality | Emotional well-being | Social functioning | General health | Mental health |
|---------------------------|----------------------------|----------------------|----------------------|---------------------|---------------------|----------------------|
| N | 159 | 159 | 159 | 159 | | |
| Group _{baseline} | 1.74 (0.72 to 4.18) | 1.93 (0.82 to 4.57) | 2.50 (0.86 to 7.28) | 1.46 (0.60 to 3.55) | 1.04 (0.33 to 3.25) | 1.98 (0.77 to 5.13) |
| Time | 1.25 (1.00 to 1.57)* | 1.28 (1.03 to 1.58)* | 1.31 (1.03 to 1.67)* | 1.10 (0.89 to 1.36) | 0.98 (0.78 to 1.24) | 1.29 (1.03 to 1.63)* |
| Group×time | 0.93 (0.67 to 1.29) | 0.97 (0.71 to 1.33) | 1.02 (0.72 to 1.44) | 1.05 (0.77 to 1.43) | 1.14 (0.81 to 1.62) | 0.97 (0.70 to 1.35) |

*p<0.05.

QoL, quality of life.

cohort of postmenopausal women, in which self-reported PA was, for the most part, stable over 8 years of follow-up. There was approximately 0.3 metabolic equivalent (MET) of actual growth in recreational PA per year×8 years=2.4 MET h/week, which represented 30 min of brisk walking in this case.²¹

Loss-to-follow-up analysis showed differences between participants and those lost to follow-up. Non-responding women differed from responding women in their weight, age and smoking status. Respondents were lighter, older and were less often regular smokers than non-responding women. These differences might have had an effect on the findings in the follow-up study. If all of the original participants had been studied, the differences between the groups might have been larger. When limiting the analyses to women responding to both follow-up measurements, the results differed. Explanation for this may be due to the fact that conscientious women responding to questionnaires may have benefited even more from available support to be physically active. A follow-up study in itself can be considered an intervention, producing a non-differential support to the original groups in the RCT.

The core strengths of the study reported here are its prospective study design and repeated assessments of PA behaviour, which made it possible to examine the differences between groups in the follow-up.¹⁷ Many studies have described PA patterns through the lens of cross-sectional data, while fewer studies have examined changes between several time points after an intervention. PA has been reported to decrease with age,²² but contrary findings have also been reported. Earlier, our research group published the finding⁶ that women in menopausal transition shifted their behaviour in the other direction. Therefore, increased PA could be explained by higher motivation for lifestyle changes during the menopausal transition. In a longitudinal study by Smith-DiJulio *et al*,²³ the researchers found that a woman's sense of control, of her life and satisfaction with it, and her ability to make use of the available social support, predicted greater well-being during menopause. This is consistent with our findings, as we observed improvement in vitality, emotional well-being and mental health during the follow-up, even though the results did not reach a level of statistical significance.

Our results may be generalised to menopausal women having daily vasomotor symptoms, such as hot flushes or sleep problems, according to the inclusion criteria in the original RCT.⁶ Overall, our study underlines the importance of PA during menopausal transition. In addition, it supports the assumption that menopause can be seen as a window of opportunity, since it may motivate women to modify their lifestyle. Menopausal women should be encouraged to participate in regular exercise and supported in this endeavour through development of easily implemented home-based exercise programmes or incorporation of PA programmes into public-health initiatives.¹⁰



CONCLUSION

Women in the intervention group showed positive long-term effects on physical and mental dimensions of QoL after 4 years. Menopause is a window of opportunity for increasing PA and thereby future QoL. This finding is important, since an increase in PA may be associated with a lower future disease burden.

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Contributors KM and RL prepared the first version of the manuscript. JR was responsible for the statistical analyses. C-HN, ET and RR participated in drafting the manuscript and have approved the final version.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The study was granted ethics approval by the Pirkanmaa Hospital District Ethics Committee, Tampere, Finland.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There are some data from the questionnaires that are unpublished but all data concerning the measurements are published.

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Errata An erratum has been published regarding this article. Please see [next page](#) or:

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Correction

Mansikkamäki K, Raitanen J, Nygård C-H, *et al.* Long-term effect of physical activity on health-related quality of life among menopausal women: a 4-year follow-up study to a randomised controlled trial. *BMJ Open* 2015;5:e008232. There are several errors in this manuscript and are described below.

1. On page 2, 'Statistical analysis' section the following sentence is incorrect:

The odds model was used for analysis of the association between the outcomes both on the physical dimensions (physical functioning; role functioning, physical; freedom from pain; and physical health) and on the psychological dimensions (role functioning; emotional; vitality; emotional well-being; social functioning; general health; and mental health) over time and between the intervention versus the control group.

The correct sentence is:

The odds model was used for analysis of the association between the outcomes both on the physical dimensions (physical functioning; role functioning, physical; freedom from pain; and physical health) and on the psychological dimensions (role functioning, emotional; vitality; emotional well-being; social functioning; general health; and mental health) over time and between the intervention versus the control group.

2. On page 3, the sentence 'The proportions for the physical and mental dimensions of QoL by time are shown in figures 1 and 2.' should be 'The proportions for the physical and mental dimensions of QoL by time are shown in figures 2 and 3.'

3. In figure 3, the middle left panel should be titled 'Social functioning' and the lower left panel should be titled 'General health'.

4. Reference 7 is incorrect. The corrected reference is:

Mansikkamäki K, Raitanen J, Nygård C-H, *et al.* Sleep quality and aerobic training among menopausal women – A randomized controlled trial. *Maturitas* 2012;72:339–45.

BMJ Open 2016;6:e008232corr1. doi:10.1136/bmjopen-2015-008232corr1



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