Change in health-related quality of life over the menopausal transition in a multiethnic cohort of middle-aged women: Study of Women's Health Across the Nation (SWAN)

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Abstract

Objective—To examine change in health-related quality of life (HRQL) during the menopausal transition, controlling for chronological aging, symptoms, and other covariates.

Design—A prospective, longitudinal study of women aged 42–52 at baseline recruited at seven US sites (N=3302) in the multiethnic Study of Women's Health Across the Nation (SWAN). Cohort eligible women had an intact uterus, at least one ovary, were not currently using exogenous hormones, were either pre- or early perimenopausal, and self-identified as one of the study's designated racial/ethnic groups. Data from the baseline interview and six annual follow-up visits are reported. HRQL was assessed with five subscales from the SF-36 with reduced functioning defined as being in the lowest 25% on a subscale. Covariates included symptoms, medical conditions, sociodemographics variables, physical activity, and psychological factors.

Results—Adjusting for baseline age, chronological aging, and relevant covariates, the odds of reduced role physical functioning were significantly greater at late perimenopause (odds ratio [OR] = 1.46; 95% confidence interval [CI] = 1.08, 1.99) and postmenopause (OR = 1.49; 95% CI = 1.09, 2.04) compared to premenopause. Menopausal status was unrelated to bodily pain, vitality, role emotional or social functioning. Hormone therapy users were more likely to report reduced functioning. Other variables significantly related to HRQL across all domains included vasomotor symptoms, urine leakage, poor sleep, arthritis, depressed mood, perceived stress, and stressful life events.

Conclusions—The menopausal transition showed little impact on HRQL when adjusted for symptoms, medical conditions, and stress.

Health-related quality of life (HRQL) has emerged as an important outcome in the evaluation of both function and disease progression among healthy and ill populations. HRQL generally denotes aspects of life most likely to be affected by changes in health status[1] and is often viewed as multidimensional and consisting of the following domains: physical health and functioning, emotional functioning, role limitations, and social functioning. According to the Wilson and Cleary[2] model, the impact of biological and physiological variables on HRQL can be mediated by symptoms and characteristics of the individual such as personality and psychological status and characteristics of the environment such as stress, economic, and social supports. This model would suggest that symptoms associated with menopause and aging, as well as other psychological or environmental factors, may mediate the relationship between the menopause transition and HRQL.

Menopause and/or its associated symptoms are often thought to have a negative impact on quality of life.[3,4] However, among non-clinic samples of women the impact of menopause on well-being or mood has shown mixed results.[5–12] A few cross-sectional studies have looked at broader quality of life outcomes, [4,13–20] also with mixed results, though some studies report greater bodily pain and role limitations due to physical health.[21] Cross-sectional studies, however, are limited by their inability to examine HRQL changes over the menopausal transition.

Two longitudinal studies have examined HRQL changes during the menopause transition[22,23] with slightly different findings. Mishra et al.[22] examined changes in SF-36 scores at two time-points over two years in 8,623 women participating in the Australian Longitudinal Study on Women's Health, aged 45–50 at baseline. Analyses comparing SF-36 scores by transition category between the two time-points (pre-pre, pre-peri, peri-peri, pre/peri-post, post-post) found that women who remained peri-menopausal at both time-points and women taking hormone therapy (HT) exhibited small, but significantly greater declines on the physical health domains than women who remained pre-menopausal. Despite this large sample, only a small percentage of women transitioned from pre or perimenopause to post menopause or remained postmenopausal at both time-points, due to the young age of the women at baseline and the short follow-up.

Kumari et al.[23] studied the impact of the menopausal transition on SF-36 scores among 2,489 women followed through the Whitehall II study, with a particular focus on symptoms. Age-adjusted results showed no impact of the menopause transition on SF-36 scores, although women who reported vasomotor symptoms or depression experienced large and significant declines. However, this study was not designed to focus on the menopause transition and

because follow-up occurred only every 2.5 years, menopause status for many women could have been misclassified.

The present paper uses longitudinal data from the large multiethnic Study of Women's Health Across the Nation (SWAN) to examine changes in HRQL over the menopausal transition, controlling for symptoms and other covariates. All women were either pre or early perimenopausal at baseline and followed for 6 annual visits. With 7 years of data, this large cohort of 3300 women at baseline provides the opportunity to examine changes in HRQL as women progress through the menopausal transition. We base our approach on the Wilson and Cleary model and hypothesize that symptoms associated with the menopausal transition are associated with changes in HRQL and that these symptoms can explain associations between changes in menopausal status and HRQL. The research objectives of the present study address the following questions: (1) Does HRQL change over the course of the menopausal transition, adjusting for chronological aging? (2) What is the role of symptoms in predicting changes in HRQL over the transition? and (3) Does HRQL change over the menopausal transition, adjusted for other factors related to HRQL?

METHODS

Study population

The Study of Women's Health Across the Nation (SWAN) is a multiethnic observational cohort study of the menopausal transition in 3302 women at seven sites across the United States.[24] Each site recruited one minority population (African-American, Hispanic, Chinese, or Japanese) and one Caucasian population from community-based samples. The details of enrollment have been previously reported.[24] Baseline eligibility criteria included the following: age 42–52 years, intact uterus and at least one ovary, no use of exogenous hormones affecting ovarian function in the past 3 months, at least one menstrual period in the previous 3 months, and self-identification with a site's designated racial/ethnic groups.

The baseline interview and six annual assessments were completed in a clinic setting where a portion of the protocol was administered by trained interviewers and other questionnaires were self-administered. Common protocols were used at all sites. Instruments were developed based on the results of ethnically-diverse focus groups to minimize language and cultural differences in understanding and responding to the questions. All study forms were available in English, Cantonese, Japanese and Spanish and bilingual staff was used, as appropriate. Each site adhered to its Institutional Review Board's guidelines for human research, with all participants giving written informed consent.

Measures

Health-related quality of life—The Medical Outcomes Study Short Form Health Survey (SF-36) was used to assess Health Related Quality of Life, using the original coding algorithm in which raw scores are transformed to a 0–100 range.[25] The SF-36 is a widely-used generic HRQL measure yielding eight subscales, of which SWAN used the following five: bodily pain, role limitations due to physical health (role-physical), role limitations due to emotional problems (role-emotional), social functioning, and vitality. We did not include the physical functioning, mental health, or health perceptions subscales because these domains were covered by other study questionnaires and we did not want to lengthen the protocol or have participants feel that we were repeating questions. For the Cantonese, Spanish and Japanese versions of the SF-36, there were no validated versions available in 1996 and translations were prepared for the study (initial translation, back translation and revision). All five SF-36 subscales were collected at baseline, follow-up visits 1–3, and follow-up visit 6. An abbreviated

version which included only bodily pain and vitality was administered at visits 4 and 5. All available SF-36 data were used in analysis.

Some of the SF-36 subscales, especially role-physical and role-emotional, were not normally distributed. The role-physical scale has five possible scores (0, 25, 50, 75, and 100) and the role-emotional scale has four possible scores (0, 33, 67, and 100). Studies have found that these scores, along with the social functioning scale, are highly skewed[13, 25–28] with many respondents scoring 100. Because of these skewed distributions, Rose et al.[28] recommend dichotomizing these scores. Since the SWAN cohort is a basically healthy group of women with high scores on the SF-36, we chose to follow these recommendations and dichotomize scores at the bottom percentile to focus on predictors of reduced function. We therefore dichotomized each outcome at the 25th percentile based on the women in our sample. We based the cut-point on our own sample because published norms for mid-aged women were based on smaller sample sizes than in SWAN and primarily on Caucasian women.[25] This cut-point was followed in our previous report of HRQL at baseline.[13]

Menopause transition status—At each study visit, menopausal status was classified as *premenopausal*, defined as menses in the previous three months with no change in menstrual regularity in the preceding year; *early perimenopausal,* as menses in the previous three months and changes in regularity in the past year; *late perimenopausal,* as no menses in the previous 3 months but menses in the previous 11 months; or *postmenopausal,* as 12 or more months of amenorrhea.[24] Women who underwent a bilateral oophorectomy (N=119) were classified as *surgically menopausal.* Women who had a hysterectomy but not a bilateral oophorectomy prior to being classified as postmenopausal were considered to have unknown menopausal status and were omitted from the time of surgery onwards (N=80). Women who had a hysterectomy only following classification as postmenopausal remained classified as postmenopausal (N=9). Because menopausal status cannot be accurately determined once a woman begins hormone therapy (HT), separate menopausal status categories were created for women who started HT during the study. Women were classified as HT users from the first visit they reported using HT forward. Women who reported having taken HT in the previous 12 months were classified as *current hormone therapy users,* while women who were past users were classified as *former hormone therapy users*. Among pre and perimenopausal women, HT use classification was irrespective of menopausal status since once a woman begins HT use, menopausal status cannot be determined.

Covariates—We were particularly interested in the contribution of symptoms to HRQL. Symptoms included in analyses were leaking urine, night sweats, and hot flashes, with frequency assessed in the past 2 weeks (never, 1–5 days, 6–14 days) and sleep disturbances. A total combined vasomotor (VMS) score was used to indicate whether hot flashes and/or night sweats were experienced never, 1–5 days, or 6 or more days in the past 2 weeks. Poor sleep was ascertained through self-report and was defined as trouble falling asleep, waking up several times a night, or waking up earlier than intended at least three times per week in the previous 2 weeks.

Additional covariates were selected based on variables found to be significantly related to HRQL at study entry, as previously reported.[13] Sociodemographic variables included age, marital status, race/ethnicity, educational attainment, and difficulty paying for basics. Ethnicity was self-defined by respondents, in response to the open-ended question: "How would you describe your *primary* racial or ethnic group?" The responses were categorized as Caucasian, African-American, Chinese, Hispanic or Japanese.

Medical conditions included self-reported past or current arthritis/osteoarthritis and migraines and were coded as yes or no. Physical activity was assessed based on frequency, intensity, and

duration of sports, active living, and household/child care activity engaged in during the past year.[29,30] Psychosocial factors included perceived stress, stressful life events, and depressed mood. Perceived stress was measured by the Perceived Stress Scale.[31] A list of stressful events (e.g., job related, money problems, divorce) in the past 12 months were used to create a 3-level variable for stressful life events: 0, 1, or 2 or more. Depressed mood was assessed using the Centers for Epidemiologic Studies Depression Scale (CES-D).[32]

Statistical analysis

To determine if HRQL changes over the course of the menopausal transition, we examined the time period from baseline through the sixth year of follow-up. We first sought to describe the distributions of outcome variables and potential covariates. We obtained means, standard deviations, medians, interquartile ranges, and frequencies for these variables in our total population and by menopausal status.

Longitudinal random effects logistic regression models were then estimated using the xtlogit procedure in STATA (Version 8, STATA Corporation, College Station, TX). Such models account for the correlation of repeated observations from each woman resulting from the longitudinal design. These models also permit women to contribute different numbers of observations and to remain in the model even if they do not have complete data for all follow-up visits. All models included a woman-specific random intercept, allowing us to provide a woman-specific interpretation. For example, for the logistic regression models, we can interpret the odds ratio as the odds of poor HRQL for a woman when she is early perimenopausal relative to when she is premenopausal.

Because of the importance of the effects of ethnicity and age on the relationship between HRQL and menopausal status, we constructed base models including these variables in our initial analyses to address our first research question of whether HRQL is associated with menopausal status, independently of chronological aging. To address our second research question on the role of symptoms, we then added symptoms to the base models. To obtain our multivariable models with other covariates, we began with the base models and then added other factors associated with HRQL in bivariate analyses (at p<0.15) or identified in the literature as potential covariates. Menopausal status, symptoms, health conditions, and measures of stress were treated as time-varying variables. Backward elimination (retaining variables with p<0.05) was employed to obtain a final parsimonious multivariable model. Lastly, we used the post-estimation command *lincom* (which calculates estimates for linear combinations of coefficients after an estimation command) to compute adjusted odds ratios for poor HRQL comparing specific status categories: early perimenopause as compared to premenopausal, late perimenopause as compared to early perimenopause, and postmenopause as compared to late perimenopause.

RESULTS

Sample characteristics

The SWAN cohort consists of 3302 women. Of these women, we excluded 103 (3.1 percent) women who had had surgical menopause during follow-up and 256 (7.8 percent) who were missing all follow-up measurements of the SF-36. The analysis data set consists of the remaining 2943 women. Table 1 presents baseline characteristics of the analytic sample. By study design, almost half of the sample was white (47.8%) with the other half consisting of African American (27.4%), Hispanic (7.5%), Chinese (8.2%), and Japanese (9.1%) women. At baseline, 54% of the sample was premenopausal and 46% were early perimenopausal; mean age of the sample was 46.4. Table 2 shows the number and percentage of women in each menopausal status by visit. In longitudinal analyses, women could contribute up to seven

observations. The number of observations by status are: pre = 3356 (18.5%); early perimenopausal = 8492 (46.9%); late perimenopausal = 1238 (6.8%); postmenopausal=1982 (10.9%); current HT user = 2154 (11.9%); and former HT user = 884 (4.9%).

SF-36 domains by menopausal transition

Table 3 provides descriptive data on the distribution of SF-36 scores for each domain for the overall sample and by menopausal transition status. Each SF-36 domain takes on values from 0 (poor) to 100 (good). As seen in this table, there is little variation of scores by menopausal status. Table 4 shows the percentage of women scoring at or below the 25th percentile and the domain score at which women were classified as having reduced functioning for each scale overall and by menopausal status.

HRQL adjusted for chronological age and aging

Our base model to examine the association of the menopausal transition and HRQL unadjusted for symptoms or psychosocial factors is shown in Table 5. In these analyses menopausal status was significant for all domains; women had significantly greater odds of reduced functioning at early peri, late peri or postmenopause than premenopause. Both current and former HT users also had greater odds of reduced functioning compared to when they were premenopausal. Baseline age was only related to vitality, role-emotional and social function with older women *less* likely to have reduced functioning. Time was negatively related to lower functioning for all domains. To address whether improved functioning over time was due to biased sample attrition, we repeated our analyses in the subset of women who completed all SF-36 administrations from baseline through the last follow-up (N = 2010). We then compared the estimates and p-values from both the full and reduced samples to identify any differences in the results. Although this reduced sample had slightly better HRQL, the results for the full and reduced samples were approximately the same and did not explain the improvement in HRQL over time.

HRQL adjusted for symptoms and other variables

Our second objective was to determine the role of symptoms in predicting HRQL over the transition. Table 6 shows the results of adding symptoms (VMS, vaginal dryness, urine leakage, and poor sleep quality) to the base model. All symptoms were significantly positively related to reduced function on all five domains. With the inclusion of symptoms in the model, menopausal status was no longer significantly related to role-emotional. Despite the significant effect of symptoms, menopausal status remained significantly related to reduced functioning for bodily pain (P = .01), vitality (P < .001), role-physical (P<.01), and social functioning (p = .04), suggesting that symptoms do not completely explain the changes in HRQL over the menopausal transition for these domains. However, when current and former HT users were removed from the analysis, menopausal status was no longer significant for bodily pain and vitality.

Table 7 shows the fully adjusted models which include symptoms and other covariates. In these analyses, menopausal status was no longer significantly related to social functioning. Status was still significantly related to bodily pain (P<.01), vitality (P<.001), and role-physical (P<. 001). However, again the HT users accounted for the significant effect for pain and vitality. For role-physical, women had significantly greater odds of reporting reduced functioning at late peri and postmenopause than premenopause (adjusted odds ratio [OR] = 1.46; 95 % confidence interval [CI] = 1.08, 1.99 and OR = 1.49, 95 % CI = 1.09, 2.04 respectively).

Across all domains, vasomotor symptoms, urine leakage, arthritis, poor sleep, CESD ≥ 16, perceived stress and stressful life events were positively related to reduced HRQL. Depressive symptoms (CESD≥16) was one of the strongest predictors of reduced functioning on all

domains with ORs ranging from 1.61 for bodily pain and 4.06 for role-emotional. Racial/ethnic differences were found mostly for the African-American and Hispanic women. African-American and Hispanic women were both more likely than Caucasian women to report reduced functioning for bodily pain and social functioning and less likely to report reduced functioning for role-emotional.

DISCUSSION

These results from SWAN provide seven years of longitudinal HRQL data on a large cohort of middle-aged women as they experience the menopausal transition. Final results show that after adjustment for a wide range of variables, menopausal status is independently related to physical limitations in role functioning, but not other HRQL domains. In analyses only adjusting for baseline chronological age and time, menopausal status was significant for all SF-36 domains assessed with women having greater odds of reduced functioning at early peri, late peri, and postmenopause than when premenopausal. Except for role-physical, the odds of reduced functioning were greatest at early and late perimenopause. However, symptoms that often co-occur with menopause (VMS, vaginal dryness, urine leakage, and poor sleep) accounted for the effect of status (when excluding HT users) on role-emotional, bodily pain, and vitality. With the addition of medical conditions, depression, and stress to the model, the social functioning domain was no longer related to menopausal status. These findings highlight the importance of controlling for important covariates in assessing the impact of the menopausal transition on HRQL. However, even controlling for this wide range of variables, late-peri and postmenopausal women were more likely to report reduced functioning on the role-physical domain than when premenopausal. These findings are consistent with Mishra et al.[22] who found significant declines in the physical health domains of the SF-36 among women who remained perimenopausal over two years, compared to women who remained premenopausal. It is possible that these results are due to health problems that may co-occur with menopause and/or aging. Our analyses only included medical conditions that were reported with a high prevalence (i.e. arthritis and migraines) and Mishra et al. did not include any health variables. A more comprehensive look at co-morbidities might explain this effect.

Despite the significant finding for role-physical, it is important to note that the actual changes in HRQL are quite small and may not be meaningful. The unadjusted SF-36 scores shown in Table 2 vary only slightly by menopausal status. The percent of women classified in the reduced functioning percentile increases between pre and late perimenopause by only 3.8% for role-physical.

With respect to HT users, our results show that both current and former HT users were more likely to report poor functioning on all domains than women who never used HT. This was significant for bodily pain, vitality, and role-physical. Separate SWAN analyses explored HT users in greater depth and did not find that HRQL was related to initiation of HT or that HRQL improved following initiation of HT.[33] Our results are also consistent with Mishra et al.[22] who found that women taking HT reported greater decline on all aspects of the SF-36 except role emotional. These findings are somewhat in contrast to research showing that HT users tend to be healthier than non users. It is possible that HT users may be healthier by more objective measures (e.g., cardiovascular risk factors), but perceive themselves as more impaired. HT users in SWAN did not report more comorbidities.[33]

Our findings support the role of symptoms in relation to HRQL. We found that vaginal dryness, urine leakage, poor sleep, and depression were highly related to all SF-36 domains. Results are consistent with our baseline findings[13] and Kumari et al.[23] who found that women who experienced vasomotor symptoms or depression showed significant declines on the SF-36.

Our results for race/ethnicity are generally consistent with our earlier baseline report of pre and early perimenopausal women.[13] We found no effect of race/ethnicity on the role-physical domain when analyses adjusted for socioeconomic status, health, and social circumstances. Despite adjusting for a wide range of variables, both analyses found significant racial/ethnic group differences for the bodily pain and social functioning domains. African-American and particularly Hispanic women, reported more bodily pain and reduced social functioning than Caucasians.

Unlike our earlier report, our present analyses found significant race/ethnicity effects for both vitality and role-emotional. African-American women were less likely to report reduced vitality than Caucasian women. African-American, Hispanic, and Japanese women reported less reduced functioning for role-emotional than Caucasian women. However, the pattern of results was similar in both analyses and the statistical differences may be due to a larger N in the present analyses.

There are several limitations to this study. First, SWAN is not composed of a true national probability sample. Women in the cohort had more education, higher incomes, were less likely to be smokers, and rated themselves higher on perceived health than eligible women who did not enroll. Since the study excluded women with past hysterectomy, bilateral oophorectomy or recent hormone use, cohort participants were less likely to have already experienced reproductive or perimenopausal problems. Second, the SF-36 has some limitations. The study did not include the SF-36 physical functioning, mental health, and general health perceptions subscales and the subscales that were included were not administered at every visit. However, this latter limitation should not impact the associations between change in menopausal status and HRQL. Although the SF-36 is viewed as a generic quality of life measure and may not tap specific quality of life issues relevant to women over the menopausal transition, it is the most widely used scale and considered appropriate for a healthy population. We should also note that the present study was not designed to determine the effect of hormone therapy on HRQL, a question best addressed in a randomized clinical trial. Finally, our analyses only included limited medical conditions and it is possible that a more comprehensive look at co-morbidities would explain the effect of menopausal status on role physical.

In conclusion, in this large multiethnic cohort of women, we found that changes in HRQL over the menopausal transition are largely explained by symptoms related to menopause and/or aging such as vasomotor symptoms, vaginal dryness, urine leakage, and trouble sleeping; health conditions such as arthritis; and depressed mood and stress. Our continued follow-up of the SWAN cohort will allow us to determine the HRQL trajectory in the early postmenopausal years.

Acknowledgments

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TABLE 1

Baseline characteristics of the analytic sample: Study of Women's Health Across the Nation, 1996–1997 (N=2943)[*]

(A) Continuous variables

	Mean	Standard Deviation	Median	Interquartile Range
Age (years)	46.4	2.7	46.2	44.1–48.3
Physical activity (3–14)	7.7	1.8	7.6	6.5–8.9
Perceived stress (4–20)	8.5	2.9	8.0	6.0–11.0

(B) Categorical variables, no. (%)

Ethnicity		
Caucasian	1408	47.8
African-American	806	27.4
Hispanic	220	7.5
Chinese	241	8.2
Japanese	268	9.1
Difficulty paying basics		
Not very hard	1798	61.5
Somewhat hard	878	30.0
Very hard	249	8.5
Education		
High school or less	685	23.5
> High school/some college	937	32.1
College/post college	1296	44.4
Marital Status		
Never married	383	13.2
Married	1952	67.4
Separated/widowed/divorced	563	19.4
Menopausal Status		
Premenopausal	1549	53.9
Early perimenopausal	1326	46.1
Total VMS 6+ days/past 2 weeks	313	10.7
Vaginal dryness		
0 days/past 2 weeks	2375	81.2
1–5 days/past 2 weeks	404	13.8
6–14 days/past 2 weeks	146	5.0
Urine leakage		
Never/past month	1563	53.9
<1 day per week/past month	900	31.0
≥1 day per week/past month	437	15.1
Poor sleep quality	896	30.6
Arthritis	566	19.3
Migraines	466	15.9

(A) Continuous variables

	Mean	Standard Deviation	Median	Interquartile Range
Number of very stressful life events				
0		1474	50.3	
1		599	20.4	
2		857	29.3	
CES-D ≥ 16		691	23.5	

[*] The total sample size does not account for the small amount of missing covariate data

TABLE 2

Menopause status at each visit

Visit	N	Pre %	Early Peri %	Late Peri %	Post %	Current Hormone Therapy User %	Former Hormone Therapy User %	Mean Age (Years)
Baseline	2875	53.9	46.1	-	-	-	-	46.4
V01	2762	25.5	61.1	4.4	2.2	6.8	-	47.4
V02	2629	16.7	57.3	7.7	4.9	11.6	1.8	48.5
V03	2599	11.5	51.1	8.5	9.4	14.7	4.8	49.4
V04	2537	7.2	43.7	9.7	15.1	17.1	7.2	50.5
V05	2461	4.4	36.6	9.8	21.6	17.4	10.2	51.5
V06	2243	3.2	28.4	9.1	28.2	18.6	12.5	52.5

TABLE 3

Descriptive statistics for SF-36 scales,[*] overall and by menopausal status.[†]

	Mean	Standard Deviation	25th Percentile	Median	75th Percentile
Bodily pain					
Overall	70.3	22.2	52.0	74.0	84.0
Premenopausal	73.3	21.6	62.0	74.0	84.0
Early perimenopausal	70.1	22.0	52.0	72.0	84.0
Late perimenopausal	69.1	22.8	51.0	72.0	84.0
Post	69.2	23.4	52.0	72.0	84.0
Current HT[‡] user	68.5	22.0	51.0	72.0	84.0
Former HT user	67.5	23.4	51.0	72.0	84.0
Role - emotional					
Overall	81.1	33.3	66.7	100.0	100.0
Premenopausal	82.5	32.0	66.7	100.0	100.0
Early perimenopausal	80.1	33.8	66.7	100.0	100.0
Late perimenopausal	81.1	33.7	66.7	100.0	100.0
Post	82.8	33.3	100.0	100.0	100.0
Current HT user	81.7	32.9	66.7	100.0	100.0
Former HT user	79.3	34.6	66.7	100.0	100.0
Role - physical					
Overall	78.3	34.9	75.0	100.0	100.0
Premenopausal	80.4	33.8	75.0	100.0	100.0
Early perimenopausal	78.2	34.7	75.0	100.0	100.0
Late perimenopausal	77.3	35.5	50.0	100.0	100.0
Post	78.6	35.7	75.0	100.0	100.0
Current HT user	75.7	36.6	50.0	100.0	100.0
Former HT user	74.9	37.6	50.0	100.0	100.0
Social function					
Overall	81.8	21.8	75.0	87.5	100.0
Premenopausal	83.6	20.9	75.0	87.5	100.0
Early perimenopausal	80.9	21.8	62.5	87.5	100.0
Late perimenopausal	81.9	22.3	75.0	87.5	100.0
Post	82.8	23.0	75.0	100.0	100.0

	Mean	Standard Deviation	25th Percentile	Median	75th Percentile
Current HT user	81.8	21.8	75.0	87.5	100.0
Former HT user	80.8	22.3	68.8	87.5	100.0
Vitality					
Overall	55.7	20.5	40.0	60.0	70.0
Premenopausal	57.8	20.7	45.0	60.0	75.0
Early perimenopausal	55.1	20.2	40.0	60.0	70.0
Late perimenopausal	55.6	20.7	40.0	60.0	70.0
Post	57.0	20.5	45.0	60.0	75.0
Current HT user	54.5	21.0	40.0	55.0	70.0
Former HT user	54.1	20.9	40.0	55.0	70.0

*The range for each scale is 0–100, where 0 is poor and 100 is good.

†Note that all observations have been collapsed over all visits (Baseline – Visit 6), and women can therefore contribute multiple observations to each menopausal status category.

‡HT=hormone therapy

TABLE 4

Percentage of women at or below the 25th Percentile for SF-36 scales, overall and by menopausal status[*]

	Bodily pain ≤52	Role-emotional ≤ 66.7	Role-physical ≤ 50	Social function ≤ 62.5	Vitality ≤ 40
Overall	25.5%	28.7%	24.3%	23.9%	26.5%
Premenopausal	21.4%	27.2%	22.2%	20.4%	24.2%
Early perimenopausal	25.7%	30.2%	24.4%	25.5%	27.0%
Late perimenopausal	28.2%	28.8%	26.0%	23.5%	26.5%
Postmenopausal	26.9%	24.4%	23.7%	24.1%	22.9%
Current HT user	28.6%	27.7%	26.7%	22.9%	30.3%
Former HT user	29.7%	30.2%	27.4%	25.0%	28.5%

[*]
Notes. All observations have been collapsed over all visits (Baseline – Visit 6), and women can therefore contribute multiple observations to each menopausal status category.

Some scales do not have a large number of different possible values, causing a large number of ties. Therefore, dichotomizing each scale at the 25th percentile of the overall distribution does not leave exactly 25% of the analysis data set in the "reduced functioning" category.

To provide a sense of what reduced functioning means, we looked at the item response patterns for women classified in the lowest 25th percentile for each domain. Women who scored at or below the 25th percentile for role-physical, answered "yes" to at least 2 of the 4 yes/no questions on whether their physical health affected various activities. For role-emotional, reduced functioning women answered "yes" to any of the three yes/no questions on whether emotional problems affected the amount of time spent on work or other activities, accomplishing less, or doing work or other activities more carefully. For bodily pain, over 99% of the reduced functioning women answered that they had at least moderate pain in the past 4 wks. For social functioning, 95% of reduced functioning women responded that their physical health or emotional problems interfered with social activities at least slightly. For vitality, 95% of reduced functioning women responded that they were full of pep or had a lot of energy only some of the time or less in the past 4 wks.

TABLE 5

Base models: p values and odds ratios of reduced functioning, estimated from multivariable random effects logistic regression[†]

	Odds Ratio (95% Confidence Interval)				
	Bodily pain	Vitality	Role emotional	Role physical	Social function
Baseline age, yrs (P)	0.09	<.0001	<.0001	0.49	0.01
	1.03 (1.00, 1.07)	0.93 (0.90, 0.96)	0.94 (0.91, 0.97)	1.01 (0.98, 1.04)	0.96 (0.93, 0.99)
Time, yrs (P)	<.0001	<.0001	<.0001	<.0001	<.0001
	0.94 (0.91, 0.97)	0.90 (0.87, 0.93)	0.87 (0.84, 0.90)	0.86 (0.83, 0.89)	0.91 (0.88, 0.94)
Race/ethnicity (P)	<.0001	0.13	0.01	0.38	<.0001
Caucasian	Reference	Reference	Reference	Reference	Reference
African American	1.63 (1.28, 2.07) ***	0.78 (0.61, 1.00) *	0.90 (0.73–1.11)	1.13 (0.91, 1.42)	1.78 (1.42, 2.23) ***
Hispanic	5.55 (3.11, 9.91) ***	0.87 (0.49, 1.58)	0.74 (0.44–1.23)	1.17 (0.68, 2.01)	3.69 (2.13, 6.37) ***
Chinese	0.91 (0.57, 1.45)	0.67 (0.42, 1.08)	0.58 (0.39–0.86) **	0.96 (0.61, 1.49)	0.83 (0.54, 1.30)
Japanese	0.91 (0.58, 1.42)	0.86 (0.53, 1.40)	0.66 (0.44–0.98) *	0.70 (0.46, 1.08)	0.85 (0.54, 1.33)
Menopausal status (P)	<.01	<.0001	0.02	<.0001	<.01
Premenopausal	Reference	Reference	Reference	Reference	Reference
Early perimenopausal	1.21 (1.03, 1.42) *	1.31 (1.12, 1.54) **	1.19 (1.02, 1.38) *	1.20 (1.03, 1.41) *	1.38 (1.17, 1.62) ***
Late perimenopausal	1.52 (1.17, 1.99) **	1.59 (1.24, 2.05) ***	1.52 (1.16, 1.99) **	1.69 (1.27, 2.25) ***	1.46 (1.09, 1.96) *
Postmenopausal	1.35 (1.02, 1.79) *	1.50 (1.15, 1.96) **	1.43 (1.08, 1.90) *	1.76 (1.30, 2.38) ***	1.72 (1.27, 2.33) ***
Current HT user	1.69 (1.32, 2.18) ***	1.96 (1.55, 2.50) ***	1.27 (0.99, 1.63)	1.73 (1.33, 2.23) ***	1.56 (1.20, 2.04) **
Former HT user	1.62 (1.15, 2.29) **	2.04 (1.49, 2.79) ***	1.62 (1.13, 2.30) **	2.09 (1.44, 3.03) ***	1.69 (1.16, 2.48) **

[†] Also adjusted for study site

*
p<.05,

**
p<.01,

***
p<.001

TABLE 6

Base models and symptoms: p values and odds ratios of reduced functioning, estimated from random effects logistic regression[†]

	Odds Ratio (95% Confidence Interval)				
	Bodily pain	Vitality	Role emotional	Role physical	Social function
Baseline age, yrs (P)	0.54	<.0001	<.0001	0.64	<.0001
	1.01 (0.98, 1.04)	0.91 (0.88, 0.95)	0.93 (0.90, 0.96)	0.99 (0.96, 1.02)	0.95 (0.92, 0.98)
Time, yrs (P)	<.0001	<.0001	<.0001	<.0001	<.0001
	0.91 (0.88, 0.94)	0.88 (0.85, 0.91)	0.85 (0.82, 0.88)	0.84 (0.80, 0.86)	0.89 (0.86, 0.92)
Race/ethnicity (P)	<.0001	0.26	0.21	0.35	<.0001
Caucasian	Reference	Reference	Reference	Reference	Reference
African American	1.66 (1.32, 2.08)***	0.79 (0.62, 1.00)*	0.90 (0.74, 1.11)	1.16 (0.94, 1.43)	1.81 (1.45, 2.25)***
Hispanic	6.05 (3.49, 10.50)***	1.14 (0.65, 2.00)	0.87 (0.53, 1.43)	1.36 (0.81, 2.29)	3.90 (2.31, 6.58)***
Chinese	1.11 (0.71, 1.72)	0.79 (0.50, 1.25)	0.69 (0.46, 1.01)	1.20 (0.79, 1.82)	0.99 (0.65, 1.51)
Japanese	1.13 (0.74, 1.75)	1.11 (0.71, 1.73)	0.82 (0.56, 1.19)	0.87 (0.58, 1.30)	1.04 (0.68, 1.58)
Menopausal status (P)	0.01	<.001	0.65	<.01	0.04
Premenopausal	Reference	Reference	Reference	Reference	Reference
Early perimenopausal	1.11 (0.94, 1.30)	1.19 (1.01, 1.39)*	1.08 (0.93, 1.25)	1.07 (0.92, 1.26)	1.28 (1.09, 1.50)**
Late perimenopausal	1.22 (0.93, 1.60)	1.25 (0.96, 1.62)	1.22 (0.93, 1.60)	1.36 (1.02, 1.81)*	1.21 (0.90, 1.62)
Postmenopausal	1.10 (0.83, 1.46)	1.20 (0.92, 1.58)	1.19 (0.89, 1.59)	1.49 (1.10, 2.01)*	1.49 (1.10, 2.02)*
Current HT user	1.55 (1.21, 1.99)**	1.78 (1.40, 2.27)***	1.14 (0.89, 1.46)	1.55 (1.20, 2.01)**	1.42 (1.10, 1.85)**
Former HT user	1.39 (0.99, 1.97)	1.58 (1.15, 2.18)**	1.32 (0.92, 1.89)	1.80 (1.24, 2.60)**	1.52 (1.04, 2.23)*
Vasomotor Symptoms (P)	<.0001	<.0001	<.0001	<.0001	<.0001
0 days/past 2 weeks	Reference	Reference	Reference	Reference	Reference
1–5 days/past 2 weeks	1.46 (1.28, 1.66)***	1.22 (1.08, 1.38)**	1.39 (1.22, 1.58)***	1.47 (1.28, 1.68)***	1.36 (1.18, 1.56)***
6–14 days/past 2 weeks	2.00 (1.70, 2.36)***	1.77 (1.51, 2.07)***	1.59 (1.35, 1.89)***	1.65 (1.39, 1.97)***	1.59 (1.33, 1.90)***
Vaginal dryness (P)	<.01	<.001	<.0001	<.001	0.04
0 days/past 2 weeks	Reference	Reference	Reference	Reference	Reference
1–5 days/past 2 weeks	1.12 (0.97, 1.31)	1.09 (0.95, 1.26)	1.25 (1.08, 1.45)**	1.06 (0.90, 1.24)	1.18 (1.00, 1.38)*
6–14 days/past 2 weeks	1.41 (1.14, 1.73)**	1.54 (1.26, 1.87)***	1.61 (1.30, 1.99)***	1.49 (1.20, 1.85)***	1.27 (1.01, 1.59)*
Urine leakage (P)	<.0001	<.0001	<.001	<.0001	<.0001

	Odds Ratio (95% Confidence Interval)					
	Bodily pain	Vitality	Role emotional	Role physical	Social function
Never/past month	Reference	Reference	Reference	Reference	Reference
< 1 day per week/past mo.	1.29 (1.13, 1.48) ***	1.30 (1.14, 1.48) ***	1.22 (1.07, 1.38) **	1.34 (1.17, 1.54) ***	1.15 (1.00, 1.32)
≥ 1 day per week/past mo.	1.76 (1.48, 2.09) ***	2.10 (1.78, 2.48) ***	1.40 (1.17, 1.66) ***	2.03 (1.70, 2.42) ***	1.68 (1.40, 2.01) ***
Poor sleep quality (P)	<.0001	<.0001	<.0001	<.0001	<.0001
	2.16 (1.91, 2.44)	2.22 (1.98, 2.49)	2.01 (1.78, 2.27)	1.96 (1.72, 2.23)	2.00 (1.75, 2.27)

†
Also adjusted for study site

*
p<.05,

**
p<.01,

***
p<.001

TABLE 7

Final multivariable models: p values and odds ratios of reduced functioning, estimated from random effects logistic regression[†]

	Odds Ratio (95% Confidence Interval)				
	Bodily pain	Vitality	Role emotional	Role physical	Social function
Baseline age, yrs (P)	0.66	<.0001	<.0001	0.82	<.01
	1.01 (0.98, 1.04)	0.91 (0.88, 0.94)	0.95 (0.92, 0.97)	1.00 (0.97, 1.02)	0.96 (0.93, 0.99)
Time, yrs (P)	<.0001	<.0001	<.0001	<.0001	<.01
	0.93 (0.90, 0.97)	0.91 (0.88, 0.94)	0.89 (0.86, 0.93)	0.86 (0.83, 0.90)	0.95 (0.91, 0.99)
Race/ethnicity (P)	<.001	<.001	<.01	0.28	<.001
Caucasian	Reference	Reference	Reference	Reference	Reference
African American	1.19 (0.96, 1.48)	0.61 (0.49, 0.78)***	0.77 (0.62, 0.94)*	0.95 (0.77, 1.18)	1.44 (1.17, 1.78)**
Hispanic	3.19 (1.86, 5.47)***	0.67 (0.38, 1.18)	0.60 (0.36, 0.99)*	0.87 (0.52, 1.48)	2.50 (1.48, 4.21)**
Chinese	1.04 (0.69, 1.58)	0.67 (0.43, 1.04)	0.78 (0.53, 1.14)	1.41 (0.94, 2.12)	1.02 (0.68, 1.53)
Japanese	1.06 (0.71, 1.57)	0.80 (0.52, 1.22)	0.69 (0.48, 0.99)*	0.77 (0.52, 1.12)	0.96 (0.65, 1.42)
Menopausal status (P)	<.01	<.0001	0.52	<.01	0.38
Premenopausal	Reference	Reference	Reference	Reference	Reference
Early perimenopausal	1.08 (0.91, 1.28)	1.10 (0.92, 1.30)	1.03 (0.87, 1.21)	1.11 (0.94, 1.31)	1.17 (0.98, 1.39)
Late perimenopausal	1.20 (0.90, 1.50)	1.18 (0.89, 1.56)	1.23 (0.91, 1.67)	1.46 (1.08, 1.99)*	1.06 (0.77, 1.46)
Postmenopausal	1.05 (0.78, 1.41)	1.06 (0.79, 1.42)	1.05 (0.77, 1.44)	1.49 (1.09, 2.04)*	1.23 (0.89, 1.70)
Current HT user	1.55 (1.20, 2.10)**	1.77 (1.37, 2.29)***	1.11 (0.85, 1.44)	1.62 (1.24, 2.12)***	1.30 (0.98, 1.71)
Former HT user	1.36 (0.96, 1.92)	1.65 (1.18, 2.30)**	1.36 (0.93, 1.97)	1.83 (1.25, 2.67)**	1.37 (0.93, 2.03)
Symptoms					
Vasomotor Symptoms (P)	<.0001	<.0001	<.01	<.0001	<.01
0 days/past 2 weeks	Reference	Reference	Reference	Reference	Reference
1–5 days/past 2 weeks	1.41 (1.23, 1.62)***	1.14 (0.99, 1.30)	1.27 (1.10, 1.46)**	1.41 (1.22, 1.63)***	1.24 (1.04, 1.52)**
6–14 days/past 2 weeks	1.79 (1.50, 2.13)***	1.48 (1.25, 1.75)***	1.31 (1.10, 1.48)**	1.37 (1.14, 1.66)**	1.26 (1.04, 1.52)*
Vaginal dryness (P)	0.12	0.01	<.01	0.01	0.03
0 days/past 2 weeks	Reference	Reference	Reference	Reference	Reference
1–5 days/past 2 weeks	1.08 (0.92, 1.26)	1.13 (0.97, 1.32)	1.27 (1.07, 1.50)**	1.10 (0.93, 1.31)	1.25 (1.05, 1.48)*
6–14 days/past 2 weeks	1.25 (1.01, 1.55)*	1.37 (1.11, 1.69)**	1.39 (1.10, 1.75)**	1.42 (1.13, 1.78)**	1.20 (0.95, 1.53)

	Odds Ratio (95% Confidence Interval)				
	Bodily pain	Vitality	Role emotional	Role physical	Social function
Urine leakage (P)	<.0001	<.0001	0.02	<.0001	<.0001
Never/past month	Reference	Reference	Reference	Reference	Reference
<1 day per wk/past mo.	1.28 (1.11, 1.47)***	1.25 (1.09, 1.43)**	1.19 (1.03, 1.37)*	1.30 (1.12, 1.50)***	1.15 (0.99, 1.33)
≥1 day per wk/past mo.	1.56 (1.31, 1.87)***	1.83 (1.53, 2.18)***	1.23 (1.02, 1.47)*	1.71 (1.43, 2.06)***	1.55 (1.29, 1.87)***
Poor sleep quality (P)	<.0001	<.0001	<.0001	<.0001	<.0001
	1.79 (1.57, 2.04)	1.77 (1.56, 2.00)	1.32 (1.15, 1.51)	1.46 (1.27, 1.67)	1.38(1.20, 1.59)
Health Conditions					
Migraines (P)	<.0001	0.49	0.27	<.0001	<.01
	1.70 (1.37, 2.10)	1.08 (0.87, 1.34)	1.13 (0.91, 1.41)	1.53 (1.23, 1.89)	1.38 (1.10, 1.72)
Arthritis (P)	<.0001	<.0001	0.05	<.0001	<.0001
	3.11 (2.66, 3.64)	1.53 (1.31, 1.80)	1.19 (1.00, 1.42)	2.40 (2.03, 2.83)	1.60 (1.34, 1.90)
Sociodemographics					
Education (P)	0.01	<.01	<.01	0.40	0.35
High school or less	1.28 (1.02, 1.60)*	0.68 (0.53, 0.87)**	0.69 (0.56, 0.86)**	0.75 (0.60, 0.94)*	1.03 (0.83, 1.28)
>H.S./some college	1.31 (1.09, 1.58)**	0.79 (0.64, 0.96)*	0.91 (0.76, 1.08)	0.92 (0.77, 1.11)	1.14 (0.95, 1.37)
College/post college	Reference	Reference	Reference	Reference	Reference
Diff paying basics (P)	<.0001	0.02	0.21	<.001	<.01
Not very hard	Reference	Reference	Reference	Reference	Reference
Somewhat hard	1.35 (1.13, 1.62)**	1.33 (1.09, 1.62)**	1.08 (0.91, 1.28)	1.40 (1.17, 1.67)***	1.35 (1.13, 1.61)**
Very hard	2.02 (1.49, 2.75)***	1.27 (0.91, 1.76)	1.29 (0.97, 1.73)	1.69 (1.25, 2.29)**	1.26 (0.94, 1.68)
Marital status (P)	0.66	0.20	0.41	0.31	<.001
Never married	1.08 (0.84, 1.38)	0.78 (0.60, 1.02)	0.98 (0.78, 1.24)	0.89 (0.70, 1.13)	0.99 (0.78, 1.26)
Married	Reference	Reference	Reference	Reference	Reference
Sep/wid/divorced	1.09 (0.88, 1.34)	0.96 (0.77, 1.21)	1.13 (0.93, 1.38)	1.10 (0.89, 1.35)	1.47 (1.20, 1.79)***
Health Behaviors					
Physical activity (3–14) (P)	<.0001	<.0001	0.35	<.0001	<.0001
	0.89 (0.85, 0.93)	0.74 (0.71, 0.78)	0.98 (0.94, 1.02)	0.91 (0.87, 0.95)	0.92 (0.88, 0.96)
Psychological factors					

Odds Ratio (95% Confidence Interval)

	Bodily pain	Vitality	Role emotional	Role physical	Social function
CES-D ≥ 16 (P)	<.0001	<.0001	<.0001	<.0001	<.0001
	1.61 (1.37, 1.89)	2.95 (2.53, 3.44)	4.06 (3.44, 4.79)	1.92 (1.62, 2.28)	3.55 (3.01, 4.18)
Perceived stress (4–20) (P)	<.0001	<.0001	<.0001	<.0001	<.0001
	1.10 (1.08, 1.13)	1.22 (1.19, 1.25)	1.28 (1.25, 1.31)	1.12 (1.09, 1.15)	1.23 (1.20, 1.26)
No. stressful life events (P)	<.0001	<.0001	<.0001	<.0001	<.0001
0	Reference	Reference	Reference	Reference	Reference
1	1.20 (1.04, 1.39) [*]	1.36 (1.19, 1.57) [***]	1.38 (1.19, 1.61) [***]	1.29 (1.10, 1.51) [**]	1.21 (1.03, 1.43) [*]
2+	1.41 (1.22, 1.63) [***]	1.56 (1.36, 1.80) [***]	2.32 (2.00, 2.69) [***]	1.53 (1.31, 1.78) [***]	1.69 (1.45, 1.98) [***]

[†] Also adjusted for study site

[*] p<.05,

[**] p<.01,

[***] p<.001