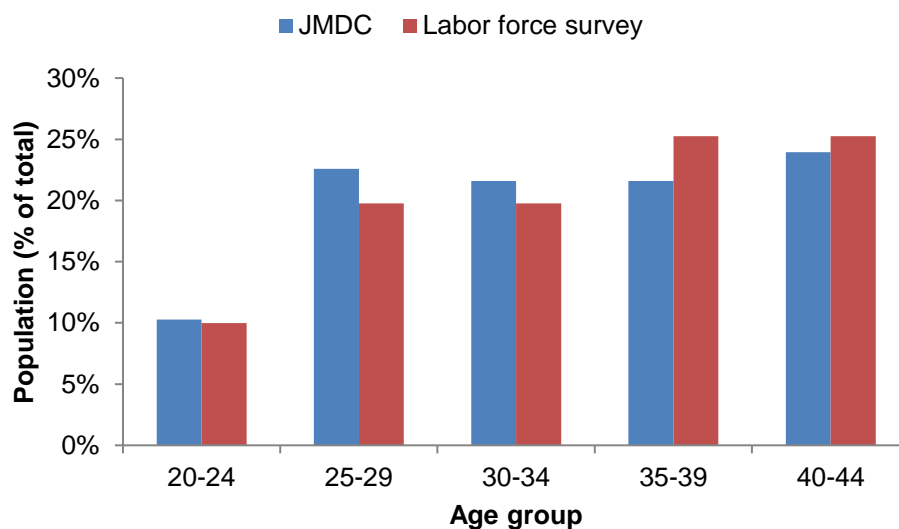


Effectiveness of Mobile Application for Menstrual Management of Working Women in Japan: Randomized Controlled Trial and Medical Economic Evaluation

Supplementary Material

Figure S1. Distribution of age group

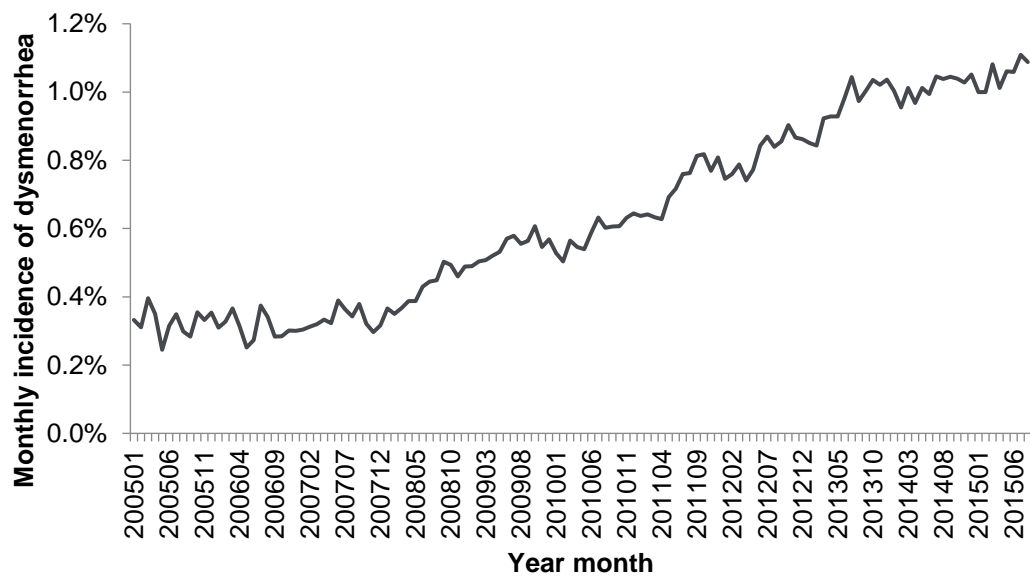


JMDC: Japan Medical Data Center.

Figure S2. Monthly incidence of dysmenorrhea (A) and depression (B) by (a) calendar year month and (b) age.

A.

(a)



(b)

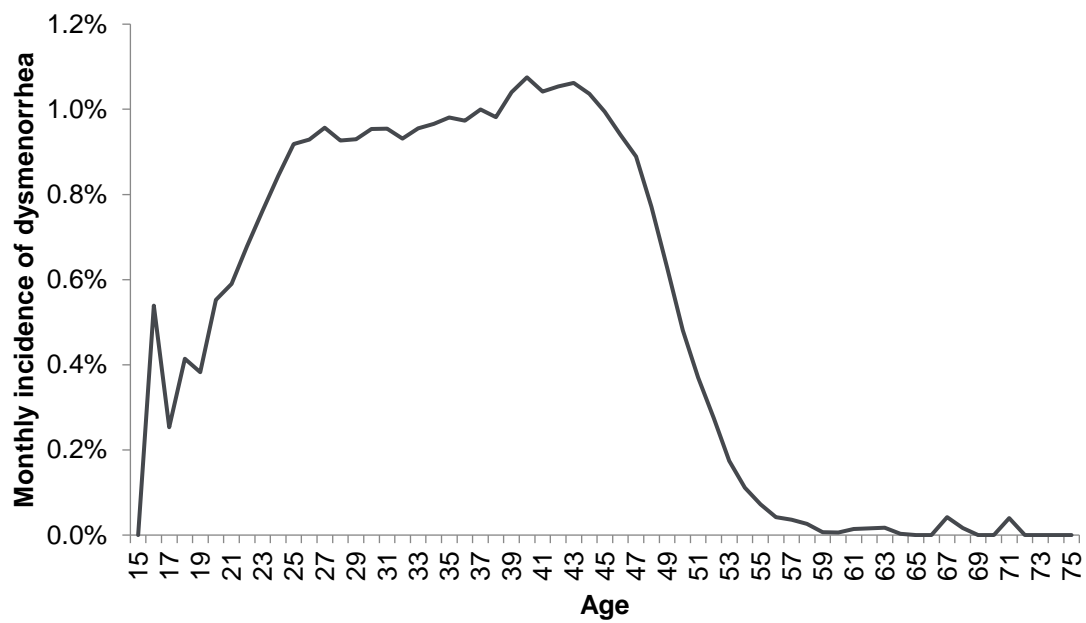
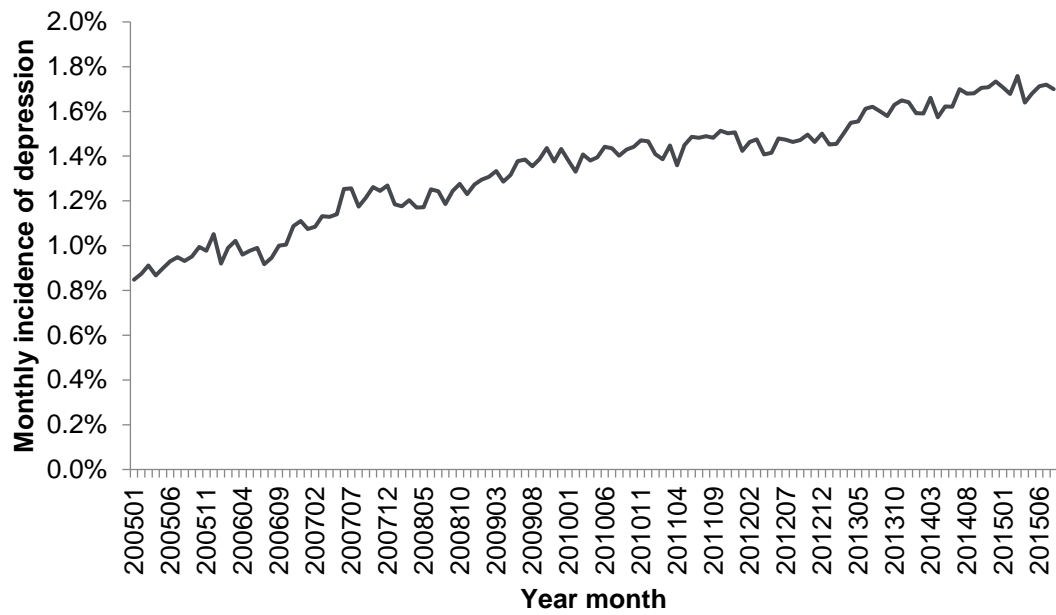


Figure S2. (cont'd)

B.

(a)



(b)

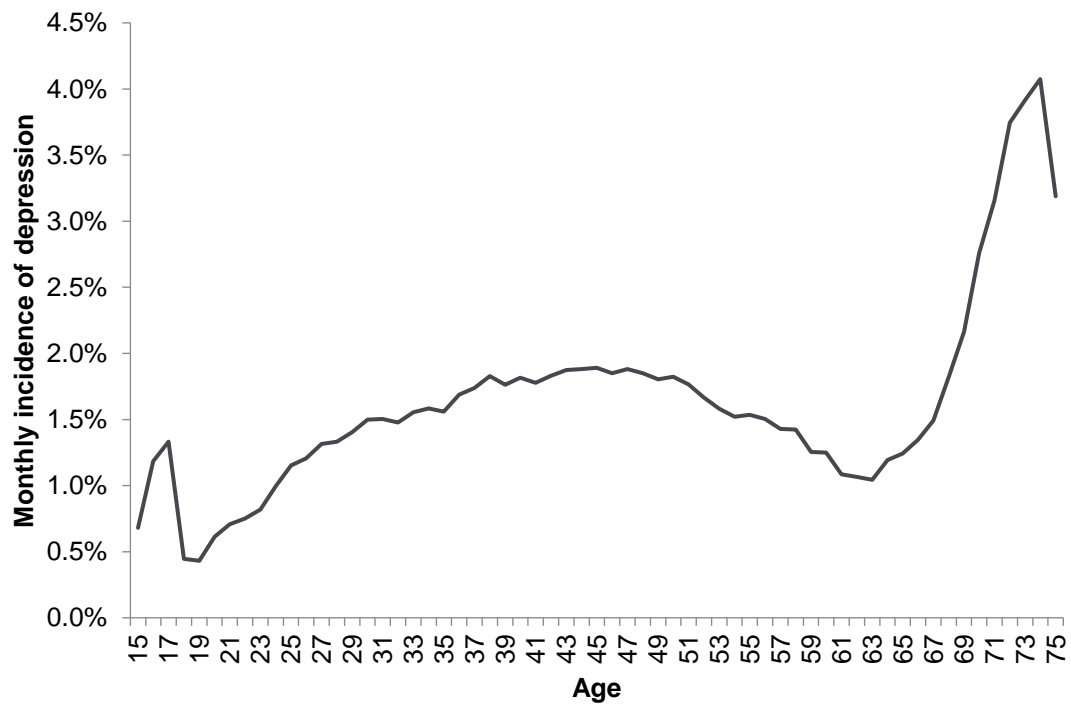
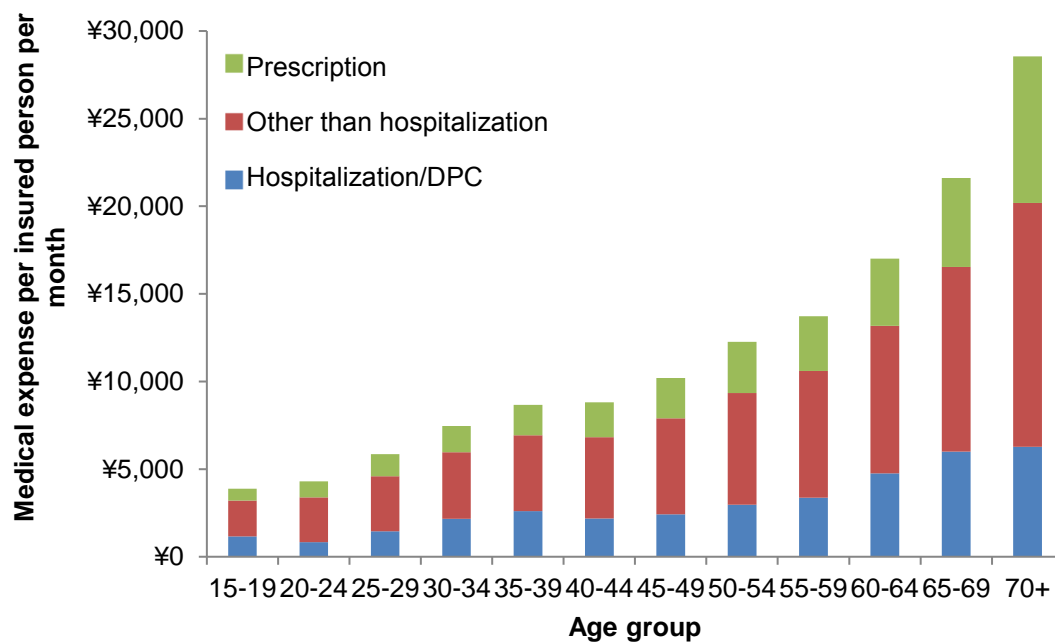


Figure S3. (A) Medical expense of all insured females and (B) relative medical expense of dysmenorrhea and depression for those without symptoms, by age group.

A.



B.

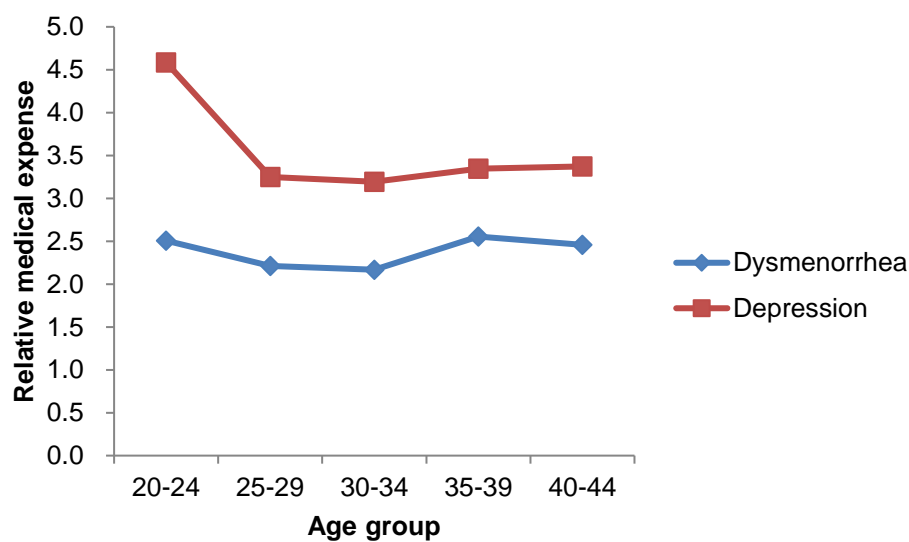


Figure S4. Monthly resignation rate

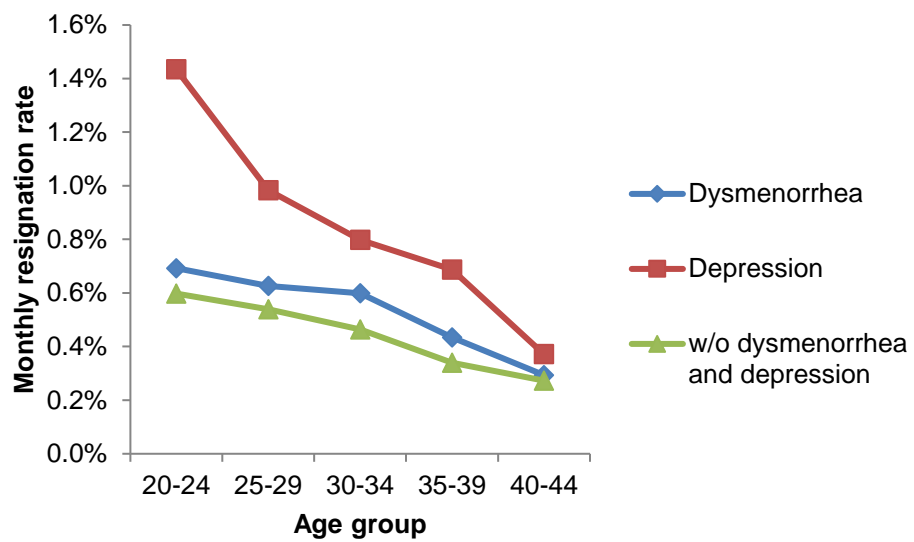


Table S1. Severity of depression based on PHQ-9 score [1,2] (underline: p<0.05)

Severity		Control group	Intervention group	P value
(Total score)		N=914	N=612	
None	Baseline	57%	56%	0.376
(0-4)	1st month	48%	43%	<u>0.036</u>
%	2nd month	43%	44%	0.385
	3rd month	44%	41%	0.212
Mild	Baseline	25%	28%	0.171
(5-9)	1st month	21%	22%	0.312
%	2nd month	19%	17%	0.231
	3rd month	18%	18%	0.399
Moderate	Baseline	12%	11%	0.235
(10-14)	1st month	10%	8%	0.270
%	2nd month	9%	6%	0.063
	3rd month	9%	5%	<u>0.002</u>
Moderately severe	Baseline	4%	5%	0.384
(15-19)	1st month	4%	2%	<u>0.028</u>
%	2nd month	4%	2%	<u>0.035</u>
	3rd month	3%	3%	0.314
Severe	Baseline	2%	1%	0.162
(20-27)	1st month	1%	1%	0.399
%	2nd month	2%	2%	0.333
	3rd month	2%	1%	0.085

Table S2. Contents of questionnaire

No	Item	Question	Answer
Q1	Condition	In the last seven days, did you have any symptoms, and how much have you been bothered by the symptoms? [1. stomachache, 2. backache, 3. tension in the breast, 4. swelling, 5. easily get tired, 6. feel weary, 7. rough skin, 8. headache, 9. constipation, 10. stiff shoulder, 11. nausea, 12. dizzy, 13. become irritated, 14. state of depression, 15. increased food appetite, 16. sleepiness, 17. decreased motivation]	0: no 1: weak 2: moderate 3: severe
Q2	Menstrual period	When was the first day of last menstrual period?	year(), month (), day()
Q3	Pregnancy	Are you pregnant?	Yes, no
Q4	WPAI [3]	Are you currently employed (working for pay)?	Yes, no
Q5		During the past seven days (excluding today), how many hours did you miss from work because of your health problems? Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems.	() hours
Q6		During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays?	() hours

Table S2. (cont'd)

No	Item	Question	Answer
Q7	WPAI [3]	During the past seven days, how many hours did you actually work?	() hours
Q8		During the past seven days, how much did health problems affect your productivity while you were working? Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as you usually do.	0 (health problems did not affect my productivity) -10 (health problems completely disturbed my work)
Q9		During the past seven days, how much did health problems affect your ability to do your regular daily activities, other than work at a job? By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like.	0 (health problems did not affect my productivity) -10 (health problems completely disturbed my work)

Table S2. (cont'd)

No	Item	Question	Answer
Q10	Diseases	Did you visit a doctor during the past one month?	<p>Yes</p> <p>(Select all diseases):</p> <p>Dysmenorrhea,</p> <p>PMS,</p> <p>Depression,</p> <p>Sleep disorder,</p> <p>Others ()</p> <p>No</p>
Q11	Medication	Do you have any drugs prescribed by a doctor?	<p>Yes</p> <p>(Select all drugs):</p> <p>Chinese</p> <p>medicine,</p> <p>Hormone drug,</p> <p>Antidepressants,</p> <p>Sleeping pills,</p> <p>Medicine for</p> <p>ulcers</p> <p>No</p>

PMS, premenstrual syndrome.

Table S2. (cont'd)

No	Item	Question	Answer
Q12	PHQ-9 [1,2]	Over the last 2 weeks, how often have you been bothered by any of the following problems? [1. Little interest or pleasure in doing things; 2. Feeling down, depressed, or hopeless; 3. Trouble falling or staying asleep, or sleeping too much; 4. Feeling tired or having little energy; 5. Poor appetite or overeating; 6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down; 7. Trouble concentrating on things, such as reading the newspaper or watching television; 8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual; 9. Thoughts that you would be better off dead or of hurting yourself in some way	0: not at all 1: several days 2: more than half the days 3: nearly every day

Table S2. (cont'd)

No	Item	Question	Answer
Q13		If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	0: not difficult at all 1: somewhat difficult 2: very difficult 3: extremely difficult

Table S3. Incidence of each symptom by sensitivity analysis with PPS (underline: $p < 0.05$)

		Control group	Intervention group	P value
Incidence (%)				
Dysmenorrhea	1st month	1.1%	0.9%	0.370
	2nd month	1.4%	1.2%	0.346
	3rd month	1.7%	0.5%	<u>0.019</u>
PMS	1st month	1.3%	1.3%	0.488
	2nd month	1.7%	0.7%	0.054
	3rd month	1.0%	1.4%	0.263
Depression	1st month	0.5%	0.4%	0.407
	2nd month	1.0%	0.2%	<u>0.041</u>
	3rd month	1.0%	0.2%	<u>0.044</u>

PPS, per protocol set; PMS, premenstrual syndrome.

Table S4. Physical conditions (underline: $p<0.05$)

Index	Control group	Intervention group	P-value
	N=914	N=612	
Baseline, average \pm SD			
Stomach ache	1.83 \pm 0.96	1.80 \pm 0.95	0.227
Backache	1.89 \pm 0.94	1.86 \pm 0.92	0.291
Tension in the breast	1.50 \pm 0.82	1.45 \pm 0.78	0.137
Swelling	2.07 \pm 1.02	2.04 \pm 1.00	0.312
Easily get tired	2.62 \pm 1.00	2.61 \pm 0.99	0.417
Feel weary	2.43 \pm 1.01	2.38 \pm 1.01	0.195
Rough skin	2.19 \pm 0.95	2.12 \pm 0.97	0.073
Headache	2.00 \pm 1.02	1.93 \pm 1.00	0.070
Constipation	1.95 \pm 1.03	1.94 \pm 1.05	0.446
Stiff shoulder	2.75 \pm 1.09	2.73 \pm 1.08	0.361
Nausea	1.36 \pm 0.71	1.31 \pm 0.66	0.080
Dizzy	1.39 \pm 0.73	1.37 \pm 0.68	0.310
Become irritated	2.17 \pm 1.05	2.13 \pm 1.04	0.264
State of depression	1.83 \pm 0.96	1.84 \pm 0.96	0.408
Increased food appetite	2.01 \pm 1.06	2.08 \pm 1.06	0.118
Sleepiness	2.59 \pm 1.03	2.65 \pm 1.01	0.141
Decreased motivation	2.21 \pm 1.03	2.26 \pm 1.05	0.200

SD: standard deviation.

Table S4 (cont'd)

Index	Control group	Intervention group	P-value
	N=914	N=612	
1st month, average \pm SD			
Stomach ache	1.81 \pm 0.93	1.86 \pm 0.93	0.158
Backache	1.90 \pm 0.93	1.95 \pm 0.94	0.174
Tension in the breast	1.50 \pm 0.79	1.59 \pm 0.87	<u>0.019</u>
Swelling	2.17 \pm 1.01	2.05 \pm 0.99	<u>0.014</u>
Easily get tired	2.62 \pm 0.99	2.60 \pm 0.97	0.343
Feel weary	2.42 \pm 1.00	2.45 \pm 0.99	0.326
Rough skin	2.20 \pm 0.92	2.18 \pm 0.97	0.364
Headache	2.02 \pm 1.02	2.01 \pm 1.00	0.419
Constipation	1.96 \pm 1.04	1.93 \pm 1.04	0.251
Stiff shoulder	2.79 \pm 1.07	2.76 \pm 1.05	0.296
Nausea	1.36 \pm 0.70	1.35 \pm 0.72	0.447
Dizzy	1.44 \pm 0.73	1.43 \pm 0.72	0.359
Become irritated	2.20 \pm 1.06	2.20 \pm 1.04	0.487
State of depression	1.87 \pm 1.00	1.89 \pm 1.00	0.344
Increased food appetite	2.07 \pm 1.04	2.12 \pm 1.06	0.183
Sleepiness	2.63 \pm 1.03	2.62 \pm 1.01	0.394
Decreased motivation	2.15 \pm 1.02	2.16 \pm 1.03	0.431

Table S4 (cont'd)

Index	Control group	Intervention group	P-value
	N=914	N=612	
2nd month, average±SD			
Stomach ache	1.79±0.90	1.76±0.91	0.238
Backache	1.89±0.93	1.90±0.97	0.411
Tension in the breast	1.60±0.84	1.53±0.82	0.052
Swelling	2.20±1.02	2.18±1.01	0.363
Easily get tired	2.63±1.00	2.64±1.00	0.404
Feel weary	2.46±1.00	2.43±0.98	0.300
Rough skin	2.20±0.95	2.13±0.94	0.058
Headache	2.00±1.00	1.92±0.96	0.056
Constipation	1.97±1.02	1.87±1.02	<u>0.031</u>
Stiff shoulder	2.76±1.08	2.66±1.11	<u>0.033</u>
Nausea	1.37±0.70	1.28±0.61	<u>0.004</u>
Dizzy	1.43±0.72	1.41±0.71	0.299
Become irritated	2.24±1.05	2.16±1.02	0.090
State of depression	1.86±1.03	1.78±0.94	0.065
Increased food appetite	2.07±1.02	2.01±1.05	0.164
Sleepiness	2.64±1.03	2.61±1.07	0.298
Decreased motivation	2.19±1.06	2.14±1.02	0.179

Table S4 (cont'd)

Index	Control group	Intervention group	P-value
	N=914	N=612	
3rd month, average \pm SD			
Stomach ache	1.80 \pm 0.90	1.76 \pm 0.90	0.176
Backache	1.92 \pm 0.94	1.92 \pm 0.93	0.497
Tension in the breast	1.60 \pm 0.86	1.60 \pm 0.88	0.460
Swelling	2.21 \pm 1.01	2.16 \pm 1.02	0.178
Easily get tired	2.64 \pm 1.00	2.67 \pm 0.99	0.317
Feel weary	2.53 \pm 0.99	2.51 \pm 0.99	0.371
Rough skin	2.22 \pm 0.94	2.17 \pm 0.95	0.162
Headache	2.08 \pm 1.04	1.94 \pm 0.96	<u>0.003</u>
Constipation	1.88 \pm 1.00	1.85 \pm 1.01	0.263
Stiff shoulder	2.75 \pm 1.11	2.61 \pm 1.06	<u>0.007</u>
Nausea	1.37 \pm 0.71	1.32 \pm 0.67	0.068
Dizzy	1.46 \pm 0.75	1.42 \pm 0.69	0.143
Become irritated	2.18 \pm 1.05	2.13 \pm 1.04	0.215
State of depression	1.85 \pm 1.00	1.81 \pm 0.99	0.225
Increased food appetite	1.88 \pm 0.98	1.99 \pm 1.08	<u>0.017</u>
Sleepiness	2.58 \pm 1.05	2.67 \pm 1.02	<u>0.048</u>
Decreased motivation	2.16 \pm 1.02	2.15 \pm 1.03	0.463

Table S5. Absenteeism calculated from the JMDC data

		Dysmenorrhea	Depression
Hospitalization	Annual incidence of hospitalization	7.4%	6.6%
	(%)		
	Average length of hospital stay per year (days)	9.4	18.0
	Number of days per month (days)	0.69	1.19
Hospital visit	Days per year (days)	12.2	17.3
Days off due to the symptom		6.8	9.8
(hospitalization+(hospital visit/2)) (days)			
Annual working days (days)		251.6	251.6
Absenteeism (%)		2.7%	3.9%
JMDC: Japan Medical Data Center.			

References:

1. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. JAMA. 1999;282(18):1737-1744.
2. Muramatsu K, Miyaoka H, Kamijima K, et al. The patient health questionnaire, Japanese version: validity according to the mini-international neuropsychiatric interview-plus. Psychol Rep. 2007;101(3 Pt 1):952-960.
3. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. Pharmacoeconomics. 1993;4(5):353-365.