from the mainland or Hong Kong to their surroundings, compared with other populations [52]. Although the Japanese may share the same tendency, PSEQ scores in three studies did not reflect this tendency. Therefore, further studies targeting the East Asian population are required to clarify the cultural differences in pain self-efficacy and its association with important pain-related outcomes.

There were several limitations to this study. First, data were missing from 25% of the sample we initially recruited. The second limitation was the relatively high mean age of our participants (64.33 years, SD = 15.12) compared with previous studies [42,51–55]. The higher age of participants in our study might be responsible for differences in types of disease and work status between the current sample and younger ones in other studies. Third, there was a large interval between the first and second assessment for examination of test–retest reliability of the PSEQ-J. However, the fact that the PSEQ-J remained quite reliable given this interval supports its overall stability.

In summary, this study showed that the PSEQ-J was a useful and psychometrically sound tool to assess pain self-efficacy in Japanese samples. Consistent with the findings using samples of patients with pain from many other cultures, our finding that the PSEQ appears to reflect more interference with social activity than physical activity appears to be a cross-cultural phenomenon. An important next step will be to determine if treatments that have been shown to improve pain self-efficacy (e.g., CBT) in other cultures might also improve self-efficacy in Japanese patients, and if these changes are subsequently associated with improvements in overall QOL.

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Appendix

現時点で「痛みはあってもこれらの事柄ができる」という自信の程度を教えて下さい。

0は「まったく自信がない」、6は「完ぺきな自信がある」です。それぞれの項目の下の番号を1つ選んで○をつけてください

記入例

0　1　2　(3)　4　5　6

全く自信がない　　完ぺきな自信がある

この質問票は以下の事柄をあなたが今まで実際に行ってきたかどうかではなく、「痛みはあるけれども、現時点でこれらの事柄を行える自信がどの程度あるか」を尋ねるものです。

1　痛みがあっても物事を楽しめる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

2　痛みがあっても家事のほとんど(掃除や皿洗いなど)をこなせる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

3　痛みがあっても友達や家族とこれまで通りに付き合える。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

4　ほとんどの場合痛みに対応できる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

5　痛みがあっても何か仕事ができる(仕事には家事も報酬のある仕事もない仕事も含む)。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

6　痛みがあっても趣味や気晴らしなどの楽しいことがたくさんできる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

7　薬がなくても痛みに対応できる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

8　痛みがあっても人生の目標のほとんどを達成できる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

9　痛みがあってもふつうに生活できる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

10　痛みがあっても徐々に活動的になれる。

0　1　2　3　4　5　6

全く自信がない　　完ぺきな自信がある

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METHODOLOGY, MECHANISMS & TRANSLATIONAL RESEARCH SECTION

Original Research Article

Validity, Reliability, and Assessment Sensitivity of the Japanese Version of the Short-Form McGill Pain Questionnaire 2 in Japanese Patients with Neuropathic and Non-Neuropathic Pain

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Abstract

Objective. The objective of this study was to define the validity, reliability, and assessment sensitivity of the Japanese version of the Short-Form McGill Pain Questionnaire 2 (SF-MPQ-2-J).

Design. This is a cross-sectional study.

Patients and Methods. The original SF-MPQ-2 was translated into Japanese to create the SF-MPQ-2-J, and the cross-cultural equivalence of assessment tool for Japanese patients was validated. The reliability of the SF-MPQ-2-J was assessed using internal consistency, reliability coefficients (Cronbach's α), and reproducibility coefficients (intraclass correlation coefficient) obtained using 234 patients with chronic pain. SF-MPQ-2-J validity was assessed based on associations identified between total and subscale scores compared with other assessment methods. A confirmatory factor analysis (CFA) was also performed to test the theoretical structure of the SF-MPQ-2-J.

Results. The internal consistencies calculated included continuous pain, $\alpha = 0.893$; intermittent pain, $\alpha = 0.875$; predominantly neuropathic pain, $\alpha = 0.917$; affective descriptors, $\alpha = 0.857$; and total score, $\alpha = 0.907$. The reproducibility coefficients calculated included continuous pain, $\rho = 0.81$; intermittent pain, $\rho = 0.78$; predominantly neuropathic pain, $\rho = 0.85$; affective descriptors, $\rho = 0.75$; and total score, $\rho = 0.83$. The CFA showed that the model fit of the readily interpretable subscales was acceptable, and the goodness of fit index value was 0.917. In addition, the mean predominantly neuropathic pain subscale score was found to be significantly higher for patients with neuropathic pain vs non-neuropathic pain.

Conclusion. These findings suggest that the reliability and validity of the SF-MPQ-2-J are excellent, and the SF-MPQ-2-J represents a cross-cultural equivalent to SF-MPQ-2. Consequently, the latter is suitable for research and clinical use, and for discriminating neuropathic pain from non-neuropathic pain.

Key Words. Neuropathic Pain; Short-Form McGill Pain Questionnaire 2; Reliability and Validity

Introduction

The McGill Pain Questionnaire (MPQ) and the Short-Form (SF)-MPQ have been widely used to assess characteristics of pain, particularly sensory and affective qualities [1,2]. The SF-MPQ was developed as a rapid evaluation tool [2] and includes 15 descriptors (11 sensory and 4 affective), a visual analog scale (VAS), and a present pain intensity scale. The validity and reliability of the SF-MPQ have previously been established [2–4], and the SF-MPQ has been applied to studies of patients with neuropathic pain (NP) [5]. However, the descriptions included in the SF-MPQ for assessing NP are not adequate. Therefore, neuropathy-specific measures have been created to assess NP [6,7], although these measures do not assess non-neuropathic pain (non-NP). Therefore, a revised version of the SF-MPQ was recently developed to more reliably assess the qualities of both NP and non-NP [8]. It is referred to as the SF-MPQ-2 and includes seven additional items to adequately cover NP symptoms compared with the SF-MPQ. The internal consistency of this version has been found to be acceptable and valid [8], and it has been translated into various languages [9]. However, a Japanese version has not been developed.

Therefore, the aim of the present study was to develop a culturally appropriate and functional Japanese translation of the SF-MPQ-2 and to assess its reliability and validity for characterizing chronic NP and non-NP in Japanese patients. The sensitivity of the SF-MPQ-2 in a clinical setting was also assessed based on its capacity to discriminate NP from non-NP in Japanese patients.

Methods and Materials

Translation and Procedures

The SF-MPQ-2 was translated into a Japanese version (SF-MPQ-2-J) according to the linguistic validation guidelines of the Mapi Research Trust under a translation agreement with Dr. Ronald Melzack and the International Quality of Life Assessment (IQOLA) protocol used in translating the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) [10]. Translators 1 and 2 were bilingual native speakers of Japanese (English was their second language), and one was a physiotherapist specializing in rehabilitation. These two translators independently produced two initial Japanese versions of the SF-MPQ-2. These versions were compared and a third reconciled version was achieved by consensus. A third translator, a bicultural and bilingual native English speaker (with Japanese as a second language) who had lived in Japan for 20 years and had no knowledge of the original English version of SF-MPQ-2 back-translated the forward translation into English in accordance with IQOLA guidelines. The translators then compared the back-translation with the original English version to confirm linguistic equivalence. Divergence between translations was resolved in the back-translation version by discussion between Translators 1 and 2. After these three rounds of translation, the construct validity of the preliminary SF-MPQ-2-J was tested using 117 patients experiencing chronic pain in a pilot study (see Appendix).

Participants

A total of 234 consecutive Japanese patients with chronic pain (133 male, 101 female) were recruited from the Pain Clinic and the Departments of Neurosurgery and Orthopedic Surgery at the Osaka University Hospital (Osaka, Japan) and the Pain Clinic at the Nishinomiya Municipal Hospital (Hyogo, Japan) between June and November 2012. Inclusion criteria included at least 16 years of age, chronic pain for >3 months, an ability to speak and read Japanese, having current symptoms, and willingness to participate in the study and to sign an informed consent form. Patient gender, age, educational level, marital status, and employment status were also recorded (Table 2). NP was defined as the presence of central post-stroke pain, avulsion of the brachial plexus, post-herpetic neuralgia, cervical or lumber radiculopathy, and diabetic neuropathy [11]. Non-NP included rheumatoid arthritis and osteoarthritis of the knee or hip. All patients were administered a preliminary SF-MPQ-2-J, as well as the standard Japanese version of the SF-MPQ (SF-MPQ-J) [12], VAS, and Long-Form (LF)-MPQ-J [13] as a comparative validated measure. The Ethics Committee of the Osaka University Hospital and Nishinomiya Municipal Hospital approved this study. All participants provided written informed consent before starting the study, and patients did not receive additional treatment or intervention between the two visits within 3 months.

Instruments

SF-MPQ-2

The SF-MPQ-2 consists of 22 descriptors that respondents rate on a 0–10 numeric scale, with "0" indicating "no pain" and "10" indicating "worst possible pain." The SF-MPQ-2 comprises four subscales: continuous (descriptor items 1, 5, 6, 8, 9, and 10; Table 5), intermittent (descriptor items 2, 3, 4, 11, 16, and 18; Table 5), predominantly NP (descriptor items 7, 17, 19, 20, 21, and 22; Table 5), and affective (descriptor items 12, 13, 14, and 15; Table 5). Subscale scores were calculated by adding the numerical values of the items, and the total score was the sum of all the values [8].

Comparison with Other Pain Assessment Tools

The construct validity of the SF-MPQ-2-J was tested against the SF-MPQ-J [2], the LF-MPQ (LF-MPQ-J) [1], the SF-36 [14,15], and the Pain Disability Assessment Scale (PDAS) [16]. Both the SF-MPQ-J and the LF-MPQ-J have proven reliable and valid for assessing chronic pain [12,13]. Table 1 lists the subcategories scored by each of these assessment tools.

Table 1 Mean scores for pain assessment questionnaires completed by patients with neuropathic and non-neuropathic pain

Pain Assessment Questionnaire	NP (N = 103)	Non-NP (N = 114)	*P* Value (NP vs Non-NP)
SF-MPQ-2			
Total score	49.2 ± 42.3 (100)	42.2 ± 37.6 (100)	0.39
Continuous pain	16.4 ± 12.6 (33.3)	15.5 ± 11.6 (36.7)	0.99
Intermittent pain	12.1 ± 13.9 (24.6)	10.5 ± 12.9 (24.9)	0.35
Neuropathic pain	13.5 ± 11.8 (27.4)	7.8 ± 10.2 (18.5)	<0.001*
Affective	7.2 ± 9.0 (14.6)	8.4 ± 9.9 (19.9)	0.27
SF-MPQ			
Total	10.9 ± 9.0	9.6 ± 8.8	0.157
Sensory (1–11)	8.8 ± 6.8	7.2 ± 6.3	0.075
Affective (12–15)	2.1 ± 2.6	2.4 ± 3.1	0.870
VAS	3.8 ± 1.9	3.6 ± 2.2	0.144
LF-MPQ			
Total	21.8 ± 16.3	19.8 ± 14.2	0.773
Sensory (1–10)	13.4 ± 9.3	13.2 ± 8.6	0.699
Affective (11–15)	2.3 ± 3.0	1.9 ± 2.5	0.529
Evaluative (16)	1.9 ± 1.9	1.7 ± 1.9	0.519
Miscellaneous (17–20)	4.2 ± 4.2	3.0 ± 3.3	0.118
SF-36			
Physical functioning	58.1 ± 24.3	60.5 ± 26.8	0.093
Role physical	56.8 ± 28.7	59.6 ± 31.7	0.177
Bodily pain	41.7 ± 17.5	40.6 ± 19.4	0.826
General health	48.1 ± 19.1	47.9 ± 17.9	0.549
Vitality	52.7 ± 19.9	47.5 ± 21.1	0.221
Social functioning	66.8 ± 25.1	65.0 ± 28.0	0.902
Role emotional	64.5 ± 31.5	65.9 ± 31.7	0.341
Mental health	59.2 ± 19.5	59.3 ± 22.7	0.570
PDAS			
Activities using the low back	6.5 ± 4.1	6.6 ± 4.1	0.467
Activities of daily living	4.4 ± 4.2	5.0 ± 4.8	0.734
Social activities	8.2 ± 6.2	9.6 ± 7.0	0.569
Total	19.2 ± 13.1	21.2 ± 14.6	0.828

* $P < 0.001$.

Values for pain are presented as the mean ± standard deviation (%). LF-MPQ = Long-Form McGill Pain Questionnaire; non-NP = non-neuropathic pain; NP = neuropathic pain; PDAS = Pain Disability Assessment Scale; SF-36 = Medical Outcome Study 36-Item Short Form Health Survey; SF-MPQ = Short-Form McGill Pain Questionnaire; SF-MPQ-2 = Short-Form McGill Pain Questionnaire 2; VAS = visual analog scale.

Statistical Analysis

Data were statistically analyzed using SPSS v. 21 (IBM, Chicago, IL, USA). The demographic data of the patients were described using means and standard deviation values. The internal consistency of each subscale of the SF-MPQ-2-J was assessed using Cronbach's α coefficient. A Cronbach's α coefficient ≥ 0.80 was considered satisfactory or adequate [17]. Reliability was determined from reproducibility coefficients (intraclass correlation coefficient [ICC]). An ICC ≥ 0.70 was considered satisfactory [17]. The validity of the questionnaire was assessed based on correlations between the total and subscale scores for each patient. Concurrent validity among the SF-MPQ-2-J, VAS, SF-MPQ-J, and LF-MPQ-J scores was descriptively evaluated using Spearman's rank correlation coefficients. Only correlations with absolute values >0.40 and with *P* values ≤0.05 were considered significant. The goodness of fit of four postulated factor structures extracted from a previous exploratory factor analysis (EFA) [8] were used to assess construct validity in a confirmatory factor analysis (CFA) performed by Amos version 21.0 for Windows (IBM, Chicago, IL, USA). Fit of the factor solutions for the CFA was evaluated based on a goodness of fit index (GFI) value > 0.90 and on a root mean square error of approximation (RMSEA) <0.05, good; <0.08, acceptable; >10, poor [18]. Scores were also compared between patients with NP and non-NP using the Wilcoxon signed-rank test. A probability value of $P < 0.05$ was considered to indicate a statistically significant difference. The protocol used was established in May 2012, and this clinical trial was registered with the

Table 2 Characteristics of the first and second cohorts analyzed

	First Cohort	Second Cohort	
	N = 96	NP (N = 103)	Non-NP (N = 114)
Age (mean years ± SD)	66.0 ± 13.2	68.7 ± 12.8	60.1 ± 15.5
Sex (N, %)			
Female	49 (51.0)	61 (59.2)	31 (27.2)
Male	47 (49.0)	42 (40.8)	83 (72.8)
Education (N, %)			
Elementary school	2 (2.1)	2 (1.9)	1 (0.9)
Junior high school	11 (11.5)	13 (12.6)	9 (7.9)
High school	38 (39.6)	42 (40.8)	44 (38.6)
Junior college	7 (7.3)	5 (4.9)	11 (9.6)
Vocational school	10 (10.4)	9 (8.7)	12 (10.5)
Bachelor degree	22 (22.9)	27 (26.2)	27 (23.7)
Postgraduate certificate	4 (4.2)	3 (3.9)	2 (1.8)
Unknown	2 (2.1)	2 (1.9)	8 (7.0)
Currently employed (N, %)			
Yes	26 (27.1)	25 (24.3)	42 (36.8)
No	70 (72.9)	78 (75.7)	72 (63.2)
Pain duration (N, %)			
<6 months	4 (4.2)	7 (6.8)	4 (3.5)
6 months to 1 year	12 (12.5)	8 (7.8)	7 (6.1)
1 year to 3 years	13 (13.5)	16 (15.5)	14 (12.3)
3 years to 5 years	18 (18.8)	19 (18.4)	14 (12.3)
>5 years	44 (45.8)	49 (47.6)	70 (61.4)
Unknown	5 (5.2)	4 (3.9)	5 (4.4)
Pain diagnosis (N, %)			
Central post stroke pain	12 (12.5)	15 (14.6)	NA
Avulsion of the brachial plexus	3 (3.1)	4 (3.9)	NA
Post-herpetic neuralgia	9 (9.4)	15 (14.6)	NA
Painful diabetic neuropathy	13 (13.5)	18 (17.5)	NA
Radicular pain	23 (24.0)	44 (42.7)	NA
Other neuropathic pain	4 (4.2)	7 (6.8)	NA
Neck or shoulder pain	4 (4.2)	NA	4 (3.5)
Low back pain	12 (12.5)	NA	17 (14.9)
Rheumatoid arthritis	0 (0.0)	NA	28 (24.6)
Osteoarthritis of the knee	0 (0.0)	NA	18 (15.8)
Osteoarthritis of the hip	0 (0.0)	NA	9 (7.9)
Other non-neuropathic pain	16 (16.7)	NA	38 (33.3)

NA = not applicable; non-NP = non-neuropathic pain; NP = neuropathic pain; SD = standard deviation.

University Hospital Medical Information Network Clinical Trials Registry (http://www.umin.ac.jp/ctr/index.htm), number UMIN000007985.

Results

The First Cohort

During the first stage of this study, 117 of 234 participants completed the SF-MPQ-2-J during two visits within 3 months. Twenty-one (17.9%) participants had missing data and were excluded from the statistical analyses performed. Thus, a total of 96 (49 male, 47 female) patients with chronic pain were included in the first analysis. The duration of pain reported by these patients was <6 months (4.2%), 6–12 months (12.5%), 1–3 years (13.5%), 3–5 years (18.8%), and >5 years (45.8%). In addition, the patients were diagnosed with central post-stroke pain (12.5%), avulsion of the brachial plexus (3.1%), post-herpetic neuralgia (9.4%), diabetic neuropathy (13.5%), radicular pain (24.0%), low back pain (12.5%), neck or shoulder pain (4.2%), or other pain (20.9%). Table 2 summarizes the characteristics and scores for this first cohort.

Reliability

Table 3 summarizes the scores and analyses performed for each of four subscales evaluated for the first and second attempts at completing the SF-MPQ-2-J by the 96 patients of the first cohort. The internal consistency of

Table 3 Internal consistency and reproducibility coefficients for the SF-MPQ-2-J

Subscale	Number of Items	Range	T1 Mean ± SD	T2 Mean ± SD	Cronbach's α Coefficient	Reproducibility Coefficients ICC (95% CI)
Continuous pain	6	0–60	16.8 ± 12.3	16.4 ± 13.3	0.892	0.81 (0.72–0.87)
Intermittent pain	6	0–60	14.3 ± 16.5	13.9 ± 14.8	0.875	0.78 (0.68–0.85)
Neuropathic pain	6	0–60	12.5 ± 12.4	11.3 ± 12.6	0.917	0.85 (0.78–0.90)
Affective	4	0–40	7.88 ± 10.1	6.91 ± 10.2	0.857	0.75 (0.65–0.83)
Total SF-MPQ-2	22	0–220	49.7 ± 42.7	47.2 ± 43.8	0.907	0.83 (0.76–0.88)
VAS	1	0–10	3.75 ± 1.94	3.79 ± 2.14	0.909	0.83 (0.76–0.89)

CI = confidence interval; ICC = intraclass correlation; SD = standard deviation; SF-MPQ-2-J = Japanese version of Short-Form McGill Pain Questionnaire 2; T1 = first attempt to complete questionnaire; T2 = second attempt to complete questionnaire; VAS = visual analog scale.

the SF-MPQ-2 was assessed using Cronbach's α coefficient, and a total score of 0.907 was obtained. For the continuous, intermittent, NP and affective subscales, the Cronbach's α coefficients were 0.892, 0.875, 0.917, and 0.857, respectively. The reproducibility coefficients (ICC) were also satisfactory and ranged in value from 0.75 to 0.85.

Validity

The total and subscale scores of SF-MPQ-2-J significantly correlated with those of the SF-MPQ-J, LF-MPQ-J, and VAS. Table 4 lists the associations that support the validity of the SF-MPQ-2-J and the validity of the subscales used. The standardized factor loadings of the four-factor models are presented in Table 5. The results of the CFA showed a good fit for each of the four subscales, and the data fit of the original four-factor models of the SF-MPQ-2-J were acceptable. Moreover, the multiple indicators of fit consistently indicated the adequacy of the model ($\chi^2 = 478$, degrees of freedom = 203, $P < 0.001$, GFI = 0.917; adjusted GFI = 0.894; RMSEA = 0.05). These results further support the construct validity of the SF-MPQ-2-J.

The Second Cohort

A total of 217 (125 males, 92 females) patients experiencing chronic NP (N = 103) and non-NP (N = 114) completed all questionnaires for the second cohort analyzed in this study (Table 2). All of these patients completed the SF-MPQ-2, SF-MPQ, LF-MPQ, SF-36, and PDAS questionnaires, and most of the results did not significantly differ between the NP and non-NP groups (Table 1). However, the mean score (%) for the NP subscale of the SF-MPQ-2 was significantly higher for patients with NP than those with non-NP.

Table 4 Intercorrelations between SF-MPQ-2-J and pain assessment tools ($P < 0.001$)

	SF-MPQ-2 (C)	SF-MPQ-2 (I)	SF-MPQ-2 (A)	SF-MPQ-2 (N)	SF-MPQ-2 (T)
SF-MPQ-2 (continuous pain)	–	–	–	–	–
SF-MPQ-2 (intermittent pain)	0.679	–	–	–	–
SF-MPQ-2 (affective)	0.609	0.529	–	–	–
SF-MPQ-2 (neuropathic pain)	0.598	0.696	0.379	–	–
SF-MPQ-2 (total score)	0.888	0.876	0.689	0.782	–
VAS	0.555	0.479	0.284	0.426	0.563
SF-MPQ (sensory descriptors)	0.549	0.533	0.350	0.500	0.615
SF-MPQ (affective descriptors)	0.426	0.441	0.739	0.314	0.563
SF-MPQ (total)	0.541	0.530	0.476	0.483	0.641
LF-MPQ (sensory)	0.692	0.594	0.457	0.557	0.718
LF-MPQ (affective)	0.442	0.496	0.597	0.365	0.534
LF-MPQ (evaluative)	0.621	0.552	0.482	0.462	0.626
LF-MPQ (total)	0.703	0.674	0.527	0.611	0.770

A = affective descriptors; C = continuous pain; I = intermittent pain; LF-MPQ = Long-Form McGill Pain Questionnaire; N = neuropathic pain; SF-MPQ = Short-Form McGill Pain Questionnaire; SF-MPQ-2 = Short-Form McGill Pain Questionnaire 2; T = total score; VAS = visual analog scale.

Table 5 Results of the confirmatory factor analysis (CFA) performed

	Factor Loadings			
Pain Description	Continuous Pain *r*	Intermittent Pain *r*	Neuropathic Pain *r*	Affective Descriptors *r*
1. Throbbing pain	0.593	–	–	–
2. Shooting pain	–	0.683	–	–
3. Stabbing pain	–	0.705	–	–
4. Sharp pain	–	0.775	–	–
5. Cramping pain	0.612	–	–	–
6. Gnawing pain	0.618	–	–	–
7. Hot-burning pain	–	–	0.674	–
8. Aching pain	0.703	–	–	–
9. Heavy pain	0.660	–	–	–
10. Tender	0.582	–	–	–
11. Splitting pain	–	0.682	–	–
12. Tiring/exhausting	–	–	–	0.688
13. Sickening	–	–	–	0.722
14. Fearful	–	–	–	0.792
15. Punishing/cruel	–	–	–	0.800
16. Electric-shock pain	–	0.720	–	–
17. Cold-freezing pain	–	–	0.720	–
18. Piercing	–	0.726	–	–
19. Pain caused by light touch	–	–	0.646	–
20. Itching	–	–	0.429	–
21. Tingling or pins and needles	–	–	0.735	–
22. Numbness	–	–	0.600	–

r = correlation coefficient.
$\chi^2 = 478$, degrees of freedom = 203, $P < 0.001$; goodness of fit index = 0.917; adjusted goodness of fit index = 0.894; root mean square error of approximation = 0.05.

Discussion

To the best of our knowledge, this is the first study to examine the validity and reliability of the SF-MPQ-2-J for assessing patients with chronic pain in the Japanese population. The validity and reliability of the SF-MPQ-2-J for this population were confirmed according to a CFA and internal consistency analyses. Moreover, the Cronbach's α coefficients identified for internal consistency (Table 3) were as high as the values obtained for the original English version of the exam [8]. The construct validity of the SF-MPQ-2-J was also found to be adequate. Furthermore, the ICC calculated using a test–retest method revealed excellent reliability (with continuous, intermittent, predominantly neuropathic, affective, and total values being 0.81, 0.78, 0.85, 0.75, and 0.87, respectively). These results are comparable with those obtained using the original SF-MPQ-2 (i.e., values ranged from 0.73 to 0.95) [8], as well as other translated versions that received a total score of 0.941 [9]. In particular, SF-MPQ-2-J was found to be equivalent to the original version of the SF-MPQ-2 in this study, and the validity of the self-administered SF-MPQ-2 pain questionnaire was demonstrated.

A CFA was conducted by proposing four subgroups for the SF-MPQ-2 in order to identify possible item correlations and to evaluate the construct validity of the questionnaire. The CFA is a hypothesis-driven technique that is used for testing the proposed factor structure of a given scale. It differs from the EFA in that it can confirm the validity of factor structure determined a priori rather than seeking a new factor structure. A good fitting four-factor model was obtained when a CFA was performed for the data available from patient responses regarding chronic pain using the same four subscales as the original English version of the SF-MPQ-2 [8]. However, the four subscales of the SF-MPQ-2 were not completely independent and were roughly intercorrelated and differentiated. Therefore, correlation errors among the SF-MPQ-2 subscales were inevitable. Accordingly, the correlation coefficient scores for some descriptors (i.e., itching and tenderness) in the CFA were actually lower than those of the other descriptors in the present study.

Previously, a few measurements were found to specifically differentiate NP from other types of pain, although it was difficult to simultaneously assess the quantitative aspects of pain [7,19,20]. In the present study,

SF-MPQ-2-J was able to detect patients with NP among those with chronic pain, and it could simultaneously quantify the associated pain. However, the validity of the discriminative capability of the SF-MPQ-2-J should be further assessed using a larger group of patients that experience acute and chronic pain, including patients experiencing varying pain conditions such as neuropathic, nociceptive, and mixed pain associated with acute pain.

There were several limitations associated with the present study. First, there was a relatively long interval between the first and second assessments of the test–retest reliability of the SF-MPQ-2-J compared with previous studies [9]. Secondly, the NP patients had a relatively higher mean age than the non-NP patients (68.7 ± 12.8 years vs 60.1 ± 15.5 years, respectively). The latter may account for the differences in the types or degree of pain reported between the two groups.

In conclusion, the SF-MPQ-2-J was found to be a reliable, valid, and sensitive pain questionnaire that includes a full range of clearly defined items applicable to evaluating both NP and non-NP. In addition, the SF-MPQ-2-J was able to differentiate NP and non-NP in the cohorts studied. Therefore, the SF-MPQ-2-J has the potential to be used as a general measure in medical research and in routine clinical practice.

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Appendix

Japanese version of the Short-Form McGill Pain Questionnaire 2 (SF-MPQ-2-J)

この質問票には異なる種類の痛みや関連する症状を表わす言葉が並んでいます。過去一週間に、それぞれの痛みや症状をどのくらい感じたか、最も当てはまる番号に × 印をつけて下さい。あなたの感じた痛みや症状に当てはまらない場合は、0 を選んで下さい。

1. ずきんずきんする痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
2. ビーンと走る痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
3. 刃物でつき刺されるような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
4. 鋭い痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
5. ひきつるような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
6. かじられるような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
7. 焼けるような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
8. うずくような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
9. 重苦しい痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
10. さわると痛い	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
11. 割れるような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
12. 疲れて くたくたになるような	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
13. 気分が悪くなるような	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
14. 恐ろしい	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
15. 拷問のように苦しい	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
16. 電気が走るような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
17. 冷たく凍てつくような痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
18. 貫くような	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
19. 軽く触れるだけで生じる痛み	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
20. むずがゆい	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
21. ちくちくする/ ピンや針	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*
22. 感覚の麻痺/ しびれ	*なし*	0	1	2	3	4	5	6	7	8	9	10	*考えられる最悪の状態*

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ORIGINAL ARTICLE

Effectiveness of a stress management program to enhance perimenopausal women's ability to cope with stress

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Abstract

Aim: To evaluate the effectiveness of a stress management program to enhance the ability to cope with stress in perimenopausal women.

Methods: In this quasi-experimental design, a stress management program was provided to an experimental group ($n = 55$), while a control group ($n = 42$) was given an informational pamphlet. The stress management program included a short lecture, group discussion, and hands-on training in 2 h sessions once a week for 3 weeks. Participants were recruited through a public announcement. Data were collected before and after the intervention, and 1 month following the intervention. The ability to cope with stress was the primary outcome, while psychological well-being and relief of symptoms were the secondary outcomes. The primary purpose of this program is to enhance the ability to cope with stress. Therefore, the aspects of knowledge, coping flexibility, and manageability were measured in the resultant ability to cope with stress.

Results: Compared to the control group, knowledge in the experimental group improved positively as the primary outcome ($P < 0.01$). Changes in coping flexibility were demonstrated within the experimental group ($P < 0.05$). A comparison between groups for the secondary outcome of psychological well-being showed that personal growth ($P < 0.05$) and happiness ($P < 0.01$) significantly improved in the experimental group. In addition, the secondary outcome of relief of symptoms indicated not improved.

Conclusion: Results suggest that the stress management program has the potential to boost perimenopausal women's ability to cope with stress and improve their psychological well-being.

Key words: care program, perimenopause, quasi-experimental design, stress coping, stress management.

BACKGROUND

Due to the recent aging population and a steep rise in medical fees, maintaining health and preventing illness after menopause is becoming an important health issue in Japan. The menopause is a turning point and a period of great physical and emotional change in a woman's life (Lock, 2005). During this period of transition, it is important for a woman to examine how she has been controlling her own health and to create a way of managing health that is most appropriate for her. Developing that health management will also have a positive impact on her health in later years (Wilmoth, 1996).

Reduced endocrine function and stress triggered by psychosocial factors are largely responsible for symptoms of menopause (The Japan Society for Menopause and Women's Health, 2014). Those factors faced by menopausal women are a mix of unavoidable life events including caring for parents, a child's search for employment, and an accumulation of daily problems, such as balancing diverse symptoms and lifestyles (Kamo, 2006). The menopausal experience is a complicated phenomenon with substantial individual variation. Therefore, it is important for a perimenopausal woman in a stressful environment to better understand the stressful situation in which she finds herself and cultivate her ability to cope by flexibly responding. Several

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researchers noted that if coping was used flexibly to suit the situation then the stress reaction was reduced, anxiety and depression were relieved, and well-being was improved (Cheng, 2001; Kato, 2001; Mino & Kanemitsu, 2004). Hence, this research focuses not on the reduction of the phenomenon of stress, but rather on the ability to cope with stress.

In fact, an integrated approach based on multiple factors is thought to be of more consequence than symptomatic therapy that focuses on a single symptom (Rotem *et al.*, 2005). A review of research (Iioka, 2009) noted that intervention studies about a variety of care programs for menopausal healthcare included drug therapy, decision-making support, therapeutic exercise, and health education. The effect of health behaviors and improvement of social psychological symptoms was a result of synergistic effects of interventions within a complex program. Generally, in Japan, outpatient treatment for menopause focuses only on drug therapy; care programs have not been implemented. Though health education is carried out at facilities such as public health centers, there have been no outcome studies and the number of studies regarding care programs combining health education and drug therapy in Japan is negligible. Therefore this study focused on perimenopausal women's ability to cope with stress by looking at the outcomes of a care program designed to improve stress-coping competency. The care program was developed based on a published work review (Iioka, 2009) of intervention studies targeting menopausal women that concluded that composite care programs and group discussions based on adult learning theory and cognitive–behavioral therapy were effective (Iioka, 2011).

Purpose and framework

This research aimed to evaluate the effectiveness of a stress management program, "A Stress Management Program to Aid Living with Menopause" (SM program), to enhance perimenopausal women's competency in coping with stress. This study viewed stress and coping through the various changes and confusion that face perimenopausal women.

Coping is a dynamic process that is constantly changing depending on the woman's individual cognitive appraisal style, amount and type of burden she is carrying, support system, and competency to cope (Lazarus & Folkman, 1984). Therefore, it is important to take an integrated perspective that includes the above process. Rather than applying specific coping strategies, the ability to cope with stress can be elevated through flexibly used coping strategies coupled with knowledge, and applied according to prevailing circumstances and an individual's condition. This study focused on stress management, not on relieving and reducing stress. Figure 1 shows this study's research framework based on definitions emerging from a systematic published

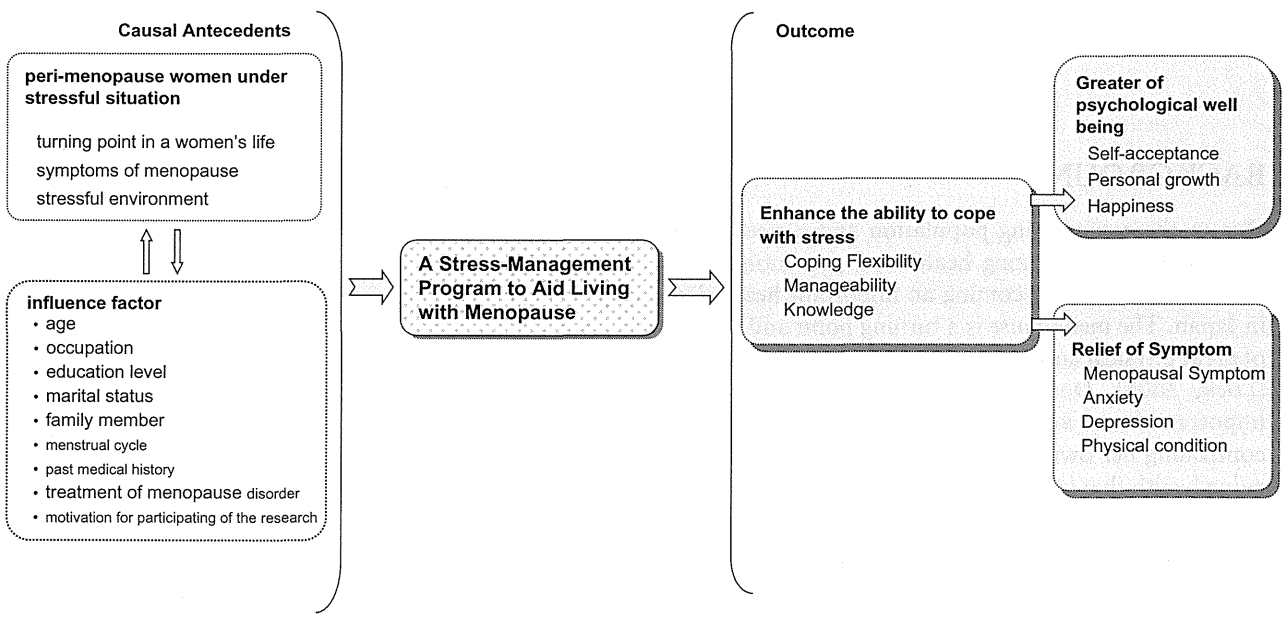

Figure 1 Conceptual framework.

Table 1 Hypotheses and measurements

	Hypothesis	Hypothesized outcomes	Instrument
Primary hypothesis	Compared with the control group, the SM program experimental group will show improved ability to cope with stress	Greater knowledge of menopause and stress management	Knowledge Test (KT)
		Increased coping flexibility	Coping Flexibility Scale (CFS)
		Heightened perception of manageability	Manageability (SCS-m)
Secondary hypothesis	Compared with the control group, the experimental group will have greater psychological well-being	Increased perception of personal growth	Personal Growth Scale (PGS)
		Increased perception of self-acceptance	Self-Acceptance Scale (SAS)
		Increased feeling of happiness	Happiness Scale (HS)
	Compared with the control group, the experimental group will experience a relief of symptoms	Improvement in perception of physical condition	Perception of Physical Condition Scale (PPC)
		Reduction in symptoms of anxiety	Hospital Anxiety and Depression Scale (HADS-A)
		Reduction in symptoms of depression	Hospital Anxiety and Depression Scale (HADS-D)
		Decreased severity of menopause related symptoms	Menopausal Symptom Assessment Chart (MSAC)

work review: "Ability to cope with stress was defined as an aptitude to assess ones coping abilities in relationship to circumstances and flexibly practice suitable coping techniques in accordance with circumstances" (Iioka, 2008, p. 31–35). In addition, the following hypotheses were formulated.

Primary hypothesis

The experimental group (EG) that participates in the SM program will demonstrate an enhanced ability over the control group (CG) to cope with stress. That enhanced ability to cope with stress will be indicated through improved coping flexibility and improved knowledge, which form the basis for coping skills.

Secondary hypotheses

1 The EG will have greater psychological well-being than the CG. Greater psychological well-being will be indicated by enhanced personal growth and self-acceptance, which target improving the decline in self-esteem, and a resulting enhanced feeling of happiness.
2 Compared with the CG, the EG will experience a relief of symptoms. The relief of symptoms will be indicated by an improvement in menopause symptoms, an improvement in anxiety and depression: factors crucial to considering the need for treatment, and an improvement in the perception of physical condition, which is an overall sense of well-being felt as a result of the previous two.

Table 1 indicates the specific outcomes and measurement tools.

METHODS

Research design

This study used a quasi-experimental design with non-random subject allocation. With the understanding that many women experiencing menopausal symptoms are psychologically fragile, randomization was not carried out to ensure the intervention would not place an undue burden on them. The EG of three to eight participants was offered an innovative composite program (SM program) of a 2 h session held once a week for 3 consecutive weeks.

The CG received one part of a self-guided learning program (SL program) each week. See Table 2 for program components

Subjects

Applications for the program were simultaneously solicited through public relations activities, utilizing posters and leaflets that summarized the two information options. To improve motivation and commitment, applicants chose the program in which they wished to participate.

Table 2 Contents of SM program and SL program

Intervention group	Program	Intervention period	Pedagogy	Topics
Experimental group (EG)	A Stress Management Program to Aid Living with Menopause (SM program)	Two hour sessions held once a week for 3 consecutive weeks. Three topics were provided every session.	Lecture	Information about menopause (mechanism of menopause, symptoms of menopause, treatment for menopause disorder)
				Information about stress management
				Dealing with stress
				Social skills training
				Cognitive restructuring
			Group discussion	Assimilation of information
				Meaning of my experience of menopause
				My stressor and response to stress
				How to deal with my stress
				My perception tendencies
				My communication style
				How to overcome menopause
			Hands on training	Stretching
				Acupressure points (by self, in pairs)
Control group (CG)	A self-guided learning program (SL program)	One part given to control group each week for 3 weeks.	Three part booklet	Content comparable to most menopause educational pamphlets
				Information about menopause (mechanism of menopause, symptoms of menopause, treatment for menopause disorder)

Inclusion criteria were: (i) one or more symptoms of menopause related to the stress response; (ii) between the ages of 44 and 56 years (the average age of menopause ± 2 standard deviations), or between the ages of 40 and 59 years; and (iii) had early menopause, late menopause, or surgical menopause. Excluded criteria were: (i) a score of 16 or higher on the Hospital Anxiety and Depression Scale (HADS); (ii) changes in treatment for menopausal symptoms in the past 3 months; (iii) a history of cancer or other chronic illness; and (iv) a diagnosis of mental illness.

Of the 60 women who applied for the EG, 55 were accepted, and of the 48 for the CG, 42 were accepted. Due to poor health, one woman in the EG dropped out, and one woman in the CG withdrew because of panic symptoms (Fig. 2).

DATA COLLECTION

Measurements

Primary outcomes (ability to cope with stress)

1 Knowledge Test (KT) (Appendix) is a true/false questionnaire developed by the researcher that tested knowledge about menopause (seven items) and stress management (eight items). A perfect score totaled 15 points. Cronbach's alpha coefficient was 0.69 for the entire scale, while it was 0.51 for the menopausal subscale and 0.59 for the stress management subscale in this study.
2 Coping Flexibility Scale (CFS) (Appendix) is a 6 point Likert scale (0 = "never"; 5 = "always") developed by the researcher on the basis of concept analysis results.

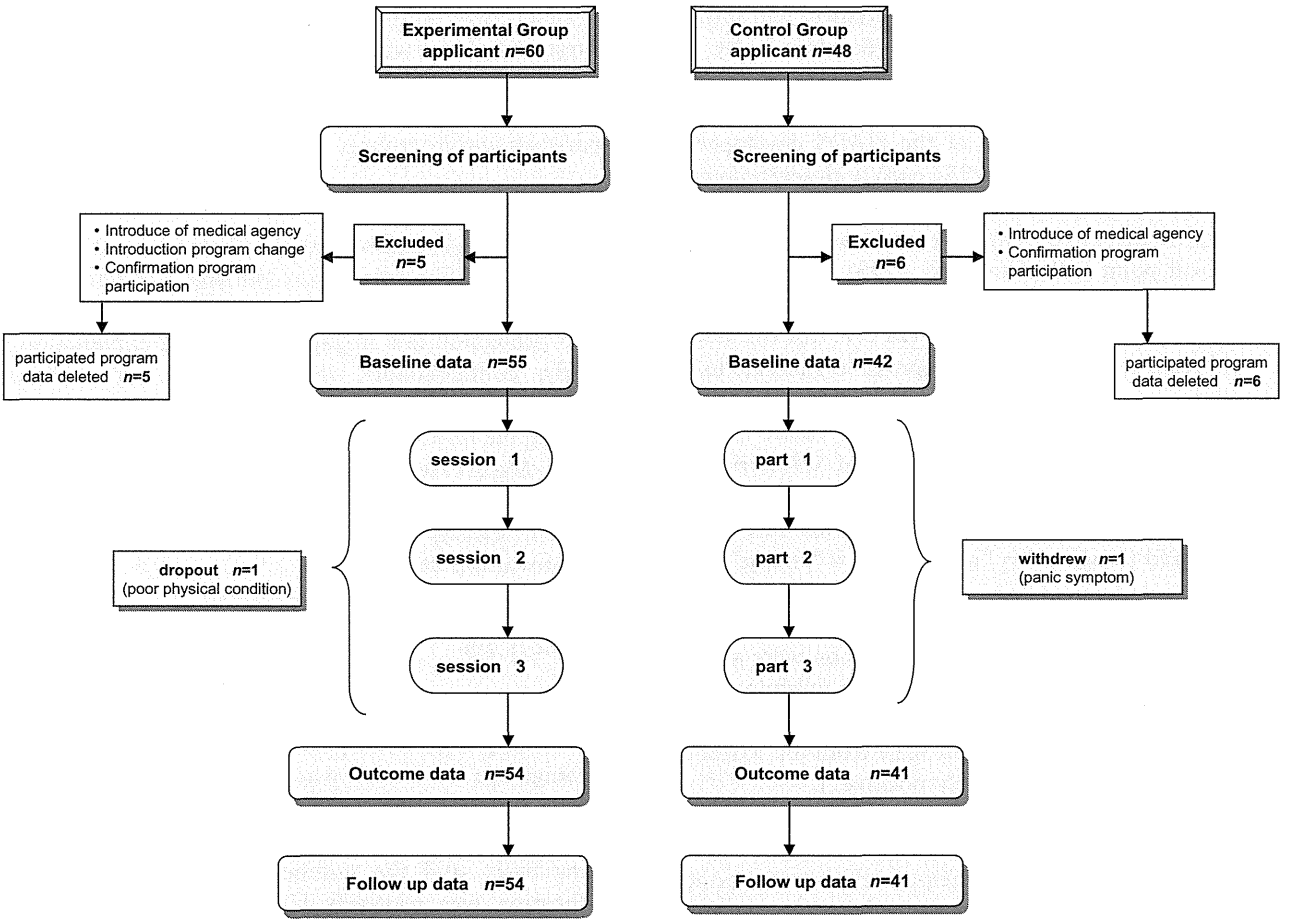

Figure 2 Flow of the participants through the research.

A factor analysis revealed two factors "ability to judge" (seven items) and "ability to flexibly respond" (five items). The cumulative contribution ratio was 50%. Cronbach's alpha coefficient was 0.79 for the entire scale, while it was 0.70 for the "ability to judge" subscale and 0.81 for the "ability to flexibly respond" subscale in this study.

3 Manageability Scale (SCS-m), a subscale of Antonovsky's (1987) Sense of Coherence Scale, was translated and further developed by Yamazaki (1997). It consists of 10 items scored from 1 ("never") to –7 ("always"). Manageability is defined as: "the sense of freedom to use the resources needed to overcome various problems when faced with future hardships or problems in major life settings" (Antonovsky, 1979; Yamazaki *et al.*, 2001). Cronbach's alpha coefficient was 0.59 for the manageability subscale in this study.

Secondary outcomes (psychological well-being)

The Personal Growth Scale (PGS) (seven items) and Self-Acceptance Scale (SAS) (eight items) are subscales of the Psychological Well-Being Scale developed by Ryff, Keyes, and Lee (1995). Scoring is a on a 7 point Likert scale ranging from 15 to 90 points. The higher score indicates more self-acceptance and growth of personality. Cronbach's alpha coefficient ranged 0.76–0.90 with reliability and validity verified (Nishida, 2000). The Happiness Scale (HS) (Appendix) is a visual analog scale (VAS) that measures feelings of happiness with extremes of 100 "extremely happy" to 0 "extremely unhappy". The HS was developed by the researcher.

Secondary outcomes (relief of symptoms)

1 Perception of Physical Condition Scale (PPC) (Appendix) is a VAS ranging between 100 ("extremely good

physical condition") and 0 ("extremely bad physical condition"). The PPC was developed by the researcher.

2 Depression (HADS-D) and anxiety (HADS-A), both of which are subscales of the HADS developed by Zigmond and Snaith (1983), each with seven items on a 4 point Likert scale. Zigmond and Snaith (1983) verified the HAD reliability and validity. The usual cut-off point is 8 (Kitamura, 1993). Created a Japanese version. Cronbach's alpha coefficient was 0.87 for the entire scale, while it was 0.79 for the anxiety subscale and 0.80 for the depression subscale in this study.

3 Menopausal Symptom Assessment Chart (MSAC) developed by the Japan Society of Obstetrics and Gynecology (Honjo & Ohama, 2001) consists of 21 symptoms scored from 1 to 4 that are individually analyzed (ranging 0 = "never" to 3 = "strong").

Program assessment

The components of each program session were assessed for ease of understanding, satisfaction, usefulness, and self-efficacy. Following every session, each component was scored on a VAS 10 point scale from 0 ("extremely negative") to 100 ("extremely positive").

Participant characteristics

Data were collected on participant characteristics (age, occupation, marital status, and medical history), information about menopause (menstrual state, treatment for menopausal disorders), stressful events, and reasons for participation.

Data collection procedure

Outcome data were collected at three points: baseline data (T1, before intervention); outcome data (T2, immediately after intervention); and follow-up data (T3, 1 month later). The distribution and collection of data was conducted through the mail from April to November 2007. The program was carried out at St Luke's College in Tokyo.

Data analysis

P-values of less than 0.05 were accepted as significant. Statistical processing used SPSS version 17.0 (SPSS, Chicago, IL, USA). Intent-to-treat analysis and last observation carried forward were used in the statistical processing. The scales used for outcomes were totaled, and changes during the data collection period were calculated as a range (T1 → T2, T2 → T3, and T1 → T3) to determine differences for each individual.

Descriptive statistics were calculated and Student's *t*-test and χ^2-test were used to identify significant differences in participant characteristics between groups.Student's paired *t*-test was used to make comparisons within groups.

Ethical considerations

This research complied with the Declaration of Helsinki, and Ethical Guidelines for Nursing Research of the International Council of Nursing and personal information protection law in Japan (including explanation of study, confidentiality, right to refuse or withdraw without harm, anonymity when research published). During the research period, back-up measures involving gynecologists were put into place. Data collection commenced after the Research Ethics Committee of St Luke's College of Nursing approved this study (approval no. 06–085).

RESULTS

Subject characteristics

The average age of the participants was 49.7 years. The average age for the EG was 50.1, and 49.1 for the CG. There were no significant differences between participant characteristics (Table 3). Most worked on a full-time basis, and the number of women with higher education was relatively high. While 80% were not receiving treatment for menopausal symptoms, nine were being treated with hormone replacement therapy and five with herbal medicines.

Outcomes of hypotheses

Table 4 shows the scores for the various outcomes. Table 5 shows the statistical results (Student's *t*-test) obtained by comparing groups using differences in data between measured points. Table 6 shows the statistical results (paired Student's *t*-test) obtained from changes within the EG.

Primary hypothesis: Ability to cope with stress

The hypothesis, "compared to the CG, the EG's ability to cope with stress will improve" was generally validated. No significant statistical differences between groups were observed in any of the four measurements for ability to cope with stress. ANCOVA found no confounding factors of participant characteristics.

1 For the KT, scores for the EG increased in T2, and were sustained in T3. Comparing ranges between groups, there was a significant statistical difference from T1 to

Table 3 Characteristics of participants ($n = 97$)

		Experimental group ($n = 55$)		Control group ($n = 42$)			
		N	%	N	%	χ^2	*P*
Occupation	Full-time worker	18	32.73	21	50.00		
	Part-time worker	13	23.64	10	23.81		
	Self-employed	5	9.09	5	11.90		
	Homemaker or without paid occupation	14	25.45	4	9.52		
	Other	5	9.09	2	4.76	5.83	0.213
Education level	Junior college graduate/college/ graduate college	30	55.56	19	45.24		
	Vocational school	10	18.52	13	30.95		
	High school	14	25.93	9	21.43		
	Junior high school	0	0.00	1	2.38	3.50	0.320
Marital status	Married	45	81.82	33	78.57		
	Single	6	10.91	5	11.90		
	Divorce	4	7.27	4	9.52	0.2	0.906
Living status	With husband	14	25.45	8	19.05		
	With husband and children	21	38.18	13	30.95		
	With parent/s	8	14.55	3	7.14		
	Alone	5	9.09	6	14.29		
	Other	7	12.73	12	28.57	5.56	0.235
Menstrual cycle	Regular	12	23.08	19	46.34		
	Irregular	15	28.85	9	21.95		
	Menopause	25	48.08	13	31.71	5.65	0.059
Treatment of menopause disorder	No treatment	42	76.36	37	88.10		
	Past treatment	2	3.64	1	2.38		
	Under treatment:	11	20.00	4	9.52	2.21	0.331
	hormonal replacement therapy	7	12.7	2	4.8		
	herbal medicine	3	5.5	2	4.8		
	other	1	1.8	0	0		
Motive of participants (total members)	Relief of Symptom	4	7.27	5	11.90		
	Want to know about menopause	19	34.55	10	23.81		
	Want to live a healthy life	31	56.36	11	26.19		
	Invitation from a friend	5	9.09	11	26.19		
	Looks interesting	1	1.82	2	4.76		
	Other	2	3.64	3	7.14		

T2 and T1 to T3 ($t = 4.09$, $P = 0.000$; $t = 4.50$, $P = 0.000$). The KT was divided into items relating to menopause and stress management, and then analyzed. Compared to stress management-related items, menopause-related items showed a greater increase in score and a significant statistical difference in comparison of ranges from T1 to T2 and T1 to T3 ($t = 4.42$, $P = 0.000$; $t = 4.03$, $P = 0.000$; respectively), indicating that learning increased significantly.

2 For the CFS, only the EG indicated an increased sense of improvement in their ability to cope. No significant statistical differences between groups were found for any of the changes. However, a within-group comparison showed a significant increase in changes in the EG from T2 to T3 ($t = 2.12$, $P = 0.039$). There were no significant changes in "ability to judge" according to an analysis of subscales, but a within-group comparison unveiled a significant statistical increase from T1 to T3 in the EG's "ability to flexibly respond" ($t = 2.74$, $P = 0.008$).

3 For the SCS-m, the average score for SCS-m increased somewhat in the EG. An examination of the ranges did not denote any significant statistical differences in changes between groups. However, there was a