Table 4 Comparison of outcome scores between experimental and control group

	Scale		Time	Experimental group N	Mean	SD	Control group N	Mean	SD	*t*	d.f.	*P*	Confidence interval Lower	Upper
Primary outcome	Knowledge Test (KT)		T1	55	11.35	1.62	42	11.27	1.55	0.25	93	0.800	−0.57	0.74
			T2	**55**	**12.87**	**1.38**	**42**	**11.24**	**1.82**	**4.89**	**90**	**0.000****	**0.97**	**2.29**
			T3	**55**	**12.96**	**1.30**	**42**	**11.32**	**1.90**	**4.76**	**67**	**0.000****	**0.96**	**2.34**
	Coping Flexibility Scale (CFS)		T1	55	36.40	7.03	42	33.97	6.45	1.75	95	0.083	−0.33	5.19
			T2	55	36.20	6.98	42	33.51	6.22	1.97	95	0.052	−0.02	5.40
			T3	**55**	**37.36**	**5.89**	**42**	**33.83**	**6.29**	**2.84**	**95**	**0.006****	**1.06**	**6.00**
	Manageability (SCS-m)		T1	55	44.49	5.84	42	44.19	6.54	0.24	95	0.814	−2.21	2.80
			T2	55	45.64	6.11	42	43.95	5.35	1.42	95	0.158	−0.67	4.05
			T3	55	45.14	5.57	42	44.24	5.83	0.78	95	0.438	−1.41	3.22
Secondary outcome (psychological well-being)	Personal Growth Scale (PGS)		T1	55	38.64	5.79	42	37.64	5.13	0.88	95	0.381	−1.25	3.24
			T2	**55**	**39.42**	**5.60**	**42**	**36.83**	**5.57**	**2.26**	**95**	**0.026***	**0.31**	**4.86**
			T3	55	39.09	5.79	42	36.93	5.09	1.92	95	0.058	−0.07	4.40
	Happiness Scale (HS)		T1	55	67.18	19.10	42	70.43	19.65	−0.82	95	0.415	−11.11	4.62
			T2	**55**	**75.78**	**15.88**	**42**	**67.21**	**19.64**	**2.31**	**77**	**0.024***	**1.18**	**15.96**
			T3	55	70.84	19.27	42	67.93	20.22	0.72	95	0.473	−5.10	10.92
	Self-Acceptance Scale (SAS)		T1	55	26.66	6.31	42	26.60	5.86	0.05	95	0.957	−2.42	2.56
			T2	55	28.33	5.60	42	26.88	4.89	1.34	95	0.185	−0.71	3.61
			T3	55	28.22	5.38	42	26.93	5.25	1.18	95	0.240	−0.88	3.46
Secondary outcome (relief of symptom)	Perception of Physical Condition (PPS)		T1	55	53.13	22.51	42	57.64	24.05	−0.95	95	0.344	−13.95	4.92
			T2	55	60.93	20.31	42	57.38	22.21	0.82	95	0.415	−5.06	12.15
			T3	55	60.05	20.24	42	57.60	21.23	0.58	95	0.563	−5.95	10.87
	Depression (HADS-D)		T1	55	5.15	3.80	42	5.31	3.51	−0.22	95	0.828	−1.66	1.33
			T2	55	4.18	2.93	42	5.48	3.64	−1.94	95	0.055	−2.62	0.03
			T3	55	4.55	3.46	42	5.31	3.15	−1.12	95	0.266	−2.12	0.59
	Anxiety (HADS-A)		T1	55	5.22	3.46	42	5.86	2.64	−1.00	95	0.32	−1.91	0.64
			T2	55	5.05	3.09	42	5.74	3.31	−1.05	95	0.30	−1.98	0.61
			T3	55	5.35	3.62	42	5.60	3.40	−0.35	95	0.73	−1.69	1.19
	Menopause Symptom Assessment Chart (MSAC)	Hot flush/flash	T1	54	2.05	1.079	42	1.64	0.932	1.973	94	0.051	−0.003	0.826
			T2	54	2.11	1.076	42	1.93	1.021	0.851	94	0.397	−0.246	0.614
			T3	42	2.143	1.072	41	2.073	0.848	0.328	81	0.744	−0.353	0.493
		Sweats easily	T1	54	2.59	1.252	42	2.19	1.110	1.640	94	0.104	−0.085	0.889
			T2	54	2.55	1.142	42	2.36	1.055	0.834	94	0.407	−0.262	0.641
			T3	42	2.381	1.147	41	2.585	1.183	−0.799	81	0.426	−0.713	0.304
													*$P < .05$	**$P < .01$

d.f., degrees of freedom; SD, standard deviation.

Table 5 Outcome score differences between experimental and control group (Student's *t*-test)

	Scale		Difference between data	Experimental group N	Experimental group Mean	Experimental group SD	Control group N	Control group Mean	Control group SD	*t*	d.f.	*P*	Confidence interval Lower	Confidence interval Upper
Primary outcome	Knowledge Test (KT)		**T1 → T2**	**55**	**1.50**	**1.75**	**42**	**0.06**	**1.47**	**4.09**	**88**	**0.000****	**0.74**	**2.15**
			T2 → T3	55	0.06	1.37	42	0.14	1.21	−0.29	89	0.775	−0.63	0.47
			T1 → T3	**55**	**1.55**	**1.56**	**42**	**0.08**	**1.56**	**4.50**	**91**	**0.000****	**0.82**	**2.12**
Secondary outcome (psychological well-being)	Personal Growth Scale (PGS)		**T1 → T2**	**55**	**0.78**	**3.52**	**42**	**−0.81**	**3.39**	**2.24**	**95**	**0.027***	**0.18**	**3.00**
			T2 → T3	55	−0.33	2.84	42	0.10	3.60	−0.65	95	0.518	−1.72	0.87
			T1 → T3	55	0.45	3.92	42	−0.71	4.01	1.44	95	0.153	−0.44	2.78
	Happiness Scale (HS)		**T1 → T2**	**55**	**8.60**	**13.54**	**42**	**−3.21**	**22.36**	**3.22**	**95**	**0.002****	**4.54**	**19.09**
			T2 → T3	55	−4.95	13.57	42	0.71	18.98	−1.71	95	0.090	−12.22	0.90
			T1 → T3	55	3.65	17.28	42	−2.50	17.01	1.75	95	0.083	−0.83	13.14
Secondary outcome (relief of symptom)	Perception of Physical Condition (PPS)		**T1 → T2**	**55**	**7.80**	**15.43**	**42**	**−0.26**	**22.10**	**2.11**	**95**	**0.037***	**0.49**	**15.63**
			T2 → T3	55	−0.87	20.43	42	0.21	22.91	−0.25	95	0.806	−9.85	7.67
			T1 → T3	55	6.93	25.15	42	−0.05	21.34	1.44	95	0.152	−2.62	16.57
	Menopause Symptom Assessment Chart (MSAC)	Hot flush/flash	T1 → T2	55	0.04	0.58	42	0.28	0.74	−1.79	75	0.077	−0.52	0.03
			T2 → T3	55	−0.07	0.50	42	0.14	0.75	−1.62	68	0.110	−0.48	0.05
			T1 → T3	**55**	**−0.04**	**0.72**	**42**	**0.43**	**0.83**	**−2.89**	**81**	**0.005****	**−0.78**	**−0.15**
		Sweats easily	T1 → T2	55	−0.05	0.93	42	0.17	0.82	−1.16	95	0.247	−0.57	0.15
			T2 → T3	**55**	**−0.21**	**0.69**	**42**	**0.21**	**0.78**	**−2.83**	**95**	**0.006****	**−0.72**	**−0.13**
			T1 → T3	**55**	**−0.25**	**1.06**	**42**	**0.38**	**0.94**	**−3.08**	**95**	**0.003****	**−1.05**	**−0.23**
													*$P < .05$	*$P < .01$

d.f., degrees of freedom; SD, standard deviation.

Table 6 Outcome score differences within groups for the experimental group (Student's paired *t*-test)

	Scale	Difference between data	Mean	SD	Confidence interval Upper	Confidence interval Lower	*t*	d.f.	*P*
Primary outcome	Coping Flexibility Scale (CFS)	T1 → T2	0.20	4.37	−0.98	1.38	0.34	54	0.736
		T2 → T3	**−1.16**	**4.08**	**−2.27**	**−0.06**	**−2.12**	**54**	**0.039***
		T1 → T3	−0.96	4.32	−2.13	0.20	−1.66	54	0.104
	Manageability (SCS-m)	**T1 → T2**	**−1.15**	**3.90**	**−2.21**	**−0.10**	**−2.19**	**54**	**0.033***
		T2 → T3	0.50	3.49	−0.45	1.44	1.06	54	0.294
		T1 → T3	−0.66	4.24	−1.80	0.49	−1.15	54	0.256
Secondary outcome (psychological well-being)	Self-acceptance Scale (SAS)	**T1 → T2**	**−1.67**	**3.95**	**−2.74**	**−0.60**	**−3.13**	**54**	**0.003****
		T2 → T3	0.11	3.21	−0.75	0.98	0.26	54	0.793
		T1 → T3	**−1.55**	**4.05**	**−2.65**	**−0.46**	**−2.85**	**54**	**0.006****
Secondary outcome (relief of symptom)	Depression (HADS-D)	**T1 → T2**	**0.97**	**2.96**	**0.17**	**1.77**	**2.43**	**54**	**0.019***
		T2 → T3	−0.37	2.63	−1.08	0.34	−1.04	54	0.304
		T1 → T3	0.60	3.74	−0.41	1.61	1.19	54	0.240
	Anxiety (HADS-A)	T1 → T2	0.16	2.75	−0.58	0.91	0.44	54	0.660
		T2 → T3	−0.29	2.76	−1.04	0.46	−0.78	54	0.438
		T1 → T3	−0.13	3.46	−1.06	0.81	−0.27	54	0.786
									*$P < .05$ **$P < .01$

d.f., degrees of freedom; SD, standard deviation.

significant increase seen within the EG from T1 to T2 ($t = 2.19$, $P = 0.033$).

Correlation coefficients were calculated to examine the relationship among the four indicators for ability to cope with stress. A significant correlation was indicated in the CFS and SCS-m ($r = 0.42$, 0.61, $P < 0.01$, respectively).

Secondary hypothesis: Psychological well-being

The hypothesis, "compared to the CG, the EG's psychological well-being will improve" was generally validated. No significant statistical difference was observed between groups in T1 for any of the three measurements for psychological well-being. In addition, the ANCOVA for the range that detected a significant difference between groups did not show any extraneous factors that became confounders in any of the three indicators.

1 For the PGS, the average score did not increase in the EG, but did drop somewhat in the CG. CG respondents indicated that they were unable to realize their growth whereas the EG respondents were able to maintain that perception. A significant statistical difference was observed by comparing the score range between groups from T1 to T2 ($t = 2.24$, $P = 0.027$), but no significant difference was seen in changes to T3. In other words, the sense of personal growth only increased immediately after the intervention.
2 For the HS, the average score increased in the EG, but decreased in the CG. This indicates that the intervention increased the sense of happiness. A significant statistical difference was observed by comparing the score range between groups from T1 to T2 ($t = 3.22$, $P = 0.002$). However, the average score for the EG in T3 was close to the T1 score, and no significant difference was seen in the comparison of range between groups from T1 to T3.
3 For the SAS, there was almost no change in average scores in either groups or significant statistical difference in range. A significant statistical increase was observed within the EG from T1 to T2 and from T1 to T3 ($t = 3.13$, $P = 0.003$; $t = 2.85$, $P = 0.006$, respectively) indicating a significant improvement in self-acceptance.

Correlation coefficients were calculated to examine the relationship among the three indicators for psychological well-being. A significant correlation was seen among all three indicators ($r = 0.37$, 0.55, $P < 0.01$, respectively).

Secondary hypothesis: Relief of symptoms

The hypothesis, "compared to the CG, the EG will experience relief of symptoms" was generally unsubstantiated. No significant statistical differences were observed between groups in T1 for any of the four measurements for relief of symptoms. In addition, the ANCOVA for the range that detected a significant difference between groups did not show any extraneous factors that could have been confounders in any of the five indicators.

1 For the PPC, following the intervention, the average EG score increased and a significant statistical difference in the range was detected between groups from T1 to T2 ($t = 2.11$, $P = 0.037$). The average EG score remained high even in T3, but no significant difference was seen.
2 For the HADS-D, the average score did not change in the CG, but decreased for the EG after the intervention, indicating a decrease of depressive symptoms. However, no significant statistical difference in range was detected between groups. A within-group comparison revealed a significant drop in the EG from T1 to T2 ($t = 2.43$, $P = 0.019$), but because the average EG score for T3 returned somewhat to the original score, no significant difference was observed.
3 For the HADS-A, the average score showed no large changes in either group, and no significant difference in either group when comparing the range between groups. A HADS-A score of 8 or higher was classified as suspicious. Therefore, two subgroups (EG, $n = 13$; CG, $n = 13$) scoring 8 or higher were analyzed. The Mann–Whitney *U*-test was conducted to compare groups. In a comparison of range from T1 to T2, the anxiety score for the EG declined significantly more ($U = 41.50$, $P = 0.026$) than the CG.
4 For the MSAC, the "hot flash" symptom grew more pronounced in T2 and T3 in the CG, and an analysis of range from T1 to T3 revealed a significant difference between groups ($t = 2.89$, $P = 0.005$). Also, the symptom "sweats easily" grew stronger for many women in the CG from T2 to T3. There was a significant statistical difference in range seen between groups from T2 to T3, and from T1 to T3 ($t = 2.83$, $P = 0.006$; $t = 3.08$, $P = 0.003$; respectively).

For the EG, the "sweats easily" symptom greatly decreased. No other symptoms showed a significant difference.

No difference was noted in the scores or ranges for the seven stress responses related to menopausal symptoms: (i) difficulty sleeping; (ii) waking up in the middle of the night; (iii) easily irritated; (iv) always anxious; (v) worrying over small things; (vi) easily brood over things; and (vii) become depressed, lethargic, and easily tired. Correlation coefficients were calculated among measurements for symptom relief. Total scores for seven MSAC symptoms were used. There was a negative correlation among HADS-A, HADS-D, and MSAC for PPC ($r = -0.27$~-0.40, $P < 0.05$). MSAC, HADS-A, and HADS-D had a somewhat strong correlation ($r = 0.62$, 0.55, $P < 0.01$, respectively).

Program assessment

The SM program was given extremely high marks. It was assessed at an average of 88 points on ease of understanding, satisfaction, usefulness, enjoyment, and self-efficacy: lectures (83.3–90.0 points), group discussions (81.5–90.8 points), and hands-on learning (83.6–93.4 points). No differences were seen in assessments for method of presentation. The three methods of presentation had synergistic results and are interpreted as functioning in an integrative manner. In the EG, most women also made changes in their health management actions. There were 12 who changed their eating habits and nine who started to exercise, a greater number than in the CG.

DISCUSSION

Program effectiveness

Primary hypothesis: Ability to cope with stress

The increase in knowledge resulting from this study is identical to existing intervention studies (Liao & Hunter, 1998; Hunter & O'Dea, 1999). The group education was particularly effective. This outcome is identical to Winzenberg *et al.* (2005) who examined differences in educational methods. Incorporating one's own experiences into a discussion of the information provided a deeper understanding that can be translated into one's own knowledge, suggesting that education gained through group discussion increases effectiveness. In addition, based on the andragogy assumptions put forth by Knowles (Merrian & Caffarella, 2005), the SM program conducted discussions regarding the knowledge provided that compared and checked against the women's own experiences while looking back on their own living conditions. It is believed that even greater educational effectiveness was displayed through discussions based on andragogy. Care programs are effective when educational views are utilized to encourage learning effectiveness, rather than simply providing information. There was a propensity toward an increase in CFS from T2 to T3. After an intervention begins, it is expected that time is needed before changes manifest in the attribute of flexibility to cope. A long period is likely necessary before women are able to flexibly apply coping skills in accordance with circumstances. Evaluation of the ability to control of the situation is similar to Bandura's self-efficacy (Lazarus & Folkman, 1984). As efficacy expectancies increase and the person judges his or her resources more adequately for satisfying task demands, the relationship is appraised as holding the

potential for more control and therefore as less threatening (Lazarus & Folkman, 1984). The most effective way to create a strong sense of efficacy is through the control experience; successful experience creates a stronger belief in personal efficacy (Bandura, 1995). It takes numerous successful experiences to become more self-aware. Thus, a long-term follow up is required. The SCS-m measures manageability understood as coping with life events. Menopausal stress in this study was treated as a mix of life events and daily problems. Examples and discussion themes that used daily problems were constructed in the SM program, suggesting the possibility of improving the ability to cope with daily problems, although the program's approach to life events was insufficient. Furthermore, it was thought that positive changes in ability to cope with daily problems could be expected at the 1 month follow up. If women could successfully cope with daily problems, then at some point they would also be able to handle life events, but quite a long follow-up period is required to confirm this change. Also, the coping ability addressed in the SM program referred to "a response pattern temporarily produced in a specific situation", but manageability includes "a uniform responsive style that exists at any time" (Antonovsky, 1979). The SM program and outcome indicators did not address this.

It is believed that the foundation for stress coping was strengthened because knowledge about menopause and coping with stress increased, and the schema for menopause led to modifications. However, those outcomes were not clearly demonstrated in indicators that questioned actual coping skills. Therefore, although it is difficult to state that the skills to cope with stress improved, the outcomes indicated the possibility of improving competency.

Secondary hypothesis: Psychological well-being

The SM program allowed participants to learn from like individuals, provided participants with numerous opportunities to speak up, and made it easier for them to feel that they were growing. Therefore, the SM program is surmised to have had a positive effect on personal growth. The SM program allowed participants to objectively reexamine themselves and encouraged self-acceptance. It included content where participants asked themselves questions such as "what are my stressors?" There are many changes in roles during menopause: women face erratic symptoms, their sense of control deteriorates, and they more easily experience identity diffusion. A reexamination of self through the program is believed to be effective for these menopausal women.

The SM program based on the cognitive–behavioral therapy method resulted in the demonstration of cognitive modifiability, but did not extend to behavior modification. However, behavior modification can be anticipated as an outcome of cognitive modifiability. While only a small fraction of the outcome of cognitive–behavioral therapy on menopause symptoms has been studied, the possibility of outcomes has been indicated (Alder *et al.*, 2006). The outcomes of this study also point to the expectation of further possibilities related to cognitive–behavioral therapy.

Group discussion is surmised to have had a large impact on these results, which are identical to Vinogradov & Yalom (2003) group psychotherapy outcomes. The SM program is also thought to have encouraged a realization of the universality of their experience, a cathartic effect, and the discovery that there is value in the present even when directly confronting a difficult reality. Reaction to change differs for each individual, but in some instances it can be accompanied by negative feelings, such as denial, confusion, regret, and anxiety (Shindo, 2001). When trying to identify with and deepen understanding of menopause, it was difficult to eliminate the aforementioned emotions through self-study. The SM program offered the chance to share negative feelings with other women undergoing a similar experience and thus diminishing the intensity.

Almost no studies exist related to menopause that measure happiness in the outcome indicators. Only one study (Ueda, 2004) measured level of satisfaction with life, but it did not show significant effects. The fact that this study showed effectiveness in HS is highly significant. The SM program relieved feelings of loneliness through discussions with others undergoing the same experience. This increased the number of opportunities for the women to feel a sense of liberation and led to heightened feelings of happiness. Also, menopausal women tend to lose sight of their role and have a reduced sense of self-esteem (Yamada, 1999). Part of the SM program asks participants to "praise themselves". They then received positive feedback from others in the areas in which they felt inadequate, giving them a conscious experience of success. The program is thought to have led to what Kan (2005) called "the happiness of doing" and "the happiness of being". The happiness of being is deeply rooted in the Eastern culture, and its relationship to health has been indicated (Kan, 2005). This study measured broad-based feelings of happiness, but the effects on feelings of happiness should be examined in more detail in the future.

Secondary hypothesis: Relief of symptoms

Although there were no specific symptom improvements, there was an enhanced sense of well-being, which is a comprehensive barometer.

In existing research on menopausal treatments, improvements in depression and anxiety symptoms were validated in a long-term, 6–10 week, composite program (Alder *et al.*, 2006). The outcomes of this research, which showed a trend toward effectiveness in a short period, should be regarded as important. These outcomes were gained because the SM program incorporated a cognitive approach, strengthened the recognition of self, reduced feelings of isolation, boosted self-worth, and improved symptoms of depression. Participants also acquired a sense of ease from knowing they were not alone, and were able to look toward the future through discussions about similar experiences. This enabled them to handle uncertain circumstances and relieve anxiety. Although screening for serious depression and anxiety symptoms is necessary, the SM program could be offered to patients who are exhibiting mild symptoms.

An effect was seen on vasomotor symptoms of menopause. Even though participants thought that vasomotor symptoms were outside of their control, a greater awareness of symptoms resulted in fewer hot flashes and sweats in the EG.

Menopausal symptoms depend on a variety of factors and can wildly vary within a single day. It is thought that this uncertainty impacted the assessment of symptom alleviation. This kind of symptom control is extremely difficult, although several long-term studies implementing 10–12 week programs using drug therapy observed improvements in menopausal symptoms (Granz *et al.*, 2000; Rotem *et al.*, 2005; Ueda, 2004). However, the fact that this study indicated symptom awareness can be potentially effective, shows a new direction for care.

Program effectiveness

The SM program aimed to improve coping ability from the stress perspective without focusing on relief of symptoms and continuation of health actions. This viewpoint has not been addressed in previous research on menopause care, and was a novel approach under the broad concept of stress in accordance with the complicated phenomenon of menopause. In addition, because a focus on improving coping skills through an educational approach without the goal of stress reduction had not been previously undertaken in stress research, it was implemented as a new endeavor. Though the outcomes of this research are not as strong as those from a long-term program that aims for behavior modification, or a treatment program utilizing tools such as drugs or acupuncture, the fact that the existence of a significant possibility for cognitive change was indicated is an important discovery, given that establishing outcomes is difficult through a short-term intervention targeting menopausal women with a tendency toward emotional imbalance. An improvement in psychological well-being was also demonstrated and the possibility for other outcomes indicated, allowing the suggestion that it is an effective form of care. Therefore, this research is significant in that a new directionality was shown in the researches of menopausal care and stress. Furthermore, it appears that focusing on the ability to cope with stress, such as stress management, is appropriate not only for menopause, but also for phenomena where individual differences are great and specific health behaviors are difficult to present. It can be considered as a demonstration of new possibilities.

The program was easily accepted with a low dropout rate and high subjective assessment. Moreover, the fact that it encouraged constant reconciliation to adapt to individual circumstances while offering numerous resources means it was an effective form of care for the menopausal women. The program was highly rated in terms of satisfaction, usefulness, enjoyment, and self-efficacy in regard of the lectures, discussions, and hands-on training. The hands-on training encouraged interaction among fellow participants, likely impacted discussions, and is expected to have synergistic outcomes. Although direct outcomes cannot be established for each intervention method in composite programs such as this, from a practical perspective, the satisfaction of participants should be one of the factors that are focused on. There is a need to give further consideration to the evaluation methods of composite programs, such as whether it is appropriate to measure every intervention or total outcomes, and how to measure synergistic outcomes.

The outcomes suggest the conceptual framework can be validated. However, the causal association between the primary outcome and secondary outcomes was not reviewed and is an issue for further examination.

Implications for health care

It is possible to offer perimenopausal women, who are experiencing a physically and mentally unstable period, a program where members proactively participate, rather than a program where the provider offers leadership. In fact, this style empowers the participants and is expected to improve psychological well-being. No

intervention studies previously existed that focused on stress in menopausal treatment, and the validation of effectiveness through this kind of approach points the way to a new kind of care. Medical care for menopause must build health care from an integrated perspective rather than simply alleviating symptoms. A framework based on dealing with stress is beneficial. This study has clarified specific care and the direction that the role of nursing should take, and the results may contribute to the development of nursing in the medical treatment of perimenopause.

Research limitations and future issues

This study used a non-equivalent control design, weakening external validity and calling into question the interactions of self-selection and changes resulting from time on outcomes. A randomized controlled trial, larger sample size and psychometric development of some indicators are needed to clearly verify program effectiveness. In addition, the program content and presentation method must be further refined.

CONCLUSION

The SM program addresses stress management and can be provided in a variety of settings. It also can be expected to have a synergetic effect when combined with treatment for menopausal disorders, and is anticipated to be effective for women who prefer not to medicate or women who have comparatively minor symptoms. Furthermore, it encourages team care, efficiency in treatment, and contributes to reducing medical fees. To offer this type of health care, however, it would be necessary to ensure medical treatment fees and human resources. Towards that end, issues that verify program effectiveness and effective nursing should be immediately addressed.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTION

Y. I. was responsible for research concept and design, acquisition of subjects and data, analysis and interpretation of data, and preparation of manuscript; H. K. suggested the entire research.

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APPENDIX

Knowledge Test: KT

Place a ○ in the ( ) when a statement below is correct and an × when inappropriate. Answer without looking at information on hand such as data, books, internet, etc.

Q1 ( ) Since women gain weight when they enter menopause, they should be careful of their diet. (M)
Q2 ( ) It is better to eliminate stress. (S)
Q3 ( ) Menopausal symptoms include symptoms caused when the hypothalamus in the brain, called the command center, panics. (M)
Q4 ( ) It is better to take some kind of action even in circumstances where it appears you cannot be in control. (S)
Q5 ( ) Various symptoms appear when the balance of energy, blood, and water circulating within the body is upset.
Q6 ( ) Menopausal stress is not a significant problem since it is not a major stress like disaster or bereavement. (S)

Q7 ( ) The reason menopausal symptoms are different for each woman is related to whether the onset of menstruation is early or late. (M)
Q8 ( ) Swimming, which is whole-body motion, is more effective than walking in the prevention of osteoporosis. (M)
Q9 ( ) Physical reaction to stress is the body's way of trying to protect itself. (S)
Q10 ( ) Menopausal symptoms usually go away in 3 years. (M)
Q11 ( ) Praising yourself becomes a source of personal energy. (S)
Q12 ( ) It is not good to express your feelings because it encourages becoming emotional. (S)
Q13 ( ) Acupuncture points are pressed when inhaling. (S)
Q14 ( ) The only symptoms of menopause are hot flashes and sweating. (M)
Q15 ( ) Hormone replacement therapy has rejuvenating effects. (M)
M, menopause item; S, stress management.

Coping Flexibility Scale: CFS

Choose an answer on the right concerning ways to cope with stress. Circle the appropriate number that indicates the extent to which each item applies to you.

		Never	Almost Never	Occasionally true	Sometimes true	Relatively true	Always	Subscale
1	When something difficult happens, I consider whether it is something I can cope with myself.	0	1	2	3	4	5	A
2	I can flexibly cope with things that happen around me.	0	1	2	3	4	5	B
3	Even though something seems like it can be immediately handled, it takes time before I realize that "it is impossible to cope with myself".	0	1	2	3	4	5	A
4	To solve problems I think I can cope with on my own, I consider them from different angles.	0	1	2	3	4	5	B
5	I think deeply about this or that, even when it comes to things that are impossible to handle myself.	0	1	2	3	4	5	A
6	There are times when I take on too much and regret it later.	0	1	2	3	4	5	A
7	I can adapt to my surroundings and make the best use of my skills.	0	1	2	3	4	5	B

Coping Flexibility Scale: CFS Continued

		Never	Almost Never	Occasionally true	Sometimes true	Relatively true	Always	Subscale
8	When something does not go well, I try a different approach.	0	1	2	3	4	5	B
9	When something bad happens, I think that it's all my fault.	0	1	2	3	4	5	A
11	At times I become physically exhausted even though I do not think I am overdoing things.	0	1	2	3	4	5	A
12	I can cope in my own way while skillfully relating to my surroundings.	0	1	2	3	4	5	B
13	I often think that my efforts go unrewarded.	0	1	2	3	4	5	A

A, ability to judge; B, ability to flexibly respond.

Perception of Physical Condition Scale (PPC), Happiness Scale (HS)

The following inquires about your current perception of physical condition and feeling of happiness. Without thinking too deeply, indicate how you feel by marking an × to show the extent of your feelings.

Please mark an × to show how you feel now about your physical condition.

Extremely good physical condition — extremely bad physical condition

Please mark an × to show your feeling of happiness right now.

Extremely happy — . . . extremely unhappy

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RESEARCH ARTICLE Open Access

Current nursing practice for patients on oral chemotherapy: a multicenter survey in Japan

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Abstract

Background: With a paradigm shift toward a chronic care model in cancer, the issue of adherence is becoming increasingly important in oncology.

Methods: We mailed two self-reported surveys on current nursing practices for patients on oral chemotherapy to all 309 designated cancer centers and 141 large general hospitals in Japan. The first survey was based on a nurse-based questionnaire containing 40 items concerning nurse's characteristics, nurse staffing at workplace, general nursing care for new patients on oral chemotherapy and those with refilled prescriptions, follow-up, and system-based approach. The second survey was based on a patient-based questionnaire containing 10 items about patient characteristics and adherence-related nursing practice for 249 patients taking oral chemotherapy of 903 systematically sampled. We used multivariate logistic regression to identify factors that were associated with adherence-related nursing practices.

Results: A total of 62 nurses (mean age: 41.5 years) from 62 hospitals who consented participated in the both nurse-based survey and patient-based survey about 249 patients. The results of nurse-based survey indicated that practices varied, but nurses were less likely to ask adherence-related questions of patients with refilled prescriptions than of new patients. The results of patient-based survey found that questions on side effects, discussions about barriers to achieving balance between treatment and daily life activities, and medication management were all significantly related to the question about unused medicines. Logistic regression revealed that adherence-related nursing practices were associated with the nurse's background, type of treatment, and healthcare system-related factors. Patient orientation on oral chemotherapy, interdisciplinary learning, and having a system-based approach for detecting prescription errors were identified as healthcare system-related factors.

Conclusions: A more systematic approach must be developed to ensure patients receive safe and effective oral chemotherapy, while nurses should play significant roles in patient education and monitoring.

Keywords: Oral chemotherapy, Medication adherence, Compliance, Interdisciplinary care, Medication management

Background

Recent progress in treatment of cancer has accelerated an expansion of the development of oral anticancer agents [1]. The availability of oral anticancer agents has a major impact on cancer care. In oral chemotherapy, some of the traditional responsibilities of healthcare providers have shifted to patients [2]. Despite increased patient's responsibility for self-management, oral therapy is preferred by patients mainly because of no need for clinic visits, no needle placement, and reduced cost [3-5].

As a growing number of patients are choosing oral chemotherapy over intravenous administration [6], the issue of adherence is becoming increasingly important in oncology [7-9]. Traditionally, adherence was not a major problem in cancer patients compared to other chronic disease [10] because cancer treatment were usually provided in acute care settings, and intravenous chemotherapy has been strictly controlled at outpatient clinic by healthcare providers. The convenience of oral medication has a flip side—serious complications and fatal outcomes. Oral chemotherapy is cost effective, if it is taken as prescribed [11]. However, if patients are non-adherent to medication, the cost burden of unused medicines is substantial.

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The terms "adherence" and "compliance" are used interchaneably, but "adherence" is generally preferred to "compliance" because "compliance" suggests that patient is a passive follower of the doctor's orders, and "adherence" implies that the treatment plan is based on a therapeutic alliance between the patient and the healthcare provider [12]. Optimal adherence is achieved "if no doses are missed, no extra doses are taken, and no doses are taken in the wrong quantity or at the wrong time" [10]. In general, a patient is considered to be adherent if he or she has taken 80% of a prescribed medication [1].

A number of factors are interrelated with medication adherence. There are three levels of barriers to adherence: patient, healthcare provider, and healthcare system levels [12]. The patient-level factors include health beliefs and socioeconomic factors, while communication and the complexity of the regimen are regarded as healthcare-provider factors [8]. Healthcare system issues include duration of treatment follow-up visits, prescribing errors, and conflicting information regarding the consequences of non-adherence [3].

To overcome barriers to patient adherence, there is no single standard intervention [13]. However, multidisciplinary and multimodal strategies are considered as effective [1]. Also, the literature places a primary emphasis on patient education [4,8,14,15]. Education should be tailored for individual patients, and patients generally prefer direct interaction with healthcare providers [4]. Other suggested interventions include systematic monitoring of patient pill taking, and use of pill diaries and pill counting [10].

The primary roles of oncology nurses in patients on oral chemotherapy include patient education, communication, symptom management, and proactive follow-up [16]. Their skills help patients with side-effect management and handling medications at home, and patient adherence to medication can be improved by follow-up care [5]. The ASCO/ONS chemotherapy administration safety standards including oral agents have been established in 2013 [7]. A national web-based survey on current nursing practice patterns for oral chemotherapy in the United States reported that only half of the nurses worked in practices with specific policies, procedures, and resources for patients on oral chemotherapy, and found erratic procedures and inadequate interdisciplinary communication in many practices [17]. Additional research is needed to determine the best practice in patient education, monitoring, and safety management, and furthermore, to identify the gaps that may exist between the nurses' roles and practice [16,17].

We conducted a multicenter cross-sectional questionnaire survey in designated cancer centers and at large general hospitals in Japan. The goal was to determine a baseline of nursing practices for oral chemotherapy in order to improve medication adherence.

Methods

Design

A cross-sectional questionnaire survey was designed and disseminated to 309 cancer centers designated by the Ministry of Health, Labour and Welfare, and 141 general hospitals with more than 300 beds in Japan.

Participants and procedures

Designated cancer centers were identified using the list of healthcare institutions in 2012 from the Ministry of Health, Labour and Welfare. In November 2012, surveys were mailed to all 309 designated cancer centers as well as to 141 general hospitals that were geographically stratified and randomly selected from all general hospitals with more than 300 beds in Japan. Using systematic sampling, every 10th patient was selected from a list of patients who had visited the chemotherapy clinic in participating hospitals during the week before the survey.

One nurse, who met the following inclusion criteria, was selected from each hospital: (1) more than three years of experience in chemotherapy clinic; (2) experience as a nursing leader in a chemotherapy clinic; and (3) willing to participate in the study.

An initial invitation to take part in the survey was sent to the nursing directors of 450 hospitals. Those who did not reply received phone calls reminding them about the survey; those who elected not to participate were questioned about their reasons. Those who agreed to participate completed the questionnaires on oral and intravenous chemotherapy.

Questionnaire

The study consists of two surveys: nurse-based and patient-based questionnaires. The nurse-based questionnaire developed for this study was based on a previous study [18] and literature review [4,16,19,20] to determine nursing practice in patients on oral chemotherapy. It consists of a total of 40 items concerning nurse's characteristics such as age, experience of nursing and oral chemotherapy (8 items), nurse staffing at workplace (4 items), general nursing care for patients who started oral chemotherapy and those with refilled prescriptions including follow-up (20 items), and details of system-based approach such as interdisciplinary learning opportunities and prescription error prevention, and prescription error prevention (8 items). Regarding general nursing care and system-based approach, the respondents answer questions "Yes" or "No".

A 10-item patient-based questionnaire includes demographic and clinical characteristics of patient (5 items: age, gender, type of cancer, and primary or recurrent treatment) and "Yes" or "No" questions about adherence-related nursing practice for individual patients (5 items: side effects, balance between treatment and daily life

activities, self-management, nurse's role of monitoring medication management, and unused medicines). Nurses in charge at chemotherapy clinics, who replied to the nurse-based questionnaire, fulfilled this patient-based questionnaire.

Ethical considerations

The study procedures were approved by the Institutional Review Board at Keio University (Approval Number: No 198, 2012). In addition, the participating hospitals individually obtained study approval if necessary. We obtained informed consent from all participating hospitals, and anonymity of responses was ensured. We obtained consent from the nurses and patients.

Statistical analysis

To assess differences between the question on unused medicine and nursing practices (addressing side effects, the balance between treatment and daily life, medication management and monitoring), we used Fisher's exact test. A multivariate logistic regression was used to identify factors associated with adherence-related nursing practices (the question on unused medicine). Explanatory variables were selected for inclusion in the model using the stepwise selection procedure. The significance level was set at 0.05.

Results

Of the 450 hospitals providing ambulatory chemotherapy, 388 declined to participate in the study. Reasons for non-participation included refusal or non-response of person in charge (the nursing director forwarded the questionnaire to the nurse in the chemotherapy clinic but did not receive a reply) (n = 257), lack of time or staffing (n = 58), prior participation in other surveys (n = 83), practical difficulties (n = 40), and other (n = 66). A total of 62 hospitals consented, and 62 nurses in those hospitals participated in the survey. Of 930 patients who were systematically sampled, 249 had received oral chemotherapy. Therefore, 62 nurses fulfilled the patient-based survey about these 249 patients who those nurses cared for.

Mean age of the nurse respondents was 41.5 (SD 6.4) years. Mean years of nursing and chemotherapy experience were 19.4 (SD 6.4) and 11.6 (SD 5.9), respectively. Most of the nurses (72.6%) were oncology certified nurses working at chemotherapy or outpatient clinics (Table 1).

Table 1 Nurse characteristics

	Mean	SD
Age	41.5	6.4
Years of nursing experience	19.4	6.4
Years of chemotherapy experience	11.6	5.9
Educational Level	**n**	**%**
Junior college and nursing school	56	90.3
≧Bachelor's degree	6	9.7
Job title		
Nurse administrator	5	8.1
Senior charge nurse	27	43.5
Staff nurse	30	48.4
Certification of oncology nurse		
Yes	45	72.6
No	17	27.4
Practice setting		
Chemotherapy clinic	49	79.0
Outpatient department	13	21.0

n = 62.

Nurse-based survey

Table 2 shows nurses' perceptions of nursing processes for oral chemotherapy. For new patients receiving oral chemotherapy, more than 90% of nurses reported that they asked their patients about emergency contacts, side effects, and family/friend support, and provided patient education on medication. In contrast, only 30.6% of nurses asked whether patients were confident about managing their medication. Patient understanding (58.1%) and medication schedule (64.5%) were rated lower than expected. Nurses were less likely to ask adherence-related questions of patients with refilled prescriptions than of new patients. Regarding unused doses of anticancer agents, 35.5% of nurses reported that they did not confirm the number of unused doses when patients had refilled prescriptions.

System-based approaches are shown in Table 3. While 40.3% of nurses provided orientation on oral chemotherapy to patients before initiation of therapy, 32.3% of hospitals reported offering interdisciplinary learning opportunities on oral chemotherapy, and 43.5% had a system-based approach for detecting prescription errors of oral anticancer agents. Only one hospital offered a telephone follow-up for patients on oral chemotherapy.

Patient-based survey

Mean number of chemotherapy patients per day was 23.9 (SD 20.22).

Demographic and clinical characteristics of the 249 chemotherapy patients are presented in Table 4. A combination of intravenous and oral chemotherapy was administered to 222 patients (89.2%). More than half of patients, both male and female, were over 65 years of age. Gastrointestinal cancer was by far the most common (69.9%), and 75.4% of treatments were for recurrences.

Table 5 shows the responses of nurses to the questions on nursing practices related to medication adherence for the 249 patients on oral chemotherapy. Questions on

Table 2 Nurse-based survey: nurses' perceptions on nursing processes

	Yes		No	
	n	%	n	%
New patients on oral chemotherapy				
Medication Schedule				
1. Do you confirm the understanding of new patients by letting them explain their medication schedule to you?	40	64.5	22	35.5
Education				
2. If the patient does not fully understand the medication protocol, do you give them information about the medication?	58	93.5	4	6.5
Side Effects				
3. Do you check whether the patient understands common side effects?	51	82.3	11	17.7
Emergency Contact				
4. Do you check whether the patient knows the emergency contact?	56	90.3	6	9.7
Management of Side Effects				
5. Do you talk about practical coping methods for side effects with the patient?	58	93.5	4	6.5
Barriers to Adherence (Physical)				
6. Do you ask the patient about physical symptoms (e.g., feeling of numbness in hands/legs) as barriers to taking the medication?	56	90.3	6	9.7
Patient Confidence in Medication Management				
7. Do you ask the patient how confident they are about managing their medication?	19	30.6	43	69.4
Balance Between Treatment and Daily Life Activities				
8. Do you talk to the patient about potential barriers to achieving balance between treatment and daily activities?	39	62.9	23	37.1
Support				
9. Do you offer support to the patient to encourage him/her or to ease anxiety?	58	93.5	4	6.5
Family/Friend Support				
10. Do you ask the patient whether he/she has a supportive family/friend?	58	93.5	4	6.5
Financial Burden				
11. Do you ask the patient whether he/she feels financially burdened?	43	69.4	19	30.6
Social Resources				
12. Do you provide information on social resources to the patient if financial problems are a barrier to treatment?	53	85.5	9	14.5
Patient Understanding				
13. Do you ask the patient about his/her understanding of oral chemotherapy (e.g., effectiveness and preference)?	36	58.1	26	41.9
Patients with Refilled Prescriptions				
Patient's Knowledge				
1. Do you ask the patient about how he/she currently manages his/her medication schedule?	44	71.0	18	29.0
Skipping				
2. Do you ask the patient whether he/she ever skips a dose of his/her oral anticancer medication?	55	88.7	7	11.3
Non-compliance				
3. Do you ask the patient whether he/she has unused medicines?	40	64.5	22	35.5
Reasons for Non-compliance				
4. Do you ask the patient about his/her reasons for not following the physician's instructions?	52	83.9	10	16.1
Support for Resolution				
5. Do you talk about problem-solving methods in regards to medication management?	46	74.2	16	25.8
Report of Skipping to Healthcare Professionals				
6. Do you ask the patient whether he/she tells his/her healthcare providers when he/she skips a dose of medicine?	48	77.4	14	22.6
Support for Management of Side Effects				
7. Do you provide the patient with further advice about coping methods for side effects?	47	75.8	15	24.2

(n=62).

Table 3 Nurse-based survey: system-based approach

	Yes		No	
	n	%	n	%
Patient Orientation				
1. Do you provide orientation to new patients on oral chemotherapy?	25	40.3	37	59.7
Telephone Follow-up				
2. Is it routine to follow up with patients by telephone after they have received their first course of oral chemotherapy?	1	1.6	61	98.4
Emergency Contact				
3. Are patients on oral chemotherapy given an emergency contact number (including for nights/holidays)?	55	88.7	7	11.3
Patient Consultation and Education				
4. Is there any process in place to provide consultation and education to patients on oral chemotherapy?	28	45.2	34	54.8
Education for Emergency Nurses				
5. Does your institution offer learning opportunities for nurses who provide care for patients on oral chemotherapy in the emergency department?	7	11.3	55	88.7
Collaboration Between Chemotherapy and Emergency Nurses				
6. Is there any collaboration system in place for the sharing of information on a patient's emergency visit between chemotherapy and emergency nurses?	15	24.2	47	75.8
Interdisciplinary Learning				
7. Do you have any interdisciplinary learning opportunities regarding oral chemotherapy?	20	32.3	42	67.7
System-based Approach for Detecting Prescription Errors				
8. Is there any system-based approach for detecting prescription errors?	27	43.5	35	56.5

n=62.

Table 4 Patient characteristics

Gender	**n**	**%**
Male	142	57.0
Female	107	43.0
Age		
<65	115	46.2
≧65	133	53.4
Unknown	1	0.4
Type of Cancer		
Breast cancer	30	12.0
Gastrointestinal cancer	174	69.9
Lung cancer	16	6.4
Others (e.g., hematological, uterine and ovary cancer)	26	10.4
Unknown	3	1.2
Purpose of Treatment		
Primary treatment	61	24.5
Recurrence treatment	188	75.5
Type of Treatment		
Combination of oral and intravenous chemotherapy	222	89.2
Only oral chemotherapy	22	8.8
Unknown	5	2.0

n=249.

side effects, discussions about barriers to achieving balance between treatment and daily life activities, and medication management were all significantly related to the question about unused medicines.

Factors predicting adherence-related nursing practices

Given that the question on unused medicines could be used as a kind of proxy for adherence-related nursing practices, a multivariable logistic regression model was created. The results of the logistic regression analysis are shown in Table 6. Nurses' experience, education and qualifications, the combination of oral and intravenous treatment, patient orientation on oral chemotherapy, interdisciplinary learning, and having a system-based approach for detecting prescription errors remained significant. The factors explained 40.3% of the variance in the model.

Discussion

This is the first report on current nursing practices for patients receiving oral chemotherapy in Japan. There was great variation in practices across the nation. The survey results demonstrated that a majority of the cancer centers and large hospitals in Japan are responding to the emerging needs of oral chemotherapy in conventional care systems, with only a minority incorporating systems specific to oral chemotherapy. Adherence-related nursing practices were associated with the nurse's background, the type of treatment, and healthcare system-related factors.

Table 5 Patient-based survey: unused medicines and other adherence-related questions (n = 249)

			Asking about unused medicines		P value
			Yes	No	
Do you talk about side effects with the patient?	Yes	214 (85.9%)	108 (98.2%)	106 (76.3%)	<0.001
	No	35 (14.1%)	2 (1.8%)	33 (23.3%)	
Do you talk about barriers to balance between treatment and daily life activities with the patient?	Yes	181 (72.7%)	101 (91.8%)	80 (57.6%)	<0.001
	No	68 (27.3%)	9 (13.2%)	59 (42.4%)	
Do you think that this patient manages his/her medication (oral chemotherapy) at home?	Yes	230 (92.4%)	105 (95.5%)	125 (89.9%)	0.148
	No	19 (7.6%)	5 (4.5%)	14 (10.2%)	
Do you think that monitoring medication management (oral chemotherapy) for this patient is your role?	Yes	202 (81.1%)	104 (94.5%)	98 (70.5%)	<0.001
	No	47 (18.9%)	6 (5.5%)	41 (29.5%)	

Fisher's exact test.

First, nurses should be aware of their role in monitoring the medication management of patients receiving oral chemotherapy. In the present study, nearly 20% of nurses were not aware of their monitoring role. Although nurses educate patients about intravenous chemotherapy, few are involved in oral chemotherapy [5]. As understanding the clinical importance of oral chemotherapy is reported to encourage adherence in 90% of patients [3], patient should be made well aware of both the benefits of medication and the risks of non-adherence [14]. Patient education is the cornerstone of successful oral chemotherapy [8,15]. A feasibility pilot study of new medication adherence interventions suggests that nurses have an important role to play in education, monitoring, and follow-up [21]. A strong patient-nurse relationship is fundamental to individualized education, leading to successful management of and adherence to treatment regimens [4].

Table 6 Factors predicting adherence-related nursing practices by logistic regression

	Odds ratio (95% CI)		p-value
Nurse factor			
Years of experience	1	-	.008
6-10 (years)	4.209	(1.240 - 14.284)	.021
<10	1.028	(0.320 - 3.300)	.963
Education University	.016	(0.003 - 0.073)	<.001
Oncology certified nurse	5.786	(2.337 - 14.324)	<.001
Patient factor			
Oral + IV combination therapy	.240	(0.070 - 0.828)	.024
System factor			
Patient orientation	3.348	(1.633 - 6.861)	.001
Interdisciplinary learning	2.997	(1.469 - 6.114)	.003
System-based approach for detecting prescription errors	3.671	(1.865 - 7.226)	<.001

Note. CI = confidence interval.
Variables entered: years of experience, education, certification; age, type of cancer, regimen; patient orientation, telephone follow-up, emergency contact, patient consultation and education, and education for emergency nurse, interdisciplinary, and system-based approach for detecting prescription errors.

The nurses were unlikely to ask how patients understood the therapy and how they managed medication at home, and very few nurses asked whether patients were confident in medication management. Patients may not be confident in medication management, but nurses do not know how they feel about isolation. At least, nurses should ask patients whether they are taking their medication as prescribed. Information the nurse could gain from this simple question is worth to ask. The answer implies patient adherence to medication. Recently, nurses' contact with patients is decreasing [18]. It is because oral chemotherapy is often administered outside of controlled settings [7], and patients usually receive medication information directly from the oncologist or pharmacist without nursing support [16]. Regular contact with a single nurse helps promote patients' trust [22], and facilitates identification of concerns about treatment and daily life activities. The patient-nurse relationship and collaboration of the healthcare team are essential components of patient adherence [23]. A proactive attitude on the part of the nurse is a key in caring for patients on oral chemotherapy.

Healthcare-system related factors were predictors of adherence-related nursing practices in this study. Such factors included patient orientation with an overview of oral chemotherapy presented by a nurse, interdisciplinary learning opportunities, and a system-based approach for detecting prescription errors. As oral chemotherapy becomes more common, more patients will require education. Patient orientation for oral chemotherapy should be systematically implemented for every patient who initiates this type of therapy. Patient education about the disease, treatment, and symptom management is the role of the oncology nurse [24], and staffing for orientation is important to ensure patients receive the necessary education.

Currently, healthcare providers have little ability to directly manage oral chemotherapy care [25]. There is

great value in creating an efficient and effective interdisciplinary team among healthcare providers in cancer care [26]. Interdisciplinary learning opportunities remind team members of their roles, integrate professional knowledge, and facilitate collective work [27].

Regarding prescription errors, intravenous chemotherapy is commonly double-checked or triple-checked by multiple staff in controlled settings. The safety issues in oral chemotherapy are just important as those in intravenous chemotherapy [2], however, the safe delivery of oral chemotherapy may depend on the competency of those dispensing the medication [7]. Including a set routine in an organization's safety infrastructure can raise the awareness of healthcare providers on safety and monitoring of administration of oral anticancer agents. Institutional safety infrastructure is critical for favourable clinical outcomes [15].

In the present study, nurses asked about adherence to medication regimens more frequently when patients were on oral chemotherapy alone, rather than on combined intravenous and oral chemotherapy. This may have been in part because nurses must focus on strict standards in administering intravenous chemotherapy, and therefore might not have the time to ask about oral medication. Adherence is not only an issue for patients new to oral chemotherapy, but also for those with refilled prescriptions [28]. As shown in the results of the present study, nurses are less likely to monitor medications of patients with refilled prescriptions. Cancer patients tend to undergo long-term treatment, and therefore the concept of follow-up, keeping track of the condition of cancer patients, is important. Shared accountability among multiple providers in cancer care makes individual accountability blur. In addition to individual commitment to care, major improvement requires coherent strategies of the organization.

There are a number of limitations to the present study. Systematic sampling is vulnerable to periodicities which might lead to bias. Very few hospitals approved the survey because of strict regulations on patient data. We confirmed that all hospitals received invitations to participate in the survey, but could not reach the person in charge at all the hospitals we approached. Thus, low response rate may have produced a bias if the replies from respondents were not representative of the national sample. The present study relied on the nurses' response to the questionnaires. We did not measure actual patient adherence to medication regimens. This survey focused on chemotherapy clinics; outpatient and primary care settings were not included. Therefore, the results of the survey do not reflect the overall picture of oral chemotherapy treatment. The results of the logistic regression suggested that nurses with higher education were unlikely to ask about unused medicines, which is difficult to explain; however, there were only 6 nurses who had educational backgrounds higher than university. This small number might have produced the unexpected result.

Conclusions

A multicenter cross-sectional survey revealed that adherence-related nursing practices were associated with the nurse's background, type of treatment, and healthcare system-related factors, including patient orientation on oral chemotherapy, interdisciplinary learning, and having a system-based approach for detecting prescription errors. With the increase of oral chemotherapy, a new model of patient care is required. A more systematic approach should be developed to ensure patients receive safe and effective oral chemotherapy, while nurses should play significant roles in patient education and monitoring.

Further studies are needed to develop an organized system of care in which nurses proactively support patients in managing safe and effective oral chemotherapy and improve medication adherence with coordination among healthcare providers.

Competing interests

All authors declare that they have no competing interest.

Authors' contributions

HK and KY[1] designed the study, developed the methodology, collected the data, performed the analysis, and wrote the manuscript. KY[2] provided his perspective regarding the study design and performed statistical analyses as a clinical epidemiologist. All authors read and approved the final manuscript.

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The Power of nursing: Guiding patients through a journey of uncertainty

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Keywords:
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A B S T R A C T

Purpose: The objective of this qualitative study was to understand the experiences of oncology nurses in patient counseling and support services in the ambulatory care setting.
Methods and sample: A qualitative study was conducted using grounded theory methods. Data were generated through four focus group interviews with 21 oncology nurses currently providing counseling and support services for cancer patients in Japan. The content was analyzed based on a constant comparison approach.
Results: The power of nursing was identified through three themes: connecting with the patient (shared needs); personalized coordination (shared action); and realizing the patient's potential (reassurance). Oncology nurses should guide patients through the uncertain cancer trajectory by identifying patients' true needs based on an established relationship, providing personalized coordination, and developing their potential. Patient-centered care can be provided in non-physical care settings such as counseling and support services.
Conclusions: Our study describes the uniqueness and significance of nursing, and provides insights into realizing the full potential of nurses. This conceptual model can be used as a guide for practice and an educational tool to build professional identity of nurses. Oncology nurses can take a leadership role in enhancing the visibility of the nurses in multidisciplinary environments.

Introduction

Cancer patients take a long journey from diagnosis to treatment and beyond. Since cancer affects not only the body but also the psychological and social status of the patient (Markides, 2011) in myriad ways, there is no single path taken by all cancer patients. The journey is shared between the patient and healthcare professionals, and nurses can provide both care and support to patients throughout their journey (Legg, 2011).

Modern healthcare systems are shifting toward a more patient-centered approach (Pelzang et al., 2010; Jayadevappa and Chhatre, 2011), which is organized around the patient's needs, values, and preferences. In the patient-centered approach, patients are actively involved in their care (Barry and Edgman-Levitan, 2012). The concept of nursing demands that nurses understand the fundamental needs of patients so that nurses can help their patients make their lives as normal and productive as possible (Henderson, 2006). The patient–nurse relationship forms the basis for nursing practice, and non-technical skills or affective aspects of care are important, as well as technical skills and the physical aspects of nursing care (Zamanzadeh et al., 2010). A partnership in nursing care is an essential part of patient-centered care, in which patients and nurses work together on decisions about daily life and care (Kvåle and Bondevik, 2008).

Despite the importance of nursing, the nursing presence is increasingly invisible to the patients and to other disciplines (Yagasaki and Komatsu, 2013). The complexity of healthcare systems increases the distance between patients and nurses. In addition, the importance of the oncology nurse's role in multidisciplinary teams is waning (Boyle, 2010). There are discrepancies of multidisciplinary awareness of other healthcare professionals' roles, and the nurse's role is consistently "unseen" among other health professionals (Jenkins et al., 2001).

In Japan, while a greater weight has been placed on diagnosis and treatment in oncology, little psychosocial support is offered

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in routine practice. Accredited cancer treatment facilities (397 accredited cancer treatment facilities as of January 2013) are required to provide patient counseling and support services by trained professionals including nurses and social workers (Ministry of Health, Labour and Welfare, 2008). There is great variation in the psychosocial support of patients in practice in Japan, and assistance in decision-making, psychosocial support and care coordination are commonly provided by exclusive staff separately from routine clinical practice.

With the expansion of these support services to various clinical settings including outpatient clinics and ambulatory chemotherapy centers, a question was posed for oncology nurses: What would be the significance of having oncology nurses provide patient counseling and support services rather than having other healthcare professionals do so? To address this question by making the significance of nursing explicit, we conducted a qualitative study to understand the experiences of oncology nurses in counseling and support services for cancer patients.

Methods

Design

A qualitative study design was used to understand the experiences of oncology nurses in counseling and support services for cancer patients in ambulatory settings. Using a grounded theory approach, we conducted focus group interviews. The grounded theory approach is focused on social processes and generates a theory that is grounded in the realities of the participants' daily-life experiences (Strauss and Cobin, 1990).

A focus group interview helps research participants explore the issues of importance to them in their own vocabulary. Interactions between participants help to identify group norms and cultural values, and group dynamics often address themes that the researchers may not have anticipated (Kitzinger, 1995).

Ethical considerations

This study was approved by the Internal Review Board of Keio University (No.205).

Participants

Eligible participants were certified nurses (palliative care, pain care, chemotherapy, radiation oncology, and breast cancer care) and master-level certified nurse specialists; having nursing counseling and support service experience; and living in the greater Tokyo area.

Recruitment

We conducted a purposive sampling from a list of certified oncology nurses in the Japanese Nursing Association between March 1, 2013 and April 19, 2013. We sent a letter explaining the research purpose, method, and interview venue and date, and a consent form to the eligible oncology nurses. Those who wished to participate in the study responded by a letter or e-mail. We ensured that participation was voluntary, that confidentiality was protected, and that there would be no consequences for refusing to take part in the study. Two focus group interviews were held, but we did not reach theoretical saturation, and we therefore recruited more nurses using the snowball technique. We obtained written informed consent from all participants.

Data collection

A total of four focus group interviews were conducted in a rental meeting room in Tokyo from March to April, 2013. Each group consisted of four to five nurses. The lead author (HK) facilitated all focus group interviews using a semi-structured interview guide which was developed by the authors and covered areas of the participants' experience of counseling for cancer patients. The interview began with general questions about the nurses' background. Then, open-ended questions about their experiences with counseling and support services for all types of cancer patients and their perceived role were covered, and finally questions about the nurses' values and beliefs in nursing care were presented. Another author (KY) took field notes during the interview. The interview guide was adjusted to cover all the interest areas after the first focus group interview.

After two initial focus group interviews, the data did not reach saturation. We used theoretical sampling, and conducted two more interviews. Finally all researchers confirmed that the data reached saturation. The durations of the focus group interviews ranged from 90 to 110 min. All interviews were conducted in Japanese, tape-recorded, and transcribed verbatim. A professional translator translated the themes and quotations to English after the completion of identification of themes and quotations to support themes.

Data analysis

The data were analyzed using grounded theory techniques (Strauss and Cobin, 1990). The focus group interviews were recorded, and transcribed verbatim. The data were analyzed in the following process. Line-by-line cording was conducted with a focus on the purpose of the research: What would be the significance of having oncology nurses provide patient counseling and support services. The data were reread, and the constant comparison method was used along properties and dimensions of categories, and then the meanings were labeled. Subcategories were derived from axial coding, and relating these subcategories led to categories. Categories were identified by relating subcategories. Finally, a core category was derived from relating all categories and subcategories as a selective coding. Regular meetings were held among the research team members to discuss the emerging categories and subcategories, and interpretation.

Rigor

The rigor of the study was confirmed by credibility, dependability, confirmability, and transferability (Guba and Lincoln, 1994). For credibility and dependability, two researchers reviewed the data to determine whether they agreed with the codes and themes identified. We confirmed the data saturation after the fourth group interview. For confirmability, one of the researchers performed an analysis according to the Grounded Theory procedure (Strauss and Cobin, 1990), and another researcher confirmed the results. For transferability, we reviewed whether the results would be applicable to others in similar situations among the researchers.

Findings

Of 30 nurses we approached for the first recruitment, 16 nurses agreed to participate in the study. We obtained data from five more nurses for the second interview by theoretical sampling. A total of 21 oncology nurses who worked for cancer centers, university hospitals or general hospitals participated in the study. The mean number of years of working experience at a counseling or support center was five years.