Effect on Mental Health of a Participatory Intervention to Improve Psychosocial Work Environment: A Cluster Randomized Controlled Trial among Nurses

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Abstract: Effect on Mental Health of a Participatory Intervention to Improve Psychosocial Work Environment: A Cluster Randomized Controlled Trial among Nurses: Ayako Uchiyama, *et al*. **Department of Preventive Medicine and Public Health, Tokyo Medical University, Japan**—**Objectives:** Improvement of psychosocial work environment has proved to be valuable for workers' mental health. However, limited evidence is available for the effectiveness of participatory interventions. The purpose of this study was to investigate the effect on mental health among nurses of a participatory intervention to improve the psychosocial work environment. **Methods:** A cluster randomized controlled trial was conducted in hospital settings. A total of 434 nurses in 24 units were randomly allocated to 11 intervention units (n=183) and 13 control units (n=218). A participatory program was provided to the intervention units for 6 months. Depressive symptoms as mental health status and psychosocial work environment, assessed by the Job Content Questionnaire, the Effort-Reward Imbalance Questionnaire, and the Quality Work Competence questionnaire, were measured before and immediately after the 6-month intervention by a self-administered questionnaire. **Results:** No significant intervention effect was observed for mental health status. However, significant intervention effects were observed in psychosocial work environment aspects, such as Coworker Support (*p*<0.01) and Goals (*p*<0.01), and borderline significance was observed for Job Control (*p*<0.10). **Conclusions:** It is suggested that a 6-month participatory intervention is effective in improving psychosocial work environment, but not mental health, among Japanese nurses.
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Psychosocial work environment has been regarded as one of the risk factors for workers' mental health[1]. Workplace intervention at the organizational level, including the improvement of psychosocial work environment, is identified to be more preferable compared with individual-level intervention because it seems a more preventive, sustaining, and fundamental approach[2–4]. However, literature reviews[5–7] have presented the insignificant effects of such organizational-level interventions, though it has been pointed out that this is mainly due to the limited number of well-designed studies, such as randomized controlled trials[5]. Furthermore, many of those studies do not include descriptions of the implementation processes of interventions, and therefore it is sometimes difficult to fully understand the interventional protocols and contents, which makes it hard to apply them to other workplaces. Therefore, interventional processes as well as outcomes should be assessed to clarify the effectiveness of workplace interventions[8–13].

Recent medical developments have brought an increase in work demands, speed, complexity, and responsibility, causing a high prevalence of psychological distress, burnout, sick leave, and absenteeism among health care workers[14, 15]. Thus, the improvement of psychosocial work environment for healthcare workers is needed. However, limited evidence is available for the effectiveness of organizational-level interventions to reduce occupational stress, specifically focused on the nursing psychosocial work environment. In addition, studies that provide sufficient information on actual implementation or interventional processes are needed[16, 17].

When conducting a workplace intervention, the participation of workers is highly recommended[18–22].

This is because workers are often well aware of the problems and possible solutions in their workplace[23], and thus we focused on a workers' participatory approach to interventional processes.

The purpose of this study was to investigate the effects on mental health among nurses of a participatory intervention aimed at improving the psychosocial work environment in hospital settings using a cluster randomized controlled design.

Subjects and Methods

Study design and setting

This study was a cluster randomized controlled trial to investigate the effect on mental health of a 6-month participatory intervention to improve psychosocial work environment.

Two private, medium-sized (448 and 197 beds) general hospitals in Japan were invited to participate in this study. There were 30 units, including 496 nurses. Three units that were not involved in direct patient care, 3 units consisting of less than or equal to 3 nurses, and nurses who were on sick leave or maternity leave were excluded before randomization. As a result, a total of 434 nurses in 24 units were chosen as the study subjects (Fig. 1). Randomization of the intervention group and the wait list control group was conducted at the unit level after stratifica-

tion by hospital and department nature (outpatient/ inpatient) and carried out by a person who was not involved in the intervention or evaluation. The units were allocated to 11 intervention units and 13 control units.

Measurement and assessment

Mental health status and psychosocial work environment were measured by a self-administered questionnaire method before and immediately after the 6-month intervention. Questionnaires were distributed and collected in sealed envelopes at the workplaces through the subchiefs of each unit. The primary outcome in the present study was set as mental health status and the secondary outcome was psychosocial work environment.

Mental health status was measured using the Japanese version of the Center for Epidemiologic Studies Depression Scale (CES-D)[24, 25]. It assesses depressive symptoms of the previous 7 days and consists of 20 items with a 4-point Likert scale, ranging from 0 (never or rarely) to 3 (usually). The CES-D scores potentially range from 0 to 60, with higher scores indicating high severity of depressive symptoms.

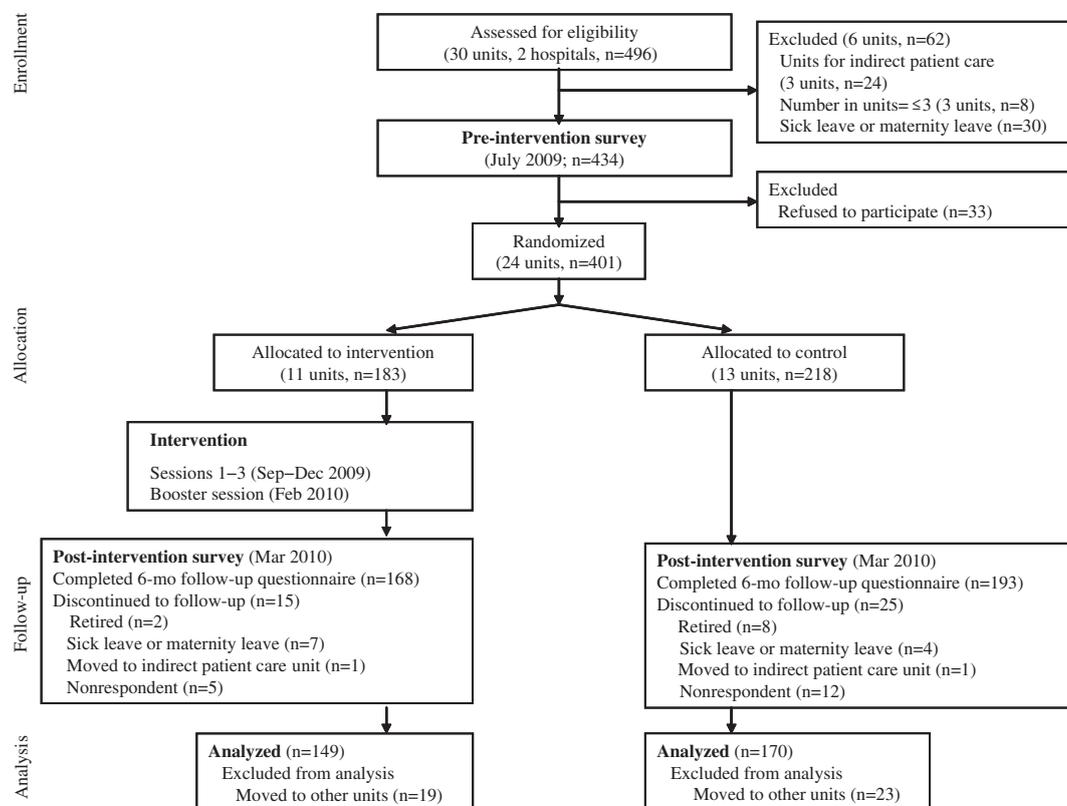Psychosocial work environment was measured by 3 questionnaires: the 22-item Japanese version of

Fig. 1. Flow of participants, a cluster randomized controlled study.

the Job Content Questionnaire (JCQ)[26, 27], the short version of the Effort-Reward Imbalance Questionnaire (ERIQ)[28], and the Quality Work Competence (QWC) questionnaire[18, 29, 30].

The Job Content Questionnaire (JCQ) consisted of subscales for Job Demands (5 items), Job Control (9 items), Supervisor Support (4 items), and Coworker Support (4 items), with a 4-point response option ranging from 1 (strongly disagree) to 4 (strongly agree). The weighted item scores were calculated as scale scores[26].

The short version of the Effort-Reward Imbalance Questionnaire (ERIQ) was based on Siegriest's ERI model. This questionnaire consisted of subscales for Effort (3 items) and Reward (7 items), with a 4-point option ranging from 1 (strongly agree) to 4 (strongly disagree). The reliability and validity of the Japanese version (Effort, 6 items; Reward, 11 items; 5-point option) were reported to be satisfactory[31].

The Quality Work Competence (QWC) questionnaire[18] was designed for the assessment of organizational conditions. It includes various aspects and characteristics of psychosocial work environment and existing occupational stress factors, which differ from those of the JCQ or ERIQ. We translated the validated English version of the QWC into Japanese. This preliminary Japanese version of the QWC was reviewed by industrial physicians, hospital nurses, a bilingual person who majored in psychology, and experts in the field of job stress research. We adopted their comments and revised the Japanese version. Then, back translation into English was performed by a bilingual professional translator. After some corrections of words and clarifications of meanings, the appropriateness of the Japanese version of the QWC was confirmed by the author of the original English version. It consists of the following 7 key assessment areas, with 4-point Likert scales ranging from 1 (not at all) to 4 (to a great extent), 1 (strongly disagree) to 4 (strongly agree), or 1 (never) to 4 (often): Goals (4 items; e.g., workplace goals are well-defined, realistic), Efficiency (4 items; e.g., planning of work tasks, resources used optimally at work), Participatory Management (6 items; e.g., latitude for deciding how work should be done, opportunity to influence workplace decisions), Competence Development (4 items; e.g., opportunity for professional development), Work Climate (5 items; e.g., positive atmosphere at work, cohesion among co-workers), Leadership (5 items; e.g., immediate supervisor is clear in his/her communication, acts consistently, acts consequently), and Feedback (3 items; e.g., performance feedback from supervisor when task has been done well/poorly, respectively)[18]. Cronbach's alphas were satisfactory (0.79–0.85). All indices were converted into percent-

age scores, ranging from a possible low of 0% to a high of 100% (e.g., if a person scored 15 points out of a maximum of 20, their percentage score was 75). For all QWC scales, higher scores are more desirable.

Sociodemographic variables, such as gender, age, career as a nurse, working hours, job position, employment status, and work schedule were also reported.

Outline of the intervention

A participatory program for improving psychosocial work environment was developed with reference to previous studies[18, 32, 33] and implemented during a 6-month period. The intervention group had an intensive intervention period for the first 3 months and a consecutive implementation period for the following 3 months. The intervention was unit based, focused on active employee participation, and based on action planning to improve the work environment. All members in the intervention units were expected to participate in a series of activities designed to improve the work environment. Subchief nurses in each intervention unit were appointed as key persons to facilitate activities within their own units. During a 3-month intensive intervention period, we invited all key persons to 30-minute group meetings and let them exchange views on their unit's intervention activities. Through these activities, they had chances to share information on good practices as well as obstacles during intervention in other units. Furthermore, 30-minute individual interviews with each key person were conducted by the first author to provide advice on facilitating other staff activities in their units. Then, each key person went back to their unit and shared necessary information with staff of their own units as follow-up tasks. They were required to fill out task sheets after every 30-minute group meeting to clarify the problems, needs, and progress of their unit and to help plan execution of the activities. Two months after the intensive intervention period (one month before the end of the 6-month intervention), a booster session was provided to check how activities proceeded in each unit. In total, the authors held key person meetings (including the booster session) 4 times. A detailed outline of our intervention is described as follows and is shown in Fig. 2.

Development phase (Steps 1–2): The results of the pre-intervention survey were reported to each unit and used for target identification and prioritization of the targeted psychosocial work environment, and as an index of improvement. In reference to their own unit's results, all members of the unit were asked to describe their ideal work environment and invited to develop action plans to improve their psychosocial work environment. Comprehensive information on
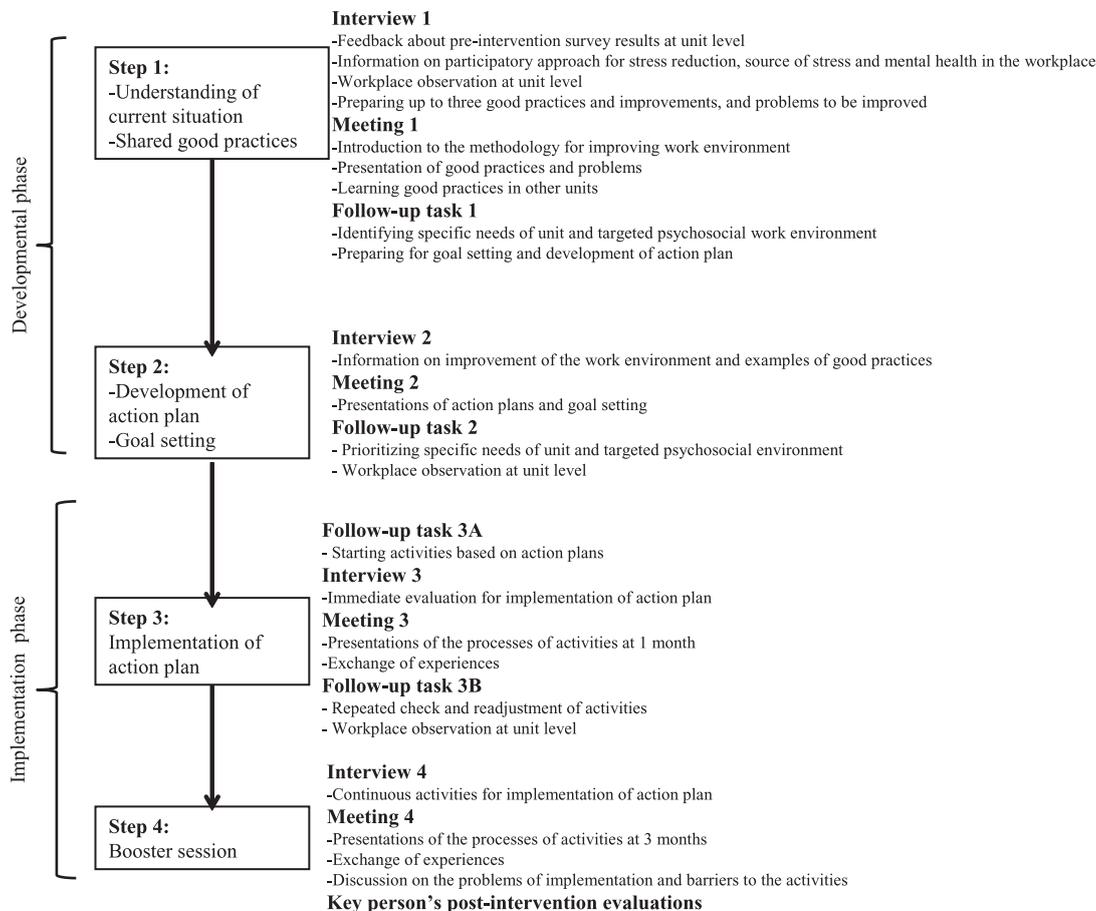
Interview 1
-Feedback about pre-intervention survey results at unit level
-Information on participatory approach for stress reduction, source of stress and mental health in the workplace
-Workplace observation at unit level
-Preparing up to three good practices and improvements, and problems to be improved
Meeting 1
-Introduction to the methodology for improving work environment
-Presentation of good practices and problems
-Learning good practices in other units
Follow-up task 1
-Identifying specific needs of unit and targeted psychosocial work environment
-Preparing for goal setting and development of action plan

Step 1:
-Understanding of current situation
-Shared good practices

Developmental phase

Interview 2
-Information on improvement of the work environment and examples of good practices
Meeting 2
-Presentations of action plans and goal setting
Follow-up task 2
- Prioritizing specific needs of unit and targeted psychosocial environment
- Workplace observation at unit level

Step 2:
-Development of action plan
-Goal setting

Follow-up task 3A
- Starting activities based on action plans
Interview 3
-Immediate evaluation for implementation of action plan
Meeting 3
-Presentations of the processes of activities at 1 month
-Exchange of experiences
Follow-up task 3B
- Repeated check and readjustment of activities
- Workplace observation at unit level

Step 3:
Implementation of action plan

Implementation phase

Interview 4
-Continuous activities for implementation of action plan
Meeting 4
-Presentations of the processes of activities at 3 months
-Exchange of experiences
-Discussion on the problems of implementation and barriers to the activities
Key person's post-intervention evaluations

Step 4:
Booster session

Fig. 2. Outline of the intervention.

mental health in the workplace and psychosocial work environment as a source of stress was provided to each unit.

Key persons were assigned to list the issues of their own units that needed to be improved and incorporate the opinions of unit members. They identified existing problems, while considering the effectiveness, feasibility, priority, and time cost of improvements. Ultimately, they proposed some action plans at their workplaces. Five points that were emphasized in this developmental phase are as follows: 1) start with problems that are easy to take action on; 2) focus on feasibility; 3) link with other management goals; 4) share experiences, such as good practices and failures, between units; and 5) work together and involve all members of the unit in decision-making, such as goal setting throughout all processes of the intervention.

Implementation phase (Steps 3–4): Nurses in the intervention group started to improve their psychosocial work environment based on the action plans proposed in the development phase. Researchers visited their workplaces and observed how their activities proceeded. Problems in the implementation of

the plans and barriers to the activities were reported to the researchers and key persons of other units. Suggestions for further improvement and sustaining autonomous activities were discussed during this period.

Evaluation of the intervention: In this study, we performed two types of evaluation, an outcome evaluation and a process evaluation. For the process evaluation, key persons were asked to look back at the whole interventional process of their unit. Descriptive information was gathered referring to qualitative content analysis[34, 35]. Qualitative content analysis is a research method for subjective interpretation of the content of text data through the systematic process of coding and identifying themes or patterns[34]. We used this qualitative research technique for the purpose of classifying large amounts of text into an efficient number of categories based on their similarities. Researchers' notes that had been obtained in key persons meetings and individual interviews as well as from key persons' task sheets were used. In addition, after the post-intervention survey, key persons evaluated the overall interventional process, includ-

ing descriptive responses. All relevant information contributing to evaluation of the intervention was obtained. From these data, information about activities, as well as information about why certain activities were not continued or conducted as planned, was provided.

The roles of the researchers were to observe, facilitate, and support the whole interventional process in order to help sustain autonomous activities. Nurses in the control units completed questionnaires and received feedback on factors other than the psychosocial environment at the baseline survey because no particular intervention activities were conducted.

Statistical analysis

Baseline characteristics of both intervention and control groups were compared with the *t*-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables. To examine the intervention effects, we assessed the interaction effects between groups (intervention and control) and time (pre and post intervention), employing multilevel modeling to take into account the variation in the units. We analyzed data using a generalized linear mixed model for repeated measures and included unit as a random effect. Paired *t*-tests were used to test changes in score for each variable in each group. Analysis of covariance (ANCOVA) was also used to compare scores for each variable at post-intervention, controlling for the pre-intervention score. The significance level was set at 0.05 (two-tailed), and borderline significance was set as 0.10. Statistical analyses were performed with SPSS 19.0 for Windows (SPSS Inc., Chicago, IL, U.S.A.).

The study design and procedure were reviewed and approved by the Research Ethics Committee of Tokyo Medical University. Written informed consent from each participant was obtained and confidentiality was protected. All participants responded anonymously to the questionnaire. For ethical reasons, nurses in the wait list control group were invited to the same intervention program after the study was completed. This study was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR), the Japanese registry of clinical trials (UMIN000004430).

Results

Baseline characteristics

A total of 496 nurses in 2 hospitals were eligible for the study (Fig. 1). Four hundred and thirty-four nurses from 24 units met the inclusion criteria for this study, and 401 nurses completed the pre-intervention questionnaire (response rate: 92.4%). A total of 183 nurses were included in the intervention group, and

218 were included in the wait list control group. Of these, 361 (90.0%) responded to the post-intervention survey. At post-intervention, 168 nurses from the intervention group and 193 nurses from the control group completed the questionnaire (response rates: 91.8 and 88.5%, respectively). Fifteen nurses in the intervention group and 25 in the control group discontinued follow-up: They retired (n=10), took sick or maternity leave (n=11), moved to an indirect patient care unit (n=2), or did not respond to the post-intervention survey (n=17). Forty-two nurses were excluded from the final analyses because they were moved to other units during the intervention period, regardless of whether or not the new unit involved patient care. In the end, 149 nurses in the intervention group and 170 nurses in the control group who stayed in the same unit during the intervention period were analyzed. Thus, the dropout rate was 20.4%.

Table 1 shows the characteristics of the intervention and control groups. There were no significant differences in sociodemographic variables between the groups. At baseline, among the psychosocial work environment scores, only the score of Job Demands was significantly lower in the intervention group than in the control group (*t* (314)=2.24, *p*=0.026; scores are shown in Table 2).

In order to test a potential selection bias of mental health status and psychosocial work environment before intervention, participants and nonparticipants were compared with nurses who were excluded from the outcome analyses. There were no significant differences in either scale of mental health status and psychosocial work environment (data not shown).

Effects of intervention

Table 2 shows the changes in the mean scores of pre and post intervention mental health status and psychosocial work environment in the intervention and control groups. The change in CES-D score as the primary outcome was not statistically significant (intervention group *t*=1.56, *p*=0.122; control group *t*=1.11, *p*=0.268). This indicated that no significant intervention effect was observed for mental health status. A favorable intervention effect was found in some variables of psychosocial work environment. The intervention group showed a statistically significant increase in the scales of Participatory Management (*t*=−2.48, *p*=0.014), Job Control (*t*=−2.28, *p*=0.024) and Coworker Support (*t*=−3.43, *p*=0.001), whereas the control group showed a statistically significant decrease in Goals (*t*=3.55, *p*=0.001). There was also a significant increase in Effort in both groups (intervention group *t*=−2.08, *p*=0.039; control group *t*=−2.72, *p*=0.007). The interaction effect was statistically significant for Goals (*F*=8.792, *p*=0.003)

Table 1. Baseline characteristics of intervention and control groups

	Intervention group (n=149)			Control group (n=170)			p^b
	n[a]	Mean ± SD	%	n[a]	Mean ± SD	%	
Gender							0.079
Female	149		100.0	166		97.6	
Male	0		0.0	4		2.4	
Age (years)	148	33.0 ± 9.6		168	31.7 ± 9.1		0.198
Career (years)	149	10.5 ± 8.3		169	9.7 ± 8.6		0.432
Working hours (/week)	115	44.3 ± 8.7		132	46.6 ± 10.5		0.063
Job position							0.254
General	123		82.6	146		85.9	
Subchief and chief	26		17.4	24		14.1	
Employment status							0.218
Regular	134		90.5	159		93.5	
Temporary	14		9.5	11		6.4	
Work schedule							0.228
Shift	107		75.4	117		70.9	
Non-shift	35		24.6	48		29.1	

[a]The numbers of subjects varied for some variables because of missing data. [b]*p*-value for comparison at baseline betweeen the intervention group and control group by *t*-test, chi-square test or exact test.

Table 2. Comparison of mental health status and psychosocial work environment pre and post intervention between the intervention and control groups

	Intervention group				Control group					Interaction effect	
		Pre-intervention	Post-intervention				Pre-intervention	Post-intervention				
Variables (Range)	n[a]	Mean (SD)	Mean (SD)	t	p^b	n[a]	Mean (SD)	Mean (SD)	t	p^b	F	p^c
Mental health												
CES-D (0–60)	133	16.1 (9.4)	15.1 (9.7)	1.56	0.122	154	15.8 (9.6)	15.2 (8.9)	1.11	0.268	0.132	0.717
Psychosocial work environment												
JCQ												
Job demands (12–48)	147	35.1 (4.5)	35.1 (4.8)	0.06	0.956	163	36.3 (5.3)	36.5 (5.2)	−0.51	0.614	0.160	0.690
Job control (24–96)	146	67.6 (8.2)	68.9 (8.0)	−2.28	0.024	162	67.9 (7.8)	67.6 (7.4)	0.44	0.660	3.840	0.051
Supervisor support (4–16)	147	11.4 (2.5)	11.5 (2.3)	−0.29	0.773	163	11.2 (2.5)	11.2 (2.3)	0.00	1.000	0.015	0.902
Coworker support (4–16)	145	11.9 (1.7)	12.4 (1.8)	−3.43	0.001	163	12.0 (2.0)	11.9 (1.8)	0.37	0.713	7.120	0.008
ERIQ												
Effort (3–12)	142	8.7 (1.7)	9.0 (1.8)	−2.08	0.039	165	8.9 (1.9)	9.2 (1.8)	−2.72	0.007	0.033	0.855
Reward (7–28)	138	18.0 (2.8)	18.2 (2.8)	−0.99	0.323	163	17.9 (2.7)	18.0 (2.8)	−0.60	0.548	0.046	0.831
QWC (0–100)												
Goals	149	58.3 (20.4)	59.7 (18.0)	−0.84	0.400	163	60.0 (16.5)	55.1 (17.9)	3.55	0.001	8.792	0.003
Efficiency	148	58.1 (18.1)	60.7 (17.1)	−1.75	0.082	164	56.0 (16.3)	55.6 (16.4)	0.34	0.734	2.560	0.111
Participatory management	148	61.4 (21.9)	65.1 (20.8)	−2.48	0.014	164	59.3 (18.3)	61.2 (18.7)	−1.41	0.160	0.748	0.388
Competence development	147	64.4 (18.6)	64.9 (17.3)	−0.30	0.767	165	62.7 (18.8)	60.6 (18.3)	1.39	0.168	0.852	0.357
Work climate	148	60.3 (15.7)	60.5 (16.6)	−0.14	0.888	166	58.8 (18.2)	57.7 (15.3)	0.85	0.398	0.608	0.436
Leadership	144	57.5 (19.4)	58.2 (16.6)	−0.53	0.598	161	54.2 (18.4)	54.5 (16.5)	−0.20	0.841	0.142	0.706
Feedback	147	62.3 (22.3)	61.0 (20.2)	0.85	0.394	166	59.8 (17.7)	59.2 (17.3)	0.44	0.661	0.092	0.762

[a]The numbers of subjects varied for some variables because of missing data. [b]*p*-value for comparison between pre and post intervention by the paired *t*-test. [c]*p*-value for the time x group interaction estimated by repeated measures analysis using generalized liner mixed models with unit as a random effect. CES-D: the Center for Epidemiologic Studies Depression Scale. JCQ: the Job Content Questionnaire. ERIQ: the Effort-Reward Imbalance Questionnaire. QWC: the Quality Work Competence Questionnaire.

and Coworker Support (F=7.120, p=0.008). In addition, borderline significance was observed for Job Control (F=3.840, p=0.051), even after taking into account the unit variation in scores.

The post-intervention scores of each variable, adjusted for pre-intervention scores, were compared between the intervention group and the control group (data not shown in table). The CES-D score was not statistically different between the groups. Almost all psychosocial factors at post-intervention were more favorable in the intervention group than in the control group. A statistically significant difference was found between the two groups for 4 out of 13 of psychosocial factors (Goals, Efficiency, Job Control, and Coworker Support), and statistically borderline significance was found for Competence Development.

Process evaluation of the intervention

Regarding their overall evaluation of the whole process of the intervention, key persons were asked "What were useful and helpful methods for facilitating activities in your unit?" after the intervention. It was found that "exchange of views with key persons of other units at group meetings" and "cognition of good practices in other units" might have been key for facilitating activities. They were also asked "How do you see changes in your unit through improving the psychosocial work environment?" Ten out of 13 key persons responded that there was an "improved work environment". Meanwhile, improved psychosocial work environment varied among units and did not necessarily correspond to the targeted psychosocial

work environment. Table 3 shows the list of reasons why psychosocial work environment improved, as evaluated by key persons. The most predominant reasons were "adopting staff's ideas and needs in goal setting" and "framework and approach of activities worked well". In regard to reasons why it did not improve, obstacles such as "(difficulty in) securing time for activities" and "(difficulty in) having a common understanding among staff" were pointed out. Detailed contents of intervention activities of the 11 intervention units are shown in Table 4. In spite of prior emphasis that the participation of all unit members was essential, all members were not necessarily involved during the implementation phase. Some activities were carried out as planned or with appropriate corrections, whereas others were not completed satisfactorily.

When we observed the results of each unit, increased Goals were noted in Units J and K, though their pre-intervention scores were the lowest. These two units work with outpatients, and each unit was functionally divided into several branches, unlike other units. These units did not have opportunities to hold whole-unit meetings and had difficulty with communication. They had set their action plans to clarify the goals of their entire outpatient units and enhance the cooperative framework among branches. Furthermore, unit members were regularly encouraged, and their motivation was stimulated due to the efforts of key persons, which helped to obtain understanding and cooperation from unit members during these activities. In Unit C, where the psychosocial work environment

Table 3. Description of reasons why psychosocial work environment improved or did not improve, adapted from evaluation sheet

What were the reasons why psychosocial work environment <u>improved</u>?	Unit
1 Adopting staff's ideas and needs in goal setting.	K, G, C, D
2 Framework and approach of activities worked well.	H, I, J, K
3 Owing to staff's understanding and cooperation, activities performed well.	K, G, I
4 Activities promoted smoother communication between staff.	B, E
5 Activities led to changing staff's consciousness of improving work environment.	B

What were the reasons why psychosocial work environment <u>did not improve</u>?	Unit
1 Securing time for activities. Time to implement action plans and to discuss activities was insufficient.	D, E, F, G, H, K
2 Having a common understanding among staff. Communication among staff and key persons was insufficient.	A, B, C, E, K
3 Activities increased staff's and key persons' burdens.	B, C, E
4 Evaluating psychosocial work environment. Realizing effectiveness and changes.	C, I, J
5 Gaps between goal setting and staff's real needs.	B, H, I
6 Keeping continuity and autonomy of activities.	D, I
7 Cooperating with new staff after personnel changes and vacant positions.	A, B
8 Intervention intensity was not enough to get staff involved in activities.	E
9 Limited interest in improving psychosocial work environment among staff.	K

Table 4. Description of planned and implemented activities during interventions in each unit

Unit	Planned and implemented activities[a]
A (n=16)	1) Team reorganization (e.g., increased number of teams) 2) Allocation of job roles within the team
B (n=16)	1) Delivering a message of support 2) Greetings and expressions of gratitude using one's name ("thank you", "that would help")
C (n=15)	1) Sharing problems of patients while expressing feelings at unit meetings 2) Conducting professional nursing study groups
D (n=15)	1) Arranging team meetings during day shift hours 2) Actively speaking in meetings at least once per day
E (n=21)	1) Effective use of unit meeting (time, contents, meeting minutes) (i.e., simplified and easy-to-read meeting minutes) 2) Rewarding good work and supporting poor work 3) Reviewing one's goals (e.g., unit, team, and individual goals)
F (n=11)	1) Clarified responsibility for assigned tasks 2) Conducting study groups for each assigned task team
G (n=4)	Conducting regular unit meetings for sharing information and discussing problems
H (n=14)	Organized staff room (i.e., cleaning duty for a week)
I (n=16)	1) Carry out one's role within unit 2) Conducting study groups (mutual enlightenment, informing nonparticipants about the contents of workshops) 3) Creating atmosphere of helping each other
J (n=6)	1) Providing opportunities for stress release and sharing information 2) Enhancement of system of calling for help from other units (i.e., check the daily schedule at morning meetings) 3) Clarified goals of outpatient unit (i.e., check their goals at unit meetings)
K (n=15)	1) Developing better relationships through regular greetings ("good morning", "have a nice evening", "good bye", "thank you") 2) Sharing information and motivating others at meetings 3) Offering compliments 4) Reporting, making contacts and advising other staff 5) Thinking positively 6) Enhancement of cooperative framework for when busy or sick and in the case of emergencies 7) Information exchange in cases of complaints and incidents 8) Having opportunities to express feelings and release stress

[a]Information retrieved from researchers' notes of key person meetings and interviews, and responses from key persons in follow-up task sheets and evaluation sheets.

was broadly improved, a key person asked all unit members their opinions regarding their workplace. Their responses may have contributed to goal setting and action plans. Nevertheless, there were some units in which all psychosocial work environment scores were not significantly improved (Units B, H, and I). In these units, participants showed less interest in improving their psychosocial work environment and wanted to improve working conditions (such as salary, working schedule, and manpower shortage) rather than psychosocial factors.

Discussion

This study evaluated the effects on mental health status among nurses of a participatory intervention for improving the psychosocial work environment using a cluster randomized controlled design. After a 6-month intervention, we could find no significant effect on the scores of depressive symptoms. We hypothesized that a workers' participatory approach improves the psychosocial work environment, and subsequently, a favorable working environment has a good effect on mental health. However, in this study, the improvement in psychosocial work environment was not reflected in the scores of depressive symptoms. The insignificant effect may be due to the timing of outcome assessment, which was immediately after the end of the 6-month intervention. In addition, it may

be due not only to the timing but also to the index of mental health, depressive symptoms. It has been pointed out that subjective symptoms vary by stress level and that depressive symptoms are more apparent at high stress levels[36]. If we had assessed relatively milder reactions such as irritation, anger, or anxiety, we may have found a positive intervention effect.

The significant favorable effect on Coworker Support in the present study was consistent with previous findings in worker participatory intervention research[20], including hospital settings[19, 32]. In our intervention, some units implemented action plans (e.g., increasing meeting opportunities to provide necessary information to unit members), which may have led to the improvement of communication among members, and thus provided a good opportunity for members to encourage each other to develop further mutual support. No significant intervention effect was observed for Supervisor Support. This may be partly attributable to increased communication between nurses at the same level, not only through supervisors.

A statistically significant intervention effect observed for Goals seems reasonable. The whole process of the intervention itself could have led to improving the score for Goals because it included the process of clarifying and setting feasible goals. However, this result should be carefully interpreted. As described in our results, some units with low Goals scores on the pre-intervention survey showed a great increase. The lower score at baseline made it easier to find positive effects because there was some room for improvement. However, the units that aimed to clarify goals and increase the score for Goals after the intervention could have learned the skills needed for appropriate goal setting. Because goal setting is the most fundamental and useful skill for behavioral change, focusing on goal setting in intervention activities may be useful and applicable to other activities.

Statistically borderline significance for Job Control was shown in this study. According to previous studies[22, 37], worker participatory intervention led to an increase in controllability. Therefore, this result of an increase in Job Control was not surprising.

The number of factors with significant effects that were observed in this study was smaller than those in previous intervention studies[18, 38]. This may be explained by the fact that some subjects in our study were suffering severely from manpower shortages and some subjects complained about their salaries, so they had higher expectations for improving working conditions (i.e., work schedules, working hours, and salaries) rather than psychosocial work environment. The psychosocial intervention did not cover these aspects. In addition, a seasonal effect may have been observed. Significant increases in Effort in both groups may be

due to the timing of the assessment at the end of the fiscal year. The feasibility of intervention needs to be considered. It has been pointed out that work environment improvement may sometimes result in participants' overexpenditure of effort as a "side effect"[5]. The process of creating action plans and implementation can be stressful and may cause negative effects[39]. The framework of our intervention, process and intensity seemed to be acceptable even during the nurses' busy ordinary work activities. This was supported by the fact none of the intervention units dropped out during the intervention period.

From the process evaluation, several considerations for future interventions were obtained. Firstly, the continuing facilitation of key persons is important for the successful implementation of the intervention. Secondly, a preliminary period for preparation before implementation is required. Some units reported on the evaluation sheets and in interviews that they needed more time to inform and convince all members of unit to be involved in the intervention. Thirdly, it is difficult to determine the best intervention period. Six months might be insufficient to implement action plans for improving the psychosocial work environment and mental health. However, if researchers set a longer study period, more effort would be required to boost key persons' motivation and autonomy of participants. At the same time, it is important not to create an excessive burden on participants because they are already fully occupied with daily work tasks. It could be argued that in the intervention group, where the baseline scores for Job Demands were significantly lower than in the control group, it was easier to improve the work environment because they had time for activities. However, as a matter of fact, "(difficulty in) securing time for activities" was the most common reason given for why psychosocial work environment did not improve in our sample. Some intervention units, in which job demands needed to be improved through work conditions (e.g., increasing personnel), could not adopt these goals and action plans because of feasibility. Time constraints and feasibility continue to be priority issues for researchers when conducting intervention studies.

Some limitations of the study must also be mentioned. Firstly, contamination of the intervention cannot be fully avoided in this study design. Though all units were located on different floors of the hospitals, with independent management of tasks and staff, information exchange was not completely prohibited. This design would be likely to lead to underestimation in the results. Secondly, only short-term intervention effects at 6 months immediately after the intervention were examined. Future studies should include longer-term effects, and the timing of assessment of

intervention could be argued. Thirdly, it was difficult to identify which specific aspects of the intervention were effective for the outcome changes because our approach was multifaceted. The process evaluation data served as a complement to the quantitative results in this study.

This study has several strengths. It used a randomized controlled design with homogeneous subjects, that is, hospital nurses. In addition, we provided information on interventional processes and obstacles in implementing intervention (e.g., "having a common understanding among staff"). This information provides useful suggestions for development of future intervention programs.

In conclusion, although there was no significant improvement in mental health status, some intervention effects on psychosocial work environment were observed. This study suggests favorable results with regard to the 6-month effectiveness of the participatory intervention for improving psychosocial work environment among nurses.

References

1) Stansfeld S, Candy B. Psychosocial work environment and mental health--a meta-analytic review. Scand J Work Environ Health 2006; 32: 443–62.
2) Karasek R. Stress prevention through work reorganisation: a summary of 19 international case studies. In: Conditions of Work Digest: Preventing Stress at Work 11. Geneva (Switherland): International Labour Office; 1992. p. 23–42.
3) Lamontagne AD, Keegel T, Louie AM, Ostry A, Landsbergis PA. A systematic review of the job-stress intervention evaluation literature, 1990–2005. Int J Occup Environ Health 2007; 13: 268–80.
4) Shimomitsu T, Odagiri Y, Kawakami N. Facilitating mental health at workplace through improvement of working environment: current problem and countermeasures. Job Stress Res 2004; 11: 87–92 (in Japanese).
5) Semmer NK. Job stress interventions and the organization of work. Scand J Work Environ Health 2006; 32: 515–27.
6) Reynolds S. Interventions: what works, what doesn't? Occup Med (Lond) 2000; 50: 315–9.
7) van der Klink JJ, Blonk RW, Schene AH, van Dijk FJ. The benefits of interventions for work-related stress. Am J Public Health 2001; 91: 270–6.
8) Egan M, Bambra C, Petticrew M, Whitehead M. Reviewing evidence on complex social interventions: appraising implementation in systematic reviews of the health effects of organisational-level workplace interventions. J Epidemiol Community Health 2009; 63: 4–11.
9) Eriksen W, Bruusgaard D, Knardahl S. Work factors as predictors of sickness absence attributed to airway infections; a three month prospective study of nurses' aides. Occup Environ Med 2004; 61: 45–51.
10) Goldenhar LM, Schulte PA. Methodological issues for intervention research in occupational health and safety. Am J Ind Med 1996; 29: 289–94.
11) Kristensen TS. Intervention studies in occupational epidemiology. Occup Environ Med 2005; 62: 205–10.
12) Nielsen K, Fredslund H, Christensen KB, Albertsen K. Success or failure? Interpreting and understanding the impact of interventions in four similar worksites. Work Stress 2006; 20: 272–87.
13) Saksvik PO, Nytrø K, Dahl-Jørgensen K, Mikkelsen A. A process evaluation of individual and organizational occupational stress and health interventions. Work Stress 2002; 16: 37–57.
14) Marine A, Ruotsalainen J, Serra C, Verbeek J. Preventing occupational stress in healthcare workers. Cochrane Database Syst Rev 2006: CD002892.
15) Ruotsalainen J, Serra C, Marine A, Verbeek J. Systematic review of interventions for reducing occupational stress in health care workers. Scand J Work Environ Health 2008; 34: 169–78.
16) Aust B, Rugulies R, Finken A, Jensen C. When workplace interventions lead to negative effects: learning from failures. Scand J Public Health 2010; 38: 106–19.
17) Mimura C, Griffiths P. The effectiveness of current approaches to workplace stress management in the nursing profession: an evidence based literature review. Occup Environ Med 2003; 60: 10–5.
18) Anderzen I, Arnetz BB. The impact of a prospective survey-based workplace intervention program on employee health, biologic stress markers, and organizational productivity. J Occup Environ Med 2005; 47: 671–82.
19) Bourbonnais R, Brisson C, Vezina M. Long-term effects of an intervention on psychosocial work factors among healthcare professionals in a hospital setting. Occup Environ Med 2011; 68: 479–86.
20) Kobayashi Y, Kaneyoshi A, Yokota A, Kawakami N. Effects of a worker participatory program for improving work environments on job stressors and mental health among workers: a controlled trial. J Occup Health 2008; 50: 455–70.
21) Tsutsumi A, Nagami M, Yoshikawa T, Kogi K, Kawakami N. Participatory intervention for workplace improvements on mental health and job performance among blue-collar workers: a cluster randomized controlled trial. J Occup Environ Med

2009; 51: 554−63.
22) Mikkelsen A, Saksvik PO, Landsbergis P. The impact of a participatory organizational intervention on job stress in community health care institutions. Work Stress 2000; 14: 156−70.
23) Kompier MA, Geurts SA, Gründemann RW, Vink P, Smulders PG. Cases in stress prevention: the success of a participative and stepwise approach. Stress and Health 1998; 14: 155−68.
24) Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Applied Psychological Measurement 1977; 1: 385−401.
25) Shima S, Shikano T, Kitamura T, Asai M. New self-rating scales for depression. Seishin Igaku 1985; 27: 717−23 (in Japanese).
26) Karasek R. Job Content Questionnaire and user's guide. Lowell (MA): University of Massachusetts; 1985.
27) Kawakami N, Kobayashi F, Araki S, Haratani T, Furui H. Assessment of job stress dimensions based on the job demands- control model of employees of telecommunication and electric power companies in Japan: reliability and validity of the Japanese version of the Job Content Questionnaire. Int J Behav Med 1995; 2: 358−75.
28) Siegrist J, Wege N, Puhlhofer F, Wahrendorf M. A short generic measure of work stress in the era of globalization: effort-reward imbalance. Int Arch Occup Environ Health 2009; 82: 1005−13.
29) Arnetz JE, Hasson H. Evaluation of an educational "toolbox" for improving nursing staff competence and psychosocial work environment in elderly care: results of a prospective, non-randomized controlled intervention. Int J Nurs Stud 2007; 44: 723−35.
30) Arnetz BB. Physicians' view of their work environment and organisation. Psychother Psychosom 1997; 66: 155−62.
31) Tsutsumi A, Ishitake T, Peter R, Siegrist J, Matoba T. The Japanese version of the Effort-Reward Imbalance Questionnaire: a study in dental techni-

cians. Work Stress 2001; 15: 86−96.
32) Bourbonnais R, Brisson C, Vinet A, Vezina M, Abdous B, Gaudet M. Effectiveness of a participative intervention on psychosocial work factors to prevent mental health problems in a hospital setting. Occup Environ Med 2006; 63: 335−42.
33) Yoshikawa T, Kawakami N, Kogi K, et al. Development of a mental health action checklist for improving workplace environment as means of job stress prevention. Sangyo Eiseigaku Zasshi 2007; 49: 127−42 (in Japanese).
34) Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005; 15: 1277−88.
35) Peterson U, Bergstrom G, Samuelsson M, Asberg M, Nygren A. Reflecting peer-support groups in the prevention of stress and burnout: randomized controlled trial. J Adv Nurs 2008; 63: 506−16.
36) Shimomitsu T, Noboru I. Response characteristics of measurement item for occupational stressors and stress reactions in Brief Job Stress Questionnaire: approaches to Item Response Theory. In: Kato M, ed. The Ministry of Labour sponsored grant for the prevention of work-related illness: The 1999 Report. Tokyo (Japan): Tokyo Medical College; 2000. p.146−52.
37) Rivilis I, Cole DC, Frazer MB, Kerr MS, Wells RP, Ibrahim S. Evaluation of a participatory ergonomic intervention aimed at improving musculoskeletal health. Am J Ind Med 2006; 49: 801−10.
38) Arnetz B, Blomkvist V. Leadership, mental health, and organizational efficacy in health care organizations. Psychosocial predictors of healthy organizational development based on prospective data from four different organizations. Psychother Psychosom 2007; 76: 242−8.
39) Briner RB, Reynolds S. The costs, benefits, and limitations of organizational level stress interventions. Journal of Organizational Behavior 1999; 20: 647−64.