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Factors associated with disabling low back pain among nursing personnel in Japan: a cross-sectional survey

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Complete List of Authors:	Yoshimoto, Takahiko; Showa University, Hygiene, Public Health and Preventive Medicine Oka, Hiroyuki; The University of Tokyo, Department of Medical Research and Management for Musculoskeletal Pain Ishikawa, Shuhei; Kameda Medical Center, Rehabilitation Kokaze, Akatsuki; Showa University, Hygiene, Public Health and Preventive Medicine Muranaga, Shingo; Kameda Medical Center, Rehabilitation Matsudaira, Ko; The University of Tokyo, Department of Medical Research and Management for Musculoskeletal Pain
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Page 1 o	of 20	BMJ Open
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15 16	6	Takahiko Yoshimoto ^{1,2*} , Hiroyuki Oka ² , Shuhei Ishikawa ³ , Akatsuki Kokaze ¹ , Shingo Muranaga ³ ,
17 18	7	Ko Matsudaira ²
19 20	8	
21 22	9	¹ Department of Hygiene, Public Health and Preventive Medicine, Showa University School of
23 24	10	Medicine, Tokyo, Japan
25 26	11	² Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century
27 28 29	12	Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan
29 30 31	13	³ Department of Rehabilitation, Kameda Medical Center, Chiba, Japan
32 33	14	Department of remainduning, realized vicedeal center, emou, supun
34 35	15	*Corresponding author:
36 37	16	Takahiko Yoshimoto
38 39	17	Department of Hygiene, Public Health and Preventive Medicine, Showa University School of
40 41	18	Medicine, 1-5-8 Hatanodai, Shinagawa-ku, Tokyo 142-8555, Japan
42 43	10	Tel: +81(3)3784-8134; Fax: +81(3)3784-7733
44 45	20	E-mail address: yoshimotot@med.showa-u.ac.jp
46 47	20	L-man address. yosinnotot@med.snowa-d.ac.jp
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23 ABSTRACT

Objectives: Low back pain (LBP) is a common cause of disability among nursing personnel. Although many studies regarding the risk factors for LBP among nursing staff have focused on the physical load at work, multidimensional assessments of risk factors are essential to identify appropriate preventive strategies. We aimed to investigate the association of multidimensional factors (individual, physical, psychological, and occupational) with disabling LBP among nursing personnel in Japan.

Design: Observational study with cross-sectional design.

31 Setting: Data was collected using the self-administered questionnaire at a tertiary medical center.

Participants: After excluding participants with missing variables, 718 nursing personnel were
 included in the analysis.

Outcome measures: A self-administered questionnaire assessed individual characteristics,
rotating night shift data, severity of LBP, previous episode of LBP, sleep problem, kinesiophobia
(Tampa Scale for Kinesiophobia), depressive condition (K6), physical flexibility, and frequency
of lifting at work. A logistic regression model was used to evaluate the factors associated with
disabling LBP (LBP interfering with work) among nursing personnel.

Results: Of all participants, 110 (15.3%) reported having disabling LBP. The multivariable
logistic regression analysis after adjustment for several confounding factors showed that
kinesiophobia (highest tertile, adjusted odds ratio [aOR]: 6.13, 95% confidence interval [CI]:
3.34-11.27), previous episode of LBP (aOR: 4.33, 95% CI: 1.50-12.41), and insomnia (aOR: 1.66,
95% CI: 1.05-2.62) were significantly associated with disabling LBP.

44 Conclusions: The present study indicated that kinesiophobia, a previous episode of LBP, and
45 sleep problems were associated with disabling LBP among nursing personnel. In the future,
46 workplace interventions considering assessments of these factors may reduce the incidence of
47 disabling LBP in nursing staff, although further prospective studies are needed.

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This study was designed to assess simultaneously the multidimensional aspects (individual,

physical, psychological, and occupational) of disabling low back pain among nursing

This paper provides results that will be useful in understanding the complexity of low back

pain and developing appropriate strategies for reducing the incidence of occupational low

The major limitations of this study are the participants at a single center and the cross-

study are the

Strengths and limitations of this study

personnel in Japan.

back pain.

sectional design.

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57 INTRODUCTION

The global burden of disease study 2017 indicated that low back pain (LBP) is one of the leading cause of disability worldwide.¹ LBP is a major public health problem with an enormous negative economic impact on individuals, industries, and societies.²³

The etiology of LBP is multifactorial and includes physical factors (physical load at work,⁴ physical flexibility,⁵ etc.) and psychological factors (depression,⁶ and fear-avoidance belief,⁷ etc.).
Among psychological factors, pain-related fear of movement/reinjury, which is known as kinesiophobia, has been suggested to be an important contributor for LBP.⁸ LBP also recurs frequently; thus, a previous episode of LBP can be a predictor of future episodes.⁹ Moreover, lifestyle factors including sleep problems can increase the risk of LBP.¹⁰

Several studies have shown that nursing personnel have a higher prevalence of LBP relative to the general population,¹¹ or other occupational groups,^{12 13} which may be related to nursing work-related factors. Indeed, in addition to the above physical and psychological factors, occupationspecific factors such as frequent manual handling¹⁴ ¹⁵ and rotating night shifts¹⁶ have been suggested to be associated with the development of LBP among nursing personnel. Because LBP could lead not only to decreased work performance, but also professional abandonment,¹⁷ clarifying the risk factors of LBP and exploring appropriate preventive strategies is essential to reduce the incidence of LBP among nursing professionals.

Although there is ample evidence showing that physical factors, including manual handling, among nursing personnel are a significant risk factor for LBP,^{14 15 17} systematic reviews of interventions for LBP in nurses have indicated that ergonomic interventions for LBP had inadequate results.^{18 19} Thus, studies investigating the factors associated with LBP among nursing personnel from a multidimensional perspective including individual, physical and psychological factors are increasingly needed. Since the prevalence of disabling LBP varies across countries and occupations,²⁰ it may be important to investigate the factors associated with disabling LBP among nursing personnel in Japan in order to design appropriate strategies for reducing the

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incidence of occupational LBP. Therefore, we aimed to perform a multidimensional assessment,
including individual, physical, psychological, and occupational aspects, of disabling LBP among
nursing personnel at a tertiary hospital in Japan.

87 METHODS

88 Study populations

This cross-sectional study was based on a survey conducted among nursing personnel at Kameda Medical Center at Chiba Prefecture, Japan during February 2017. During this period, an anonymous, self-administered questionnaire was distributed to 1,152 workers at the nursing department in the center. After the workers answered the questionnaires, they put them in sealed envelopes. Then, occupational health staff collected and sent the envelopes to the authors. Staff other than the authors were not allowed to open the sealed envelopes. Written informed consent was obtained from each participant. All procedures were approved by the Research Ethics Committee of Kameda Medical Center (Approval No. 16-159) and carried out according to the Declaration of Helsinki.

99 Study measures

The following items were assessed using the self-administered questionnaire: age, sex, height, weight, occupation type (registered nurse, assistant nurse, midwife, or nursing aid), rotating night shift (frequency of shift work per month), severity of LBP, previous episode of LBP, sleep problem, fear-avoidance (kinesiophobia), depressive condition, physical flexibility, and lifting at work. Body mass index (BMI) was calculated as weight (kg) divided by the square of height (m). The severity of LBP, evaluated by respondents, was classified into four grades; grade 0 (no LBP), grade 1 (LBP that did not interfere with work), grade 2 (LBP that interfered with work), and grade 3 (LBP that interfered with work and required sick leave). These grades were determined with reference to Von Korff's grading method.²¹ The area of LBP (between the costal

109 margin and inferior gluteal folds) was indicated as a diagram in the questionnaire.²² LBP was 110 defined as pain lasting for \geq 1 day and experienced during the past one month, in accordance with 111 the standard definition of LBP proposed by Dionne et al.²³ LBP associated with menstrual periods, 112 pregnancy, or febrile illness was excluded. Individuals with disabling LBP were defined as those 113 who had LBP interfering with work, irrespective of sick leave because of LBP (grade 2 or 3).²⁴ 114 Past LBP history characteristics were evaluated in a question regarding the previous episode of 115 LBP.

Sleep problems were assessed using questions about the sleep duration and sleep habits in the previous month.²⁵ Disability of sleep duration was defined by durations < 6 hours. Difficulty initiating sleep was defined as taking more than 30 min to fall asleep. Difficulty maintaining sleep and early morning awakening were defined by the occurrence of nocturnal awakenings or early morning awakenings three times or more per week. The presence of insomnia was defined if the participants reported at least one positive response to the three symptoms of sleep habits above.²⁵ To assess fear of movement/(re)injury, we used the short version of the Tampa Scale for Kinesiophobia (TSK-11).²⁶ The TSK-11 consists of 11 items, each of which is scored on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). The total scores range from 11 to 44, with higher scores indicating greater fear of movement/(re)injury. The Japanese version of TSK-11 has been translated and validated by Matsudaira et al.^{27 28} Participants' scores were classified into tertiles according to their total scores.

Depressive condition was evaluated by using the Kessler 6-item psychological distress scale (K6).²⁹ The K6 consists of six items that assess how frequently respondents experienced symptoms of psychological distress such as nervousness, negative affect, fatigue, and worthlessness over the past 30 days. Each item was rated on a 5-point scale ranging from 0 (none of the time) to 4 (all of the time), with the total score ranging from 0 to 24. The K6 has been translated to a Japanese version, whose reliability and validity have been confirmed by Furukawa et al.³⁰ Individuals with a K6 score of \geq 10 were defined as having a depressive condition in

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accordance with a previous study.³¹

Physical flexibility was assessed by using the modified finger-to-floor distance³² which mainly represents trunk flexibility. The grade of this item was rated on a 7-point scale: 1) fingertips cannot reach across the knees; 2) fingertips can reach across the knees but wrists not; 3) wrists can reach beyond the knees, but fingertips cannot reach the ankles; 4) fingertips can reach the ankles; 5) fingertips can touch the floor; 6) all of the fingers can touch the floor; and 7) palms can touch the floor. Flexibility was classified into two groups based on whether wrists could reach beyond the knee, but fingertips could not reach the ankles.²⁴

Physical work demand was measured with a question exploring the frequency of lifting at work.
The frequency of lifting was divided into 0, 1-4, 5-9, 10 times per shift, and lifting ≥5 times per
shift was defined as frequent with reference to a previous study.¹⁶

147 Statistical analysis

148 Data were presented as median (25th, 75th percentile) for continuous variables or number (%) 149 for categorical variables. Characteristics of participants were compared using the chi-squared test 150 for categorical variables and Wilcoxon rank-sum test for continuous variables. To assess factors 151 associated with disabling LBP, a logistic regression model was used to estimate the odds ratio 152 (OR) and 95% confidence interval (CI) for disabling LBP. In the model, the following factors 153 were included for adjustment: sex, age, BMI, frequency of shift work, sleep duration, insomnia, 154 previous episode of LBP, TSK and K6 scores, flexibility, lifting at work. Multicollinearity was 155 not suspected as all variance inflation factors (VIFs) were <2. A p-value less than 0.05 was 156 considered to be statistically significant (two-sided). All statistical analyses were performed using 157 JMP version 13.0 (SAS Institute Inc., Cary, NC, USA).

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5 159 **RESULTS**

160 Of all workers at the nursing department in the center, 1075 respondents provided answers in

161 the questionnaires. Since the present study was focused on nursing personnel who provide direct 162 care in the center, 146 employees who were not related to direct nursing care (clerical work or 163 providing guidance to patients, etc.) were excluded. We further excluded 211 participants with 164 missing data for any variable. As a result, 718 nursing staff completed the questionnaire with no 165 missing data and were included in the analysis.

The median age of participants in the present study was 31.0 years, and 79.7% of the participants were women. Of the included participants, 15.3% were reported to have disabling LBP. The characteristics of participants with or without disabling LBP are shown in Table 1. The proportions of insomnia (p < 0.001) and previous episode of LBP (p < 0.001) among participants with disabling LBP were higher relative to those observed in participants without disabling LBP. The proportions of those who had high TSK (p < 0.001) or K6 (p < 0.038) scores were higher in the disabling LBP group than in the no disabling LBP group. In contrast, the groups with and without disabling LBP showed no significant differences for physical flexibility and the frequency of lifting at work.

We calculated the crude and adjusted ORs and their 95% CIs for disabling LBP (Table 2). The
non-adjusted analysis showed that insomnia, previous episode of LBP, and TSK and K6 scores
were significantly associated with disabling LBP. Multivariable analysis after adjusting for sex,
age, BMI, and all explanatory variables showed that insomnia (adjusted OR [aOR]: 1.66, 95%
CI: 1.05-2.62), a previous episode of LBP (aOR: 4.31, 95% CI: 1.50-12.41), and TSK score (aOR:
2.08, 95% CI: 1.11-3.89 in middle, aOR: 6.13, 95% CI: 3.34-11.27 in high) remained significantly
associated with disabling LBP.

Table 1. Characteristics	of the study pa	rticipants
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	Disabling LBP	No disabling LBP	<i>p</i> -value
	(n = 110)	(n = 608)	
Sex (women)	79 (71.8%)	493 (81.1%)	0.026
Age, years	27.5 (24.0, 40.0)	31.0 (24.0, 42.0)	0.052
Body mass index, kg/m ²	21.6 (19.8, 23.3)	21.2 (19.5, 23.9)	0.793
Occupation type			
Registered nurse	88 (80.0%)	495 (81.4%)	0.886
Assistant nurse (practical nurse)	2 (1.8%)	16 (2.6%)	
Midwife	4 (3.6%)	18 (3.0%)	
Nursing aid	16 (14.5%)	79 (13.0%)	
Frequency of shift work, per month	6.0 (2.5, 10.0)	6.0 (0.0, 10.8)	0.571
Sleep duration			
>6 hours	78 (70.9%)	436 (71.7%)	0.864
<6 hours	32 (29.1%)	172 (28.3%)	
Insomnia			
Not have insomnia	47 (42.7%)	366 (60.2%)	< 0.00
Have insomnia	63 (57.3%)	242 (39.8%)	
Previous episode of LBP			
No	4 (3.6%)	97 (16.0%)	< 0.00
Yes	106 (96.4%)	511 (84.0%)	
TSK			
Low (≤17)	18 (16.4%)	252 (41.4%)	< 0.00
Middle (18-23)	32 (29.1%)	206 (33.9%)	
High (≥24)	60 (54.5%)	150 (24.7%)	
K6			
<10	78 (70.9%)	485 (79.8%)	0.038
≥10	32 (29.1%)	123 (20.2%)	
Flexibility			
Flexible	75 (68.2%)	443 (72.9%)	0.314
Not flexible	35 (31.6%)	165 (27.1%)	
Lifting			
Not frequent	45 (40.9%)	289 (47.5%)	0.200
Frequent	65 (59.1%)	319 (52.5%)	

Data are presented as number (percentage) or median (25th, 75th percentile).

LBP, Low back pain; TSK, Tampa scale for kinesiophobia

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Table 2. Association between disabling low back pain and independent variables from logistic

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regression	models

	Crude		Adjusted*	
	OR (95% CI)	<i>p</i> -value	OR (95% CI)	<i>p</i> -value
Frequency of shift work, per month	1.00 (0.97-1.04)	0.783	0.98 (0.94-1.02)	0.390
Sleep duration				
>6 hours	1.00		1.00	
<6 hours	1.04 (0.66-1.63)	0.864	1.12 (0.68-1.83)	0.659
Insomnia				
Not have insomnia	1.00		1.00	
Have insomnia	2.03 (1.34-3.06)	< 0.001	1.66 (1.05-2.62)	0.029
Previous episode of LBP				
No	1.00		1.00	
Yes	5.03 (1.81-13.97)	0.002	4.31 (1.50-12.41)	0.007
TSK				
Low (≤17)	1.00		1.00	
Middle (18-23)	2.17 (1.19-3.99)	0.012	2.08 (1.11-3.89)	0.022
High (≥24)	5.60 (3.19-9.84)	< 0.001	6.13 (3.34-11.27)	< 0.001
K6				
<10	1.00		1.00	
≥ 10	1.62 (1.02-2.55)	0.039	1.06 (0.64-1.75)	0.834
Flexibility				
Flexible	1.00		1.00	
Not flexible	1.25 (0.81-1.94)	0.314	0.95 (0.59-1.53)	0.846
Lifting				
Not frequent	1.00		1.00	
Frequent	1.31 (0.87-1.98)	0.201	0.99 (0.62-1.58)	0.973

LBP, Low back pain; TSK, Tampa scale for kinesiophobia; OR, Odds ratio; CI, Confidence interval *Adjusted for sex, age, body mass index, and all other variables which indicated in this table.

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185 DISCUSSION

> 186 The present study investigated the association of disabling LBP with related factors via a multifaceted assessment among nursing personnel at a tertiary hospital. The results of our 187 188 multivariable logistic regression analysis showed that insomnia, previous episodes of LBP, and

kinesiophobia were independently associated with disabling LBP. To our knowledge, this is the first study that identified a significant association of pain-related fear and insomnia with disabling LBP among nursing personnel in Japan.

In this study, disabling LBP was set as the outcome of interest to identify risk factors for LBP among nursing personnel. In occupational fields, absence from work (absenteeism) due to LBP is often used as the outcome of disability. However, the number of individuals taking a sick leave due to LBP is considerably small. A previous international epidemiological study showed that the prevalence of absenteeism due to musculoskeletal disorders, mainly LBP, was much less common in Japan relative to that in the UK.¹² Moreover, it has been suggested that the loss of work performance due to LBP has a greater negative economic impact on individuals and workplaces in terms of healthcare costs and work productivity than sick leaves due to LBP.^{33 34} Therefore, it may be appropriate to define disabling LBP as LBP interfering with work performance with or without sick leave.

Our results showed that high TSK scores were significantly associated with disabling LBP among nursing personnel after adjustment for various confounding factors (the OR [95% CI] of the highest tertile of TSK: 6.13 [3.34-11.27]). This result was similar to those obtained in our previous studies with white-collar workers³¹ and workers at nursing care facilities,³⁵ which implies that kinesiophobia is an important factor for LBP regardless of job type. Kinesiophobia, an irrational and debilitating fear of movement/(re)injury, can cause a negative vicious cycle in the fear-avoidance model.³⁶ Avoidance of behavior based on kinesiophobia can cause physical inactivity, which has a negative impact on physical and psychological aspects and results in persistence of LBP. Werti et al reported that fear-avoidance beliefs were an important prognostic factor for LBP chronicity⁷ and predicted poor treatment responses in subjects with LBP of less than 6 months.³⁷ Moreover, a recent systematic review has indicated that a greater degree of kinesiophobia at baseline predicted the progression of disability and the subsequent decline of quality of life among subjects with chronic musculoskeletal pain.³⁸ Therefore, our results suggest

that assessment of negative beliefs such as kinesiophobia may help prevent the chronicity of LBP in the workplace.

We found that the presence of a previous episode of LBP was a significant factor associated with disabling LBP, which is consistent with our earlier study in Japan.²⁴ Previous systematic reviews also showed that individuals with a history of LBP were at increased risk of future episodes.^{9 39} Indeed, LBP has been suggested to be liable to recurrence. The recurrence rate of LBP within the first year after the episode has been reported to range from 24% to 50% or more.³⁹ ⁴⁰ This may be because individuals with LBP sometimes reduce their levels of physical activity. which leads to physical deconditioning, including functional changes of the trunk. A recent study indicated that trunk muscle mass was associated with LBP disability.⁴¹ Additionally, our results may indicate that individuals with LBP continue to have the risk factors responsible for the initial occurrence of LBP. Thus, a previous episode of LBP may be an important predictor of future episodes also among nursing personnel.

In this study, sleep disturbance defined as insomnia was found to be an independent factor relevant to disabling LBP among nursing personnel. Previous studies reported that more than 50% of those who suffer from LBP have sleep problems.^{42 43} Although the relationship between disturbed sleep and pain has been considered to be bidirectional, recent studies have focused on the influence of disturbed sleep on pain. Several prospective studies have indicated that sleep problems were associated with a higher risk of chronic musculoskeletal pain onset including LBP.^{10 44} Our findings may be attributable to the decreased pain threshold consequent to sleep disturbance, which has been indicated by experimental studies.⁴⁵ Although the mechanism underlying the association between sleep disturbance and pain remains to be fully understood, the mesolimbic dopamine system has been suggested to play a role via an overlapping neurophysiological mechanism between sleep and pain;⁴⁶ however, because the potential mechanisms involved in these interactions are beyond the scope of our study, further studies including pathophysiological assessments are needed. Our results suggest that in the treatment of

individuals with disabling LBP, assessment and management of both sleep problems and LBP
may have more positive effects on recovery relative to those achieved by targeting sleep or LBP
independently.

The present study investigated the association of disabling LBP with multidimensional factors among nursing personnel, including selective variables with reference to previous findings. These factors were assessed using validated tools, which would reduce the risk of classification bias. However, the study had some limitations. First, participants were recruited from a single hospital, which might limit the generalizability of our results. Second, due to the cross-sectional design, the causality of the associations cannot be determined. Finally, our results might be affected by some potential confounding factors such as psychosocial work-related stress, other lifestyle habits, or socioeconomic status that were not considered in our study.

In conclusion, the present findings obtained with a multivariable logistic regression analysis showed that kinesiophobia, previous episodes of LBP, and insomnia were significantly associated with disabling LBP among nursing personnel. In the future, workplace interventions considering the assessment of these factors can help reduce the incidence of disabling LBP among nursing staff, although further prospective studies are needed to elucidate a causal relationship.

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268 Competing interests:

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279 Authors' contributions

TY and KM contributed to the conceptualization of this study. TY and SI contributed to the data
acquisition. TY and HO analyzed and interpreted the data. SM, AK, and KM contributed to the
supervision of this study. TY drafted the manuscript. All authors have read and approved the final
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	Item No	Recommendation	Page No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	P 1
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what was done and what was found	P 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P 4
Objectives	3	State specific objectives, including any prespecified hypotheses	P 4-5
Methods			
Study design	4	Present key elements of study design early in the paper	P 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P 5
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants	P 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P 5-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P 5-7
Bias	9	Describe any efforts to address potential sources of bias	P 13
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how due study size was arrived at Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P 5-7
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	Р7
		(b) Describe any methods used to examine subgroups and interactions	P 7
		(c) Explain how missing data were addressed	P 7
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy	NA
		(<u>e</u>) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	P 7-8
		(b) Give reasons for non-participation at each stage	P 8
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Р 7-9
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	P 8
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	P 8, 10

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		(b) Report category boundaries when continuous variables were	P 9-10
		categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute	NA
		risk for a meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions,	NA
		and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	P 10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential	P 13
		bias or imprecision. Discuss both direction and magnitude of any	
		potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	P 11-13
		limitations, multiplicity of analyses, results from similar studies, and	
		other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	P 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present	P 13
		study and, if applicable, for the original study on which the present	
		article is based	
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*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Factors associated with disabling low back pain among nursing personnel at a medical center in Japan: A comparative cross-sectional survey

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7 8	2	Factors associated with disabling low back pain among nursing personnel at a medical center in
9 10	3	Japan: A comparative cross-sectional survey.
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15 16 17	6	Takahiko Yoshimoto ^{1,2*} , Hiroyuki Oka ² , Shuhei Ishikawa ³ , Akatsuki Kokaze ¹ , Shingo Muranaga ³ ,
18 19	7	Ko Matsudaira ²
20 21	8	
22 23	9	¹ Department of Hygiene, Public Health and Preventive Medicine, Showa University School of
24 25	10	Medicine, Tokyo, Japan
26 27	11	² Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century
28 29	12	Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan
30 31	13	³ Department of Rehabilitation, Kameda Medical Center, Chiba, Japan
32 33 34	14	
34 35 36	15	*Corresponding author:
37 38	16	Takahiko Yoshimoto
39 40	17	Department of Hygiene, Public Health and Preventive Medicine, Showa University School of
41 42	18	Medicine, 1-5-8 Hatanodai, Shinagawa-ku, Tokyo 142-8555, Japan
43 44	19	Tel: +81(3)3784-8134; Fax: +81(3)3784-7733
45 46	20	E-mail address: yoshimotota@gmail.com
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ABSTRACT

Objectives: Low back pain (LBP) is a common cause of disability among nursing personnel. Although many studies regarding the risk factors for LBP among nursing staff have focused on the physical load at work, multidimensional assessments of risk factors are essential to identify appropriate preventive strategies. We aimed to investigate the association of multidimensional factors (individual, physical, psychological, and occupational) with disabling LBP among nursing personnel in Japan.

Design: Observational study with comparative cross-sectional design.

Setting: Data was collected using the self-administered questionnaire at a tertiary medical center.

Participants: After excluding participants with missing variables, 718 nursing personnel were included in the analysis.

Outcome measures: A self-administered questionnaire assessed individual characteristics, rotating night shift data, severity of LBP, previous episode of LBP, sleep problem, kinesiophobia (Tampa Scale for Kinesiophobia), depressive condition (K6), physical flexibility, and frequency of lifting at work. A logistic regression model was used to evaluate the factors associated with disabling LBP (LBP interfering with work) among nursing personnel.

Results: Of all participants, 110 (15.3%) reported having disabling LBP. The multivariable logistic regression analysis after adjustment for several confounding factors showed that kinesiophobia (highest tertile, adjusted odds ratio [aOR]: 6.13, 95% confidence interval [CI]: 3.34-11.27), previous episode of LBP (aOR: 4.33, 95% CI: 1.50-12.41), and insomnia (aOR: 1.66, 95% CI: 1.05-2.62) were significantly associated with disabling LBP.

Conclusions: The present study indicated that kinesiophobia, a previous episode of LBP, and sleep problems were associated with disabling LBP among nursing personnel. In the future, workplace interventions considering assessments of these factors may reduce the incidence of disabling LBP in nursing staff, although further prospective studies are needed.

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4 5 6	49	Strengths and limitations of this study
7 8	50	> This study focused on disabling low back pain as the outcome of interest which was
9 10	51	considered as a serious problem in workplace.
11 12	52	> This study was designed to assess simultaneously the multidimensional aspects (individual,
13 14	53	physical, psychological, and occupational) of disabling low back pain among nursing
15 16 17	54	personnel in Japan.
18 19	55	> This paper provides results that will be useful in understanding the complexity of low back
20 21	56	pain and developing appropriate strategies for reducing the incidence of occupational low
22 23	57	back pain.
24 25	58	> This study was conducted among participants at one medical center, which might limit the
26 27	59	generalizability of our findings.
28 29	60	> The cross-sectional design of this study could not clarify a causal relationship.
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61 INTRODUCTION

62 The global burden of disease study 2017 indicated that low back pain (LBP) is one of the 63 leading cause of disability worldwide.¹ LBP is a major public health problem with an enormous 64 negative economic impact on individuals, industries, and societies.²³

The etiology of LBP is multifactorial and includes physical factors (physical load at work,⁴ physical flexibility,⁵ etc.) and psychological factors (depression,⁶ and fear-avoidance belief,⁷ etc.).
Among psychological factors, pain-related fear of movement/reinjury, which is known as kinesiophobia, has been suggested to be an important contributor for LBP.⁸ LBP also recurs frequently; thus, a previous episode of LBP can be a predictor of future episodes.⁹ Moreover, lifestyle factors including sleep problems can increase the risk of LBP.¹⁰

Several studies have shown that nursing personnel have a higher prevalence of LBP relative to the general population or other occupational groups,¹¹⁻¹³ which may be related to nursing work-related factors. Indeed, in addition to the above physical and psychological factors, occupationspecific factors such as manual handling^{14 15} and rotating night shifts^{16 17} have been suggested to be associated with the development of LBP among nursing personnel. Because LBP could lead not only to decreased work performance, but also professional abandonment,¹⁸ clarifying the risk factors of LBP and exploring appropriate preventive strategies is essential to reduce the incidence of LBP among nursing professionals.

Although there is ample evidence showing that physical factors, including manual handling, among nursing personnel are a significant risk factor for LBP,^{14 15 18} systematic reviews of interventions for LBP in nurses have indicated that ergonomic interventions for LBP had inadequate results.¹⁹²⁰ Thus, studies investigating the factors associated with LBP among nursing personnel from a multidimensional perspective including individual, physical and psychological factors are increasingly needed. Since the prevalence of disabling LBP varies across countries and occupations,²¹ it may be important to investigate the factors associated with disabling LBP among nursing personnel in Japan in order to design appropriate strategies for reducing the

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87 incidence of occupational LBP. Therefore, we aimed to perform a multidimensional assessment,
88 including individual, physical, psychological, and occupational aspects, of disabling LBP among
89 nursing personnel at a tertiary hospital in Japan.

91 METHODS

92 Study populations

This comparative cross-sectional study was based on a survey conducted among nursing personnel at Kameda Medical Center at Chiba Prefecture, Japan during February 2017. During this period, an anonymous, self-administered questionnaire was distributed to 1,152 workers at the nursing department in the center. After the workers answered the questionnaires, they put them in sealed envelopes. Then, occupational health staff collected and sent the envelopes to the authors. Staff other than the authors were not allowed to open the sealed envelopes. Written informed consent was obtained from each participant. All procedures were approved by the Research Ethics Committee of Kameda Medical Center (Approval No. 16-159) and carried out according to the Declaration of Helsinki.

103 Study measures

The following items were assessed using the self-administered questionnaire: age, sex, height, weight, occupation type (registered nurse, assistant nurse, midwife, or nursing aid), rotating night shift (frequency of shift work per month), severity of LBP, previous episode of LBP, sleep problem, fear-avoidance (kinesiophobia), depressive condition, physical flexibility, and lifting at work. Body mass index (BMI) was calculated as weight (kg) divided by the square of height (m). The severity of LBP, evaluated by respondents, was classified into four grades; grade 0 (no LBP), grade 1 (LBP that did not interfere with work), grade 2 (LBP that interfered with work), and grade 3 (LBP that interfered with work and required sick leave). These grades were determined with reference to Von Korff's grading method.²² The area of LBP (between the costal

margin and inferior gluteal folds) was indicated as a diagram in the questionnaire.²³ LBP was defined as pain lasting for ≥ 1 day and experienced during the past one month, in accordance with the standard definition of LBP proposed by Dionne et al.²⁴ LBP associated with menstrual periods, pregnancy, or febrile illness was excluded. Individuals with disabling LBP were defined as those who had LBP interfering with work, irrespective of sick leave because of LBP (grade 2 or 3).²⁵ Past LBP history characteristics were evaluated in a question regarding the previous episode of LBP.

Sleep problems were assessed using questions about the sleep duration and sleep habits in the previous month.²⁶ Disability of sleep duration was defined by durations < 6 hours. Difficulty initiating sleep was defined as taking more than 30 min to fall asleep. Difficulty maintaining sleep and early morning awakening were defined by the occurrence of nocturnal awakenings or early morning awakenings three times or more per week. The presence of insomnia was defined if the participants reported at least one positive response to the three symptoms of sleep habits above.²⁶ To assess fear of movement/(re)injury, we used the short version of the Tampa Scale for Kinesiophobia (TSK-11).²⁷ The TSK-11 consists of 11 items, each of which is scored on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). The total scores range from 11 to 44, with higher scores indicating greater fear of movement/(re)injury. The Japanese version of TSK-11 has been translated and validated by Matsudaira et al.²⁸²⁹ Participants' scores were classified into tertiles according to their total scores.

Depressive condition was evaluated by using the Kessler 6-item psychological distress scale (K6).³⁰ The K6 consists of six items that assess how frequently respondents experienced symptoms of psychological distress such as nervousness, negative affect, fatigue, and worthlessness over the past 30 days. Each item was rated on a 5-point scale ranging from 0 (none of the time) to 4 (all of the time), with the total score ranging from 0 to 24. The K6 has been translated to a Japanese version, whose reliability and validity have been confirmed by Furukawa et al.³¹ Individuals with a K6 score of ≥ 10 were defined as having a depressive condition in

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accordance with a previous study.³²

Physical flexibility was assessed by using the modified finger-to-floor distance³³ which mainly represents trunk flexibility. The grade of this item was rated on a 7-point scale: 1) fingertips cannot reach across the knees; 2) fingertips can reach across the knees but wrists not; 3) wrists can reach beyond the knees, but fingertips cannot reach the ankles; 4) fingertips can reach the ankles; 5) fingertips can touch the floor; 6) all of the fingers can touch the floor; and 7) palms can touch the floor. Flexibility was classified into two groups based on whether wrists could reach beyond the knee, but fingertips could not reach the ankles.²⁵

Physical work demand was measured with a question exploring the frequency of lifting at work.
The frequency of lifting was divided into 0, 1-4, 5-9, 10 times per shift, and lifting ≥5 times per
shift was defined as frequent with reference to a previous study.¹⁶

151 Statistical analysis

We conducted a multivariable logistic regression analysis because our dependent variable (disabling LBP) was dichotomous. One guideline has suggested that a sample size with at least 10 cases for each independent variable is required to estimate a discriminant function parameters accurately in logistic regression analysis.³⁴ Therefore, based on this guideline and our 11 predictor variables, we required 110 cases for our analysis. Moreover, considering the prevalence of disabling LBP and missing data, we calculated 1,000 participants to ensure the accurate estimation in the analysis.

Data were presented as median (25th, 75th percentile) for continuous variables or number (%) for categorical variables. Characteristics of participants were compared using the chi-squared test for categorical variables and Wilcoxon rank-sum test for continuous variables. To assess factors associated with disabling LBP, a logistic regression model was used to estimate the odds ratio (OR) and 95% confidence interval (CI) for disabling LBP. In the model, the following factors were included for adjustment: sex, age, BMI, frequency of shift work, sleep duration, insomnia,

previous episode of LBP, TSK and K6 scores, flexibility, lifting at work. Multicollinearity was not suspected as all variance inflation factors (VIFs) were <2. A p-value less than 0.05 was considered to be statistically significant (two-sided). All statistical analyses were performed using JMP version 13.0 (SAS Institute Inc., Cary, NC, USA).

Patient and public involvement

Patients and the public were not involved in the design or planning of the study.

RESULTS

Of all workers at the nursing department in the center, 1075 respondents provided answers in the questionnaires (response rate: 93.3%). Since the present study was focused on nursing personnel who provide direct care in the center, 146 employees who were not related to direct nursing care (clerical work or providing guidance to patients, etc.) were excluded. We further excluded 211 participants with missing data for any variable. As a result, 718 nursing staff completed the questionnaire with no missing data and were included in the analysis (completion rate: 66.8%).

The median age of participants in the present study was 31.0 years, and 79.7% of the participants were female. The distribution of LBP severity according to grade was as follows: grade 0 (n = 233), grade 1 (n = 375), grade 2 (n = 104), and grade 3 (n = 6). Thus, 15.3% of the included participants were reported to have disabling LBP. The characteristics of participants with or without disabling LBP are shown in Table 1. The proportions of insomnia (p < 0.001) and previous episode of LBP (p < 0.001) among participants with disabling LBP were higher relative to those observed in participants without disabling LBP. The proportions of those who had high TSK (p < 0.001) or K6 (p < 0.038) scores were higher in the disabling LBP group than in the no disabling LBP group. In contrast, the groups with and without disabling LBP showed no significant differences for physical flexibility and the frequency of lifting at work.

We calculated the crude and adjusted ORs and their 95% CIs for disabling LBP (Table 2). The
non-adjusted analysis showed that insomnia, previous episode of LBP, and TSK and K6 scores
were significantly associated with disabling LBP. Multivariable analysis after adjusting for sex,
age, BMI, and all explanatory variables showed that insomnia (adjusted OR [aOR]: 1.66, 95%
CI: 1.05-2.62), a previous episode of LBP (aOR: 4.31, 95% CI: 1.50-12.41), and TSK score (aOR:
2.08, 95% CI: 1.11-3.89 in middle, aOR: 6.13, 95% CI: 3.34-11.27 in high) remained significantly
associated with disabling LBP.

disabiling LLL.

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Table 1. Characteristics of the study participants
Disabling

	Disabling LBP	No disabling LBP	<i>p</i> -value
	(n = 110)	(n = 608)	
Sex			
Male	31 (28.2%)	115 (18.9%)	0.026
Female	79 (71.8%)	493 (81.1%)	
Age, years	27.5 (24.0, 40.0)	31.0 (24.0, 42.0)	0.052
Body mass index, kg/m ²	21.6 (19.8, 23.3)	21.2 (19.5, 23.9)	0.793
Occupation type			
Registered nurse	88 (80.0%)	495 (81.4%)	0.886
Assistant nurse (practical nurse)	2 (1.8%)	16 (2.6%)	
Midwife	4 (3.6%)	18 (3.0%)	
Nursing aid	16 (14.5%)	79 (13.0%)	
Frequency of shift work, per month	6.0 (2.5, 10.0)	6.0 (0.0, 10.8)	0.571
Sleep duration			
>6 hours	78 (70.9%)	436 (71.7%)	0.864
<6 hours	32 (29.1%)	172 (28.3%)	
Insomnia			
Not have insomnia	47 (42.7%)	366 (60.2%)	< 0.001
Have insomnia	63 (57.3%)	242 (39.8%)	
Previous episode of LBP			
No	4 (3.6%)	97 (16.0%)	< 0.001
Yes	106 (96.4%)	511 (84.0%)	
TSK			
Low (≤17)	18 (16.4%)	252 (41.4%)	< 0.001
Middle (18-23)	32 (29.1%)	206 (33.9%)	
High (≥24)	60 (54.5%)	150 (24.7%)	
К6			
<10	78 (70.9%)	485 (79.8%)	0.038
≥10	32 (29.1%)	123 (20.2%)	
Flexibility			
Flexible	75 (68.2%)	443 (72.9%)	0.314
Not flexible	35 (31.6%)	165 (27.1%)	
Lifting			
Not frequent	45 (40.9%)	289 (47.5%)	0.200
Frequent	65 (59.1%)	319 (52.5%)	

Data are presented as number (percentage) or median (25th, 75th percentile).

LBP, Low back pain; TSK, Tampa scale for kinesiophobia

Table 2. Association between disabling low back pain and independent variables from logistic	
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regression models

	Crude		Adjusted*	
	OR (95% CI)	<i>p</i> -value	OR (95% CI)	<i>p</i> -value
Frequency of shift work, per month	1.00 (0.97-1.04)	0.783	0.98 (0.94-1.02)	0.390
Sleep duration				
>6 hours	1.00		1.00	
<6 hours	1.04 (0.66-1.63)	0.864	1.12 (0.68-1.83)	0.659
Insomnia				
Not have insomnia	1.00		1.00	
Have insomnia	2.03 (1.34-3.06)	< 0.001	1.66 (1.05-2.62)	0.029
Previous episode of LBP				
No	1.00		1.00	
Yes	5.03 (1.81-13.97)	0.002	4.31 (1.50-12.41)	0.007
TSK				
Low (≤17)	1.00		1.00	
Middle (18-23)	2.17 (1.19-3.99)	0.012	2.08 (1.11-3.89)	0.022
High (≥24)	5.60 (3.19-9.84)	< 0.001	6.13 (3.34-11.27)	< 0.001
K6				
<10	1.00		1.00	
≥ 10	1.62 (1.02-2.55)	0.039	1.06 (0.64-1.75)	0.834
Flexibility				
Flexible	1.00		1.00	
Not flexible	1.25 (0.81-1.94)	0.314	0.95 (0.59-1.53)	0.846
Lifting				
Not frequent	1.00		1.00	
Frequent	1.31 (0.87-1.98)	0.201	0.99 (0.62-1.58)	0.973

LBP, Low back pain; TSK, Tampa scale for kinesiophobia; OR, Odds ratio; CI, Confidence interval *Adjusted for sex, age, body mass index, and all other variables which indicated in this table.

DISCUSSION

> The present study investigated the association of disabling LBP with related factors via a multifaceted assessment among nursing personnel at a tertiary hospital. The results of our multivariable logistic regression analysis showed that insomnia, previous episodes of LBP, and

kinesiophobia were independently associated with disabling LBP. To our knowledge, this is the first study that identified a significant association of pain-related fear and insomnia with disabling LBP among nursing personnel in Japan.

In this study, disabling LBP was set as the outcome of interest to identify risk factors for LBP among nursing personnel. In occupational fields, absence from work (absenteeism) due to LBP is often used as the outcome of disability. However, the number of individuals taking a sick leave due to LBP is considerably small. A previous international epidemiological study showed that the prevalence of absenteeism due to musculoskeletal disorders, mainly LBP, was much less common in Japan relative to that in the UK.¹¹ Moreover, it has been suggested that the loss of work performance due to LBP has a greater negative economic impact on individuals and workplaces in terms of healthcare costs and work productivity than sick leaves due to LBP.^{35 36} Therefore, it may be appropriate to define disabling LBP as LBP interfering with work performance with or without sick leave.

Our results showed that high TSK scores were significantly associated with disabling LBP among nursing personnel after adjustment for various confounding factors (the OR [95% CI] of the highest tertile of TSK: 6.13 [3.34-11.27]). This result was similar to those obtained in our previous studies with white-collar workers³² and workers at nursing care facilities,³⁷ which implies that kinesiophobia is an important factor for LBP regardless of job type. Kinesiophobia, an irrational and debilitating fear of movement/(re)injury, can cause a negative vicious cycle in the fear-avoidance model.³⁸ Avoidance of behavior based on kinesiophobia can cause physical inactivity, which has a negative impact on physical and psychological aspects and results in persistence of LBP. Werti et al reported that fear-avoidance beliefs were an important prognostic factor for LBP chronicity⁷ and predicted poor treatment responses in subjects with LBP of less than 6 months.³⁹ Moreover, a recent systematic review has indicated that a greater degree of kinesiophobia at baseline predicted the progression of disability and the subsequent decline of quality of life among subjects with chronic musculoskeletal pain.⁴⁰ Therefore, our results suggest

that assessment of negative beliefs such as kinesiophobia may help prevent the chronicity of LBPin the workplace.

We found that the presence of a previous episode of LBP was a significant factor associated with disabling LBP, which is consistent with our earlier study in Japan.²⁵ Previous systematic reviews also showed that individuals with a history of LBP were at increased risk of future episodes.^{9 41} Indeed, LBP has been suggested to be liable to recurrence. The recurrence rate of LBP within the first year after the episode has been reported to range from 24% to 50% or more.⁴¹ ⁴² This may be because individuals with LBP sometimes reduce their levels of physical activity. which leads to physical deconditioning, including functional changes of the trunk. A recent study indicated that trunk muscle mass was associated with LBP disability.⁴³ Additionally, our results may indicate that individuals with LBP continue to have the risk factors responsible for the initial occurrence of LBP. Thus, a previous episode of LBP may be an important predictor of future episodes also among nursing personnel.

In this study, sleep disturbance defined as insomnia was found to be an independent factor relevant to disabling LBP among nursing personnel. Previous studies reported that more than 50% of those who suffer from LBP have sleep problems.^{44 45} Although the relationship between disturbed sleep and pain has been considered to be bidirectional, recent studies have focused on the influence of disturbed sleep on pain. Several prospective studies have indicated that sleep problems were associated with a higher risk of chronic musculoskeletal pain onset including LBP.^{10 46} Our findings may be attributable to the decreased pain threshold consequent to sleep disturbance, which has been indicated by experimental studies.⁴⁷ Although the mechanism underlying the association between sleep disturbance and pain remains to be fully understood, the mesolimbic dopamine system has been suggested to play a role via an overlapping neurophysiological mechanism between sleep and pain;⁴⁸ however, because the potential mechanisms involved in these interactions are beyond the scope of our study, further studies including pathophysiological assessments are needed. Our results suggest that in the treatment of

individuals with disabling LBP, assessment and management of both sleep problems and LBP
may have more positive effects on recovery relative to those achieved by targeting sleep or LBP
independently.

The present study investigated the association of disabling LBP with multidimensional factors among nursing personnel, including selective variables with reference to previous findings. These factors were assessed using validated tools, which would reduce the risk of classification bias. However, the study had some limitations. First, participants were recruited from a single hospital, which might limit the generalizability of our results. Second, due to the cross-sectional design, the causality of the associations cannot be determined. Finally, our results might be affected by some potential confounding factors such as psychosocial work-related stress, other lifestyle habits, or socioeconomic status that were not considered in our study.

In conclusion, the present findings obtained with a multivariable logistic regression analysis showed that kinesiophobia, previous episodes of LBP, and insomnia were significantly associated with disabling LBP among nursing personnel. In the future, workplace interventions considering the assessment of these factors can help reduce the incidence of disabling LBP among nursing staff, although further prospective studies are needed to elucidate a causal relationship.

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publish, or preparation of the manuscript.

1 2		
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5 6	282	
7 8	283	Competing interests:
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11 12	285	study; grants and personal fees from AYUMI Pharmaceutical Corporation, Nippon Zoki
13 14	286	Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd, Shionogi & Co., Ltd., Eli Lilly Japan,
15 16	287	Astellas Pharma Inc., Toto Ltd., Eisai Co., Ltd., Teijin Pharma Limited, Japan Inc., and Hisamitsu
17 18 19	288	Pharmaceutical Co., Inc.; personal fees from Pfizer Inc., Janssen Pharmaceutical K.K., Kaken
20 21	289	Pharmaceutical Co., Ltd., Mochida Pharmaceutical Co., Ltd., and Daiichi Sankyo Company,
22 23	290	Limited; grants from Sompo Holdings, Inc., MTG, NuVasive Japan, and Murata Manufacturing
24 25	291	Co., Ltd.; grants from Okamura Corporation; and non-financial support from Trunk Solution Co.,
26 27	292	Ltd. outside the submitted work. The other authors report no conflicts of interest in this work.
28 29	293	
30 31	294	Authors' contributions
32 33	295	TY and KM contributed to the conceptualization of this study. TY and SI contributed to the data
34 35 26	296	acquisition. TY and HO analyzed and interpreted the data. SM, AK, and KM contributed to the
36 37 38	297	supervision of this study. TY drafted the manuscript. All authors have read and approved the final
39 40	298	manuscript.
41 42	299	Data availability statement
43 44	300	Data availability statement
45 46	301	The data used in the current study are available on reasonable request and only after approval by
47 48	302	the Research Ethics Committee of Kameda Medical Center.
49 50 51 52	303	
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	Item No	Recommendation	Page No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	P 1
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what was done and what was found	P 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P 4
Objectives	3	State specific objectives, including any prespecified hypotheses	P 4-5
Methods			
Study design	4	Present key elements of study design early in the paper	P 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P 5
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants	P 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P 5-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment	Р 5-7
		methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	P 13
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Р 5-7
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	Р7
		(b) Describe any methods used to examine subgroups and interactions	P 7
		(c) Explain how missing data were addressed	P 7
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy	NA
		(e) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	P 7-8
		(b) Give reasons for non-participation at each stage	P 8
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Р 7-9
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	P 8
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	P 8, 10

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		(b) Report category boundaries when continuous variables were	P 9-10
		categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute	NA
		risk for a meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions,	NA
		and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	P 10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential	P 13
		bias or imprecision. Discuss both direction and magnitude of any	
		potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	P 11-13
		limitations, multiplicity of analyses, results from similar studies, and	
		other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	P 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present	P 13
		study and, if applicable, for the original study on which the present	
		article is based	

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.