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A randomized controlled trial of mindfulness-based stress reduction for insomnia secondary to cervical cancer: Sleep effects

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ABSTRACT

Aim: To evaluate the efficacy of mindfulness-based stress reduction on objective and subjective sleep parameters and hypnotic medication use of patients with insomnia secondary to cervical cancer.
Methods: This was a randomized controlled trial enrolled insomnia patient who were caused or worsened by cervical cancer. Seventy patients with insomnia caused or aggravated by cervical cancer were at random divided into either a usual care group or an 8-week mindfulness-based stress reduction group. Subjective sleep parameters, objective sleep parameters and hypnotic medication consumption were assessed at baseline, after the program, 6- and 12-month after finishing the interventions.
Results: The results showed that mindfulness-based stress reduction had a positive effect on subjective sleep parameters (Total wake time: $\Delta = 45.32$, $P < 0.05$; Sleep efficacy: $\Delta = 6.87$, $P < 0.05$; Total sleep time: $\Delta = 22.22$, $P < 0.01$). Compared with control group, polysomnography data in mindfulness-based stress reduction group were not improved significantly. There were no associations between subjective sleep parameters and objective sleep parameters.
Conclusion: Mindfulness-based stress reduction had a definite impact on patients with insomnia that was secondary to cervical cancer just after the intervention, but no long-term influences.
Trial registration: ChiCTR1800018571; 9/25/2018; retrospectively registered.

1. Introduction

Cervical cancer is the second most common type of cancer among women in Southeast Asia and the leading cause of cancer deaths among women in low- and middle-income countries (Shrestha, Neupane, Vedsted, & Kallestrup, 2018). Therapies for stages I and II cervical cancer patients involve surgical operation that is integrated with chemotherapy/radiotherapy. Considering radiotherapy- and hysterectomy-induced urodynamic modifications (decreased storage, bladder emptying ability, and urinary incontinence) (Lin, Wu, Yang, Sheu, & Lin, 2004), cervical cancer patients are more likely to have bad sleep quality (Lin et al., 2004; Lutgendorf et al., 2002). During the time of diagnosis and treatment, patients with cervical cancer frequently have high distress (Costanzo, Lutgendorf, Rothrock, & Anderson, 2006). Since they are susceptible to a broad scope of troubles (loss of fertility, early menopause, sexual disharmony, and poor living circumstances) (Burns, Costello, Ryan-Woolley, & Davidson, 2007). Throughout therapy, the patients can be made in sensory discomfort and pain by chemotherapy-induced peripheral neurotoxicity (CIPN) (Markman, 1996). Activities restriction throughout the day and decrease exposure to natural illumination can lead to alterations in the regularity of rhythms (Lee, Cho, Miaskowski, & Dodd, 2004). These phenomena consequently make cervical cancer patients possibly at elevated danger for sleep disturbance. Non-pharmacological therapies, nevertheless, are preferred by cancer patients for sleep troubles (Davidson, Feldman-Stewart, Brennenstuhl, & Ram, 2007), stimulating the need for studies concerned with non-pharmacological interventions for insomnia secondary to cancer.

Psychological interventions ought to be the favored option, in relation to hypnotic medications, while insomnia is chronic (Hall, 1998). Though cognitive-behavioral treatment has been recognized as a reliable non-pharmacological therapy for insomnia, it does not focus on anxieties and raised psychological distress of recurrence among cancer survivors (Espie et al., 2008). Positive effects on depression and anxiety were shown by a study concerned with mindfulness-based treatment for cancer patients (Piet, Wurtzen, & Zachariae, 2012). Furthermore, several studies have revealed that Mindfulness-based stress reduction (MBSR) significantly enhanced outcomes of subjective sleep parameters

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(SSP) among cancer survivors (Carlson, Speca, Patel, & Goodey, 2003; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003). However, studies carried out on insomnia linked to cervical cancer are rare.

Previous researches provided mixed outcomes of relaxation training's effect on insomnia symptoms of tumor patients (Stam & Bultz, 1986). More lately, nonrandomized studies illustrated certain results for insomnia (i.e., improved subjective sleep) (Davidson, Waisberg, Brundage, & MacLean, 2001; Simeit, Deck, & Conta-Marx, 2004). A randomized trial, however, is still needed to better explore the effect of MBSR on patients with insomnia secondary to cancer.

Therefore, the study's object was to evaluate MBSR's influences on sleep parameters and hypnotic medication use of patients with insomnia secondary to cervical cancer. This study was a randomized controlled trial. It was registered on Chinese Clinical Trial Registry (registered number: ChiCTR1800018571). The ethic approval was obtained from the ethic committee of Wuchang University of Technology. All written informed consent was obtained from the participators.

2. Methods

In this study, participants were recruited between June 2017 and July 2017 from a tertiary hospital in China, subsequently, those who were eligible for the trial were selected (more detail information was shown in the section of participants). Doctors were asked to assist in identification of eligible patients. If patients met the inclusion criteria, then doctors would invite them to join an introduction meeting. During the meeting, informed consent was collected. After participants were enrolled, they were assigned through a computer-based random assignment program with a 1:1 allocation ratio. Then participants received an e-mail (send by the organizer) that contained the assignment information (MBSR group or the control group). Both the main researchers and patients were kept blind to allocation through the study period.

Before the intervention, a self-report questionnaire, including the information of medical history and demographic data, was acquired. In addition, the subjective sleep parameters (SSP) including the sleep diary and the insomnia severity index (ISI) and the objective sleep parameters (OSP) including polysomnography (PSG) and wrist actigraphy was obtained as the baseline data for the MBSR group or control group.

For the MBSR group, the MBSR was conducted during August 2017 and September 2017. The MBSR facilitator was a professor from Wuchang University of Technology. He has almost 8 years of experience in delivering MBSR to cancer patients. We run the MBSR intervention as one group for all 35 patients. Each time was a two-hour of MBSR conducted at afternoon on every Sunday in the Third Hospital of Wuhan. The specific implementation plan was shown in Table 1. For the control group, the patients were given usual care.

In order to assess the effect of MBSR, the subjective sleep parameters and objective sleep parameters were assessed after the program (September 2017), 6- and 12-month after finishing the interventions (March 2018 and September 2018). All the subjective sleep parameters and objective sleep parameters were collected at the hospital. The PSG data were the averages of nights 2 and nights 3 for each assessment point. Taking patients' adaptation to the laboratory setting into consideration, night 1 was excluded. In addition, patients were asked to wear an actigraphy on their wrist for three uninterrupted 24 h durations (Carter, 2006; Littner et al., 2003). Besides, at every assessment time point, the patients spent 3 successive nights in the laboratory to objectively evaluate therapeutic advance (Ancoli-Israel et al., 2006; Mormont & Waterhouse, 2002).

Table 1
The content of MBSR.

Time	Content
First week	Somatosensory scans (experiencing body sensation)
Second week	Mindfulness breathing exercise (experience gas in and out)
Third week	Perceive inner thoughts, emotions and meditation
Fourth week	Mindfulness stretching exercise
Fifth week	Body scanning
Sixth week	Meditation in nature
Seventh week	Mindfulness awareness, mindfulness eating
Eighth week	Sharing and summarizing

2.1. Participants

Adults with cervical cancer diagnosis were eligible for the trial provided that they had finished radiation treatments and chemotherapy no < 1 month before participating our study. Patients were asked to satisfy insomnia's diagnostic criteria, defined as time awake after sleep onset or sleep latency > 30 min and sleep efficiency of not > 85%, with disturbances occurring 3 or more days per week for producing considerable damage and at the very least 1 month in functioning (Edinger et al., 2004). Meanwhile, only patients whose insomnia was assessed to be associated with cervical cancer were involved in the research. In addition, the patients with weighty psychiatric disorder or severe major depression were excluded.

The exclusion criteria are as follows: (i) presence of another weighty psychiatric disorder or severe major depression; (ii) presence of sleep disorders except insomnia (e.g., periodic limb movements, sleep apnea); (iii) presence of another sickness impacting the immune system (e.g., the infection of HIV); (iv) current participation in psychotherapy; (v) regularly using a psychotropic medication except hypnotics (e.g., antidepressants), unless the dose that was used was steady in the past month and did not rise during the study.

Patients that used a steady dose of hypnotic medication would not be eliminated from the study, if they satisfied all criteria that were depicted. Therefore, hypnotic users involved in the research all reported clinically significant insomnia in spite of medication usage (thus recommending restricting its usage). The Inclusion of such patients may push external validity of the study up. The alterations in hypnotic consumption were regarded as results of our research. Some researches carried out in the context of main (Backhaus, Hohagen, Voderholzer, & Riemann, 2001; Espie, Inglis, Tessier, & Harvey, 2001a) or secondary (Currie, Wilson, Pontefract, & DeLaplante, 2000; Rybarczyk, Lopez, Benson, Alsten, & Stepanski, 2002) insomnia have involved patients taking hypnotic medications and then utilized this variable as a result. Statistical analyses were however carried out to guarantee these patients' inclusion did not have an influence on the intervention's effect on other sleep variables.

2.2. Outcome measures

2.2.1. Medical history and demographic data

Data were acquired through self-report questionnaires. Demographic data included age, marital status, education and occupation. Medical history data encompassed dates and types of therapies, cancer diagnosis, insomnia condition and so on.

2.2.2. Subjective sleep parameters (SSP)

Sleep diary: Standard subjective assessment tool for insomnia, which allows patients to monitor sleep for long periods of time at home. Patients should be asked to record the previous night's sleep immediately after getting up in the morning. Sleep latency, total wake time (TWT), total sleep time (TST), sleep efficiency (SE) and sleep quality can be obtained from the sleep diary. Sleep diary is a key tool to obtain baseline data of patients before treatment, sleep changes during treatment, effect evaluation after treatment and follow-up evaluation.

Insomnia Severity Index: The Insomnia Severity Index (ISI) (Morin, 1993) includes seven items. According to the grading scale (0–4 points), the total score is 0–28 points. 0–7 points: no sleep disorders; 8–14

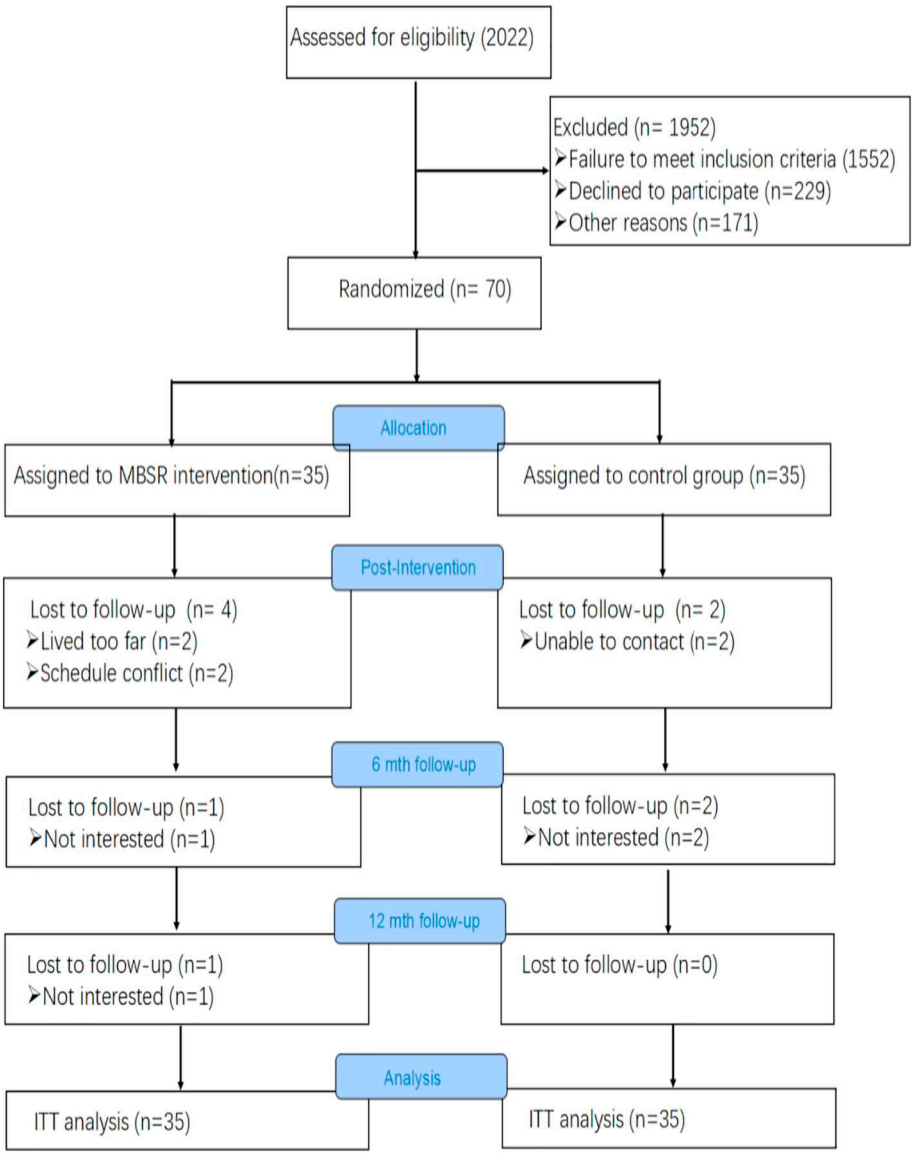

Fig. 1. The CONSORT flow diagram.

points: general sleep, in the subclinical insomnia stage; 15–21 points: moderate insomnia; 22–28 points: severe insomnia.

2.2.3. Objective sleep parameters (OSP)

Polysomnography (PSG): Polysomnography is an objective criterion used in sleep studies to obtain baseline levels of sleep disorders in insomniacs. PSG not only recorded electroencephalogram (EEG), ocular and mandibular electromyogram (EMG), but also recorded electrocardiogram (ECG), oxygen saturation and nasal respiratory pressure during sleep. Respiration and anterior tibialis electromyography were also assessed to rule the presence of periodic limb movements or sleep apnea out. This procedure was conducted by a competent technician who was unfamiliar with experimental circumstance.

Wrist actigraphy: The actigraphy uses an accelerometer to sense and document movement (Webster, Kripke, Messin, Mullaney, & Wyborney, 1982). Actigraphy is adopted among tumor patients and supplies clinical outcomes' predictive validity. In general, it has compliance's approximations at 88% more than a 5-day duration (Berger & Farr, 1999). In accordance with recommendations (Berger et al., 2008), sleep parameters were assessed using the following measures: (i) latency to fall asleep; (ii) SE; (iii) Number of waking bouts; (iv) TST.

2.3. Sample size

The significant difference in insomnia severity is a decrease of 8 points on the ISI (Morin, Belleville, Belanger, & Ivers, 2011). Based on previous studies, the standard deviation was 6 points (Savard, Simard, Ivers, & Morin, 2005). The significance level was set at 5%. Taking 20% attrition into consideration, 35 patients in every arm would supply enough power (80%).

2.4. Statistical methods

Firstly, independent-samples *t*-test, x^2 test, and Fisher's exact test were applied to compare the arms regarding clinical and demographic variables. Secondly, linear mixed model (LMM) for repeated measures was used to analyze the data. All the obtained data from to quantify the treatment's impact were analyzed based on an intent-to-treat analysis without imputing missing data. All statistical tests were two-sided. $P < 0.05$ was regarded to be statistically significant (SAS version 9.3; SAS Institute, Inc., Cary, NC).

Table 2
Demographics and clinical characteristics of intention-to-treat sample.

	Demographic or clinical characteristic	MBSR (n = 35)		Control (n = 35)	
		No.	%	No.	%
Age, years	Mean	57.78		58.45	
	SD	11.12		11.08	
Marital status	Married or living with partner	30	85.71	23	65.7
	Other	5	14.29	12	34.3
Education, years	Mean	15.13		15.14	
	SD	3.66		4.07	
Occupation	Employed	19	54.29	20	57.14
	Retired	9	25.71	10	28.57
	Other	7	20.00	5	14.29
Time since cancer diagnosis, years	Mean	3.53		3.46	
	SD	4.12		4.18	
Cancer stage at diagnosis	I	22	62.86	24	68.57
	II	8	22.86	6	17.14
	III	5	14.29	5	14.29
Previous treatment	Surgery	23	79.3	26	83.9
	Chemotherapy	15	51.7	14	45.2
	Radiation	12	41.4	15	48.4
	Hormonal	4	13.8	5	16.1
Current treatment	Hormonal	8	27.6	13	41.9
	Sedatives/hypnotics	10	34.5	9	29.0
	Anxiolytics	9	31.0	12	38.7
	Antidepressants	11	37.9	10	32.3
Insomnia duration, years	Mean	2.22		2.45	
	SD	1.45		1.72	
Insomnia type	Initial	10	28.57	9	25.71
	Middle	11	31.43	8	22.86
	Late	0	0.00	0	0.00
	Mixed	14	40.00	18	51.43
Dairy quantity of hypnotics used (diazepam equivalent, mg)	Mean	1.62		1.81	
	SD	2.34		2.82	

3. Result

3.1. Participants

Between June 2017 and July 2017, 2022 patients were evaluated and 70 were at random assigned. Each group have 35 parents. Research process was showed in Fig. 1. The demographic, treatment and insomnia characteristics of the two groups were not statistically different at baseline (Table 2). During the intervention, some patients drop out (4 for the MBSR group and 2 for the control group). At 6-month follow-up and 12-month follow-up, more 2 patients dropped out (Fig. 1).

3.2. Effect of MBSR on SSP

3.2.1. Sleep diaries

Estimated marginal group mean and standard error for TWT, SE and TST are showed in Table 3. The LMM on TWT comparing the effects of the two groups showed a significant interaction (P = 0.004). Compared

Table 3
Objective sleep parameters (OSP).

Outcomes	Assessment Time								Effect Size (Cohen's d)	
	Baseline		Post		6-month		12-month			
	Estimated Marginal Group Mean	SE	Estimated Marginal Group Mean	SE	Estimated Marginal Group Mean	SE	Estimated Marginal Group Mean	SE	Baseline to 6 months	Baseline to 12 months
Sleep diary										
TWT, minutes										
MBSR	115.71	60.04	73.11	33.61	64.61	33.28	66.92	30.02	0.80	0.92
Control	86.80	66.98	85.84	70.18	85.11	71.21	84.92	72.30	0.03	0.07
SE, %										
MBSR	77.24	11.02	84.11	10.79	87.71	6.35	88.93	6.52	0.60	1.33
Control	80.88	13.04	81.44	12.39	79.12	14.09	79.33	13.88	0.06	0.04
TST, minutes										
MBSR	367.28	73.96	389.14	70.24	409.81	41.33	413.62	69.69	0.17	0.86
Control	357.21	67.94	366.82	81.49	360.12	80.10	358.42	66.12	0.11	0.12
ISI (total scale)										
MBSR	17.22	4.42	10.82	5.68	9.66	4.67	9.42	4.11	1.35	1.58
Control	16.20	3.62	15.42	5.90	16.13	3.42	15.33	6.21	0.02	0.05

NOTE, TWT, total wake time; TST, total sleep time; SE, sleep efficiency; ISI, Insomnia Severity Index; MBSR, mindfulness-based stress reduction; SE, standard Error. No significant differences were found at baseline on any of the patient-reported outcome measures.

Table 4
Objective sleep parameters (OSP).

Outcomes	Assessment time								Effect size (Cohen's *d*)	
	Baseline		Post		6-month		12-month			
	Estimated marginal group mean	SE	Estimated marginal group mean	SE	Estimated marginal group mean	SE	Estimated marginal group mean	SE	Baseline to 6 months	Baseline to 12 months
PSG										
TWT, minutes										
MBSR	83.42	56.71	75.12	40.21	92.21	57.14	98.70	56.23	0.25	0.54
Control	75.32	35.11	70.12	29.22	72.13	38.26	71.40	39.27	0.11	0.19
TST, minutes										
MBSR	389.22	60.75	398.32	47.23	377.66	57.92	376.41	56.63	0.40	0.62
Control	402.56	53.49	403.71	40.12	403.62	39.32	404.32	40.43	0.04	0.09
SE, %										
MBSR	81.44	7.32	82.63	8.62	83.32	9.23	82.77	9.72	0.23	0.59
Control	82.55	5.78	83.42	4.92	82.17	6.35	82.12	6.78	0.22	0.20
Actigraphy										
TWT, minutes										
MBSR	73.46	37.82	62.88	26.12	64.18	31.06	67.31	27.78	0.48	0.59
Control	60.72	29.47	60.34	23.58	59.22	24.78	59.44	27.12	0.04	0.10
TST, minutes										
MBSR	382.52	44.11	384.04	56.77	380.11	66.21	381.23	65.11	0.01	0.17
Control	355.62	54.91	376.48	62.17	368.23	63.78	369.24	64.18	0.33	0.30
SE, %										
MBSR	81.50	7.11	82.92	8.14	80.81	11.30	81.12	8.03	0.61	0.84
Control	82.14	5.56	83.62	5.12	84.42	4.02	82.43	5.20	0.01	1.40

with control group, the rates of reduction in TWT of MBSR group revealed significantly greater. Throughout all therapy weeks, the MBSR group had 45.32 fewer minutes of TWT while the control group had only 0.96 fewer minutes. There were also significant interactions on SE Table 2. Demographics and clinical characteristics of intention-to-treat sample ($N = 70$) and TST. The alteration caused by the MBSR group exceeded that caused by control group. In respect of SE, for the MBSR group, the greatest alteration was noticed from baseline to the program's post ($\Delta = 6.87$, $P < 0.001$). No significant changes were produced by the control group at the study process' different assessment points. For TST, MBSR group was significantly better than control group after the program ($\Delta = 22.22$, $P < 0.001$).

3.2.2. ISI

For ISI, a significant interaction was revealed by the LMM, which was conducted to compare the average effects of the MBSR to control group ($P < 0.0001$). The MBSR group showed significantly reduction on the ISI compared with control group. The MBSR group got a decrease of 6.40 in ISI scores from baseline to post, and the Control group just had a diminution of 0.78 in ISI scores (Table 3). The LMM comparing ISI scores between the 2 groups (MBSR group vs. Control group) revealed a significant interaction ($P < 0.05$). With regard to the long-term effect, the reduction rate of ISI scores was significantly higher in the MBSR group than that in the Control group from baseline to 6-month follow-up.

3.3. Effect of MBSR on OSP

LMM analysis of OSP using actigraphy and PSG showed that only two actigraphy-based measurement variables (TST and TWT) were significantly found, while no significant changes of PSG-based sleep parameters were found. Firstly, comparing the effect of MBSR group to control group, the LMM on actigraphy-measured TWT showed a significant change ($P < 0.05$). Compared with control group, the TWT in MBSR group was reduced by 10.58 min. However, there was no significant difference among the groups at post ($P = 0.66$). Secondly, the LMM for on TST measured by actigraphy suggested a significant interaction ($P < 0.01$) between the two groups. Again, there was no significant difference among the groups at post ($P = 0.49$, Table 4) for estimated marginal group mean and standard error on OSP.

3.4. MBSR adherence and sleep parameters

There were no statistically correlations between the quantity of MBSR training and sleep parameters measures (Lengacher et al., 2015).

4. Discussion

This research aimed at evaluating MBSR's efficacy as a therapy for chronic insomnia that was secondary to cervical cancer. In summary, MBSR was discovered to have small impacts on insomnia secondary to cervical cancer. But the long-term effect was not satisfied. First, the findings illustrated therapy efficacy's evidence for MBSR to decrease TWT, raise SE and TST in SSP from baseline to post-intervention. Secondly, PSG data between the two groups showed no significantly differences. Furthermore, the effect sizes in this study are overall similar to previous studies concerned with sleep problems (Redeker et al., 2017), offering evidence that compared with UC, MBSR is a viable non-pharmacological therapy for insomnia associated with cervical cancer.

SSP consequences suggested that patients in MBSR group had better SE and less sleep problems compared with patients in control group, which were consistent with previous researches. For instance, Garland et al. (2014) found improvements in sleep problems and sleep disturbance among patients suffering insomnia comorbid with cancer. In addition, Ong et al. (2014) also discovered the positive effect of MBSR for chronic insomnia.

Small nonsignificant improvements were discovered in OSP among the patients in MBSR group. Consistent with our discoveries, Cincotta, Gehrman, Gooneratne, and Baime (2011) reported that MBSR was not discovered to enhance OSP outcomes in a nonrandomized study ($P = 0.06$). Therefore, our research offers the empirical evidence for a definite relationship between OSP improvements and MBSR to some degree.

The dissociation between OSP and SSP is a well-known phenomenon in sleep researches (Zhang & Zhao, 2007) and is beginning to appear in medication-based sleep studies as well. Lacking the

correlation between SSP and OSP is interpreted as a result of PSG's infirm ecologic validity. Insomnia is a circumstance defined mainly by a subjective complaint of poor sleep. Questionnaires and sleep diaries can better explain this subjective discontent with sleep (Krystal, 2004).

There are also some notable limitations. Due to the study design, MBSR's impacts on chronic insomnia could have been the results of influences of meeting regularly with other participants (Espie, Inglis, Tessier, & Harvey, 2001b). Additionally, the possibility of speculating on MBSR's effects is limited by the use of an 8-week MBSR program. For the reason that MBSR applies various kinds of meditative skills, it is hard to resolve which skills are connected with which outcomes. Therefore, in order to better explore the relationship between the component of MBSR and the outcome, the training time of MBSR should be appropriately prolonged.

5. Conclusion

In conclusion, the study suggests that patients with chronic insomnia secondary to cervical cancer may benefit from MBSR in short-term efficacy, but the long-term maintenance effect is not satisfactory. By serving as a more desirable choice to supplementation with hypnotics, MBSR may offer cervical cancer patients a sustainable recovery from sleep.

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Declaration of Competing Interest

We confirm that this manuscript has not been published elsewhere and is not under consideration by another journal. All authors have approved the manuscript and agree with submission. The authors have no conflicts of interest to declare.

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