Acupuncture for insomnia in patients with breast cancer undergoing chemotherapy: a randomised sham-controlled trial (abridged secondary publication)

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KEY MESSAGES

1. Insomnia is a highly prevalent symptom during and after chemotherapy.
2. Acupuncture was not superior to the sham control in reducing the Insomnia Severity Index score from baseline to 6 weeks (mean difference= -0.4, P=0.609). However, it achieved superior short-term and long-term outcomes in improving sleep onset latency, total sleep time, sleep efficiency, anxiety, depression, and quality of life. The acupuncture group exhibited a higher cessation rate of sleeping medication use (56.5% vs 14.3%, P=0.011).
3. Acupuncture could be considered for the management of chemotherapy-associated insomnia and for tapering or replacing sleeping medications in patients with breast cancer.

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Introduction

More than one-fourth of patients with breast cancer experience insomnia during chemotherapy. Insomnia increases the risks of psychiatric and physical comorbidities and reduces patients' willingness to complete treatment. This study aimed to evaluate the efficacy and safety of acupuncture for chemotherapy-associated insomnia in patients with breast cancer.

Methods

Women aged 18 to 75 years with a diagnosis of stage I-IV breast cancer who were undergoing or had completed chemotherapy within the past 6 months and had insomnia were invited to participate. Insomnia was defined as occurring at least 3 nights per week and persisting for >1 month, based on the diagnostic criteria for brief insomnia disorder in the Diagnostic and Statistical Manual of Mental Disorders (5th Edition). The Insomnia Severity Index (ISI) score was required to be at least 10 over the past 2 weeks. Patients were excluded if they had other sleep disorders, irregular sleep patterns or shift work; severe hearing, visual, or language impairments; severe haematological dysfunction; pacemakers or other electronic implants that could interfere with electroacupuncture; acupuncture treatment within the past 3 months; or participation in other clinical trials within the past 3 months.

Permuted block randomisation was used. Investigators and participants were blinded to group allocation. Acupuncture treatments were administered by registered Chinese medicine practitioners with at least 5 years of clinical practice experience. Participants received 15 treatment sessions; 12 sessions were provided twice weekly over 6 consecutive weeks as intensive treatment, and then three sessions were provided once every 4 weeks between weeks 7 and 18 to maintain treatment effects. Participants were followed up between weeks 19 and 42.

The active acupuncture regimen consisted of electroacupuncture at body acupoints and auricular acupressure. Six acupoints (EX-HN1, GV20, GV24, PC6, KI3, and SP6) were selected for insomnia treatment. Four additional acupoints were used to address comorbid symptoms. Auricular acupressure involved embedding hard, black *Vaccaria* seeds on the surfaces of three bilateral auricular points (Heart, Shenmen, and Sympathetic).

Sham acupuncture was performed at points located 1 to 2 cm adjacent to the meridian-based acupoints. Streitberger non-invasive retractable needles were used. Sham auricular acupressure was performed at points in the helix region (HX7, HX8, HX9). Soft stem piths of Medulla Junci were used to

TABLE 1. Characteristics of participants

Characteristic	Active acupuncture (n=69)*	Sham acupuncture (n=69)*	Total (n=138)*
Age, y	51.7±9.6	52.7±8.3	52.2±9.0
Body mass index, kg/m2	22.8±2.9	24.0±16.9	23.4±12.1
Marital status			
Married or living with partner	48 (69.6)	45 (65.2)	93 (67.4)
Single, separated, divorced, or widowed	21 (30.4)	24 (34.8)	45 (32.6)
Education level			
Primary or below	7 (10.1)	8 (11.6)	15 (10.9)
Secondary	33 (47.8)	33 (47.8)	66 (47.8)
Post-secondary or above	29 (42.0)	28 (40.6)	57 (41.3)
Household monthly income, HK$			
<20 000	36 (52.2)	39 (56.5)	75 (54.3)
20 000-50 000	23 (33.3)	13 (18.8)	36 (26.1)
>50 000	10 (14.5)	15 (21.7)	25 (18.1)
No answer	0	2 (2.9)	2 (1.4)
Occupation			
Professional and associate professional	22 (31.9)	20 (29.0)	42 (30.4)
Skilled and semi-skilled worker	3 (4.3)	3 (4.3)	6 (4.3)
Unskilled worker	19 (27.5)	12 (17.4)	31 (22.5)
Retired/unemployed/housework	25 (36.2)	34 (49.3)	59 (42.8)
Menopausal status			
Premenopausal	4 (5.8)	1 (1.4)	5 (3.6)
Perimenopausal	13 (18.8)	13 (18.8)	26 (18.8)
Postmenopausal	52 (75.4)	55 (79.7)	107 (77.5)
Breast cancer stage			
I	13 (18.8)	19 (27.5)	32 (23.2)
II	29 (42.0)	26 (37.7)	55 (39.9)
III	15 (21.7)	17 (24.6)	32 (23.2)
IV	10 (14.5)	7 (10.1)	17 (12.3)
No answer	2 (2.9)	0	2 (1.4)
Prior surgery	61 (88.4)	64 (92.8)	125 (90.6)
Prior radiotherapy	37 (53.6)	40 (58.0)	77 (55.8)
Prior hormonal therapy	34 (49.3)	38 (55.1)	72 (52.2)
Adjuvant chemotherapy	51 (73.9)	57 (82.6)	108 (78.3)
Chemotherapy			
In progress	15 (21.7)	17 (24.6)	32 (23.2)
Post	54 (78.3)	52 (75.4)	72 (52.2)
Chemotherapy regimens			
Adriamycin and cyclophosphamide, or docetaxel and cyclophosphamide	14 (20.3)	20 (29.0)	34 (24.6)
Docetaxel, adriamycin, and cyclophosphamide	6 (8.7)	10 (14.5)	16 (11.6)
Adriamycin and cyclophosphamide, or epirubicin and cyclophosphamide + docetaxel or paclitaxel	13 (18.8)	9 (13.0)	22 (15.9)
Fluorouracil, epirubicin and cyclophosphamide + docetaxel	8 (11.6)	5 (7.2)	13 (9.4)
Carboplatin-containing	17 (24.6)	14 (20.3)	31 (22.5)
Others	11 (15.9)	11 (15.9)	22 (15.9)
Insomnia duration, mo	9.0 (3.0-13.5)	10.0 (5.5-15.0)	9.0 (4.8-14.0)
Sleep aids, prior 2 weeks			
Sleep medications	26 (37.7)	19 (27.5)	45 (32.6)
Chinese herbal medicine	16 (23.2)	24 (34.8)	40 (29.0)
Prior acupuncture	50 (72.5)	46 (66.7)	96 (69.6)
Insomnia Severity Index	17.4±4.3	16.7±4.5	17.1±4.4
Pittsburgh Sleep Quality Index	13.6±3.4	12.7±3.3	13.1±3.4
Actiwatch			
Sleep onset latency, min	14.2±14.5	14.2±12.3	14.2±13.4
Wake after sleep onset, min	112.6±40.2	112.5±38.4	112.5±39.2
Total sleep time, min	359.1±51.1	357.7±51.3	358.4±51.0
Sleep efficiency, %	72.8±7.9	72.9±7.5	72.8±7.7
Sleep diary			
Sleep onset latency, min	51.5±38.6	47.8±35.7	49.6±37.1
Wake after sleep onset, min	58.0±44.0	56.2±47.1	57.1±45.4
Total sleep time, min	319.4±85.2	331.1±96.8	325.3±91.1
Sleep efficiency, %	64.8±15.4	68.2±17.9	66.5±16.8
Hospital Anxiety and Depression Scale			
Anxiety	9.2±3.9	8.6±3.2	8.9±3.6
Depression	8.4±4.1	8.1±3.8	8.3±3.9
Brief Fatigue Inventory	5.6±2.1	5.6±2.1	5.6±2.1
Brief Fatigue Inventory-Short Form			
Pain severity	3.4±2.9	4.3±2.4	3.9±2.7
Pain interference	3.3±3.1	3.9±2.7	3.6±2.9
Functional Assessment of Cancer Therapy-Breast Cancer	80.3±21.3	82.5±19.7	81.4±20.4
Acupuncture Expectancy Scale	14.8±3.4	14.8±3.3	14.8±3.3

* Data are presented as mean ± standard deviation or No. (%) of participants

mimic auricular acupressure.

The primary outcome was the change in ISI score from baseline to 6 weeks of treatment. Secondary outcomes included sleep measures (Actiwatch recordings, sleep diaries, and the Pittsburgh Sleep Quality Index), depression and anxiety (measured using the Hospital Anxiety and

Depression Scale), fatigue (measured using the Brief Fatigue Inventory), pain (measured using the Brief Pain Inventory-Short Form), and quality of life (measured using the Functional Assessment of Cancer Therapy-Breast Cancer).

The proportion of participants prescribed sleeping medications was recorded, along with the dosage and weekly frequency of use. The dosage was standardised by conversion to diazepam-equivalent dosages. Four mean dosages were calculated by averaging values across 2-week periods at four time points (prior to study entry, post-treatment 6 and 18 weeks, and before the end of follow-up).[1] The cessation rate of sleeping medication use was determined.

Based on a previous study involving participants with an ISI score difference of 2.5 and a pooled standard deviation of 4.7,[2] a sample size of 138 participants was required to achieve a 95% level of significance and 80% power, assuming a 20% dropout rate. Efficacy was analysed according to the intention-to-treat principle. Missing data were handled using the multiple imputation method under the missing-at-random assumption. Comparisons were made using a mixed-effects model adjusted for baseline values, time, group, and their interaction.

Results

Of 415 patients screened, 166 were eligible, but 28 declined to participate. The remaining 138 participants were randomly assigned to receive either active acupuncture (n=69) or sham acupuncture (n=69). Among these, 15 (10.9%) participants discontinued within the first 6 weeks, and 23 (16.7%) discontinued before trial completion. The active acupuncture group had a lower discontinuation rate (8.7% vs 24.6%, P=0.012) and a higher rate of completing at least 12 treatments (97.1% vs 81.2%). The two groups were comparable in terms of baseline characteristics (Table 1).

The active acupuncture group demonstrated a higher cessation rate of sleeping medication use during weeks 18 to 20, compared with the sham control group (56.5% vs 14.3%, P=0.011). However, the two groups did not differ significantly in dosage of sleeping medications and weekly frequency of use.

Both groups showed a reduction in ISI scores from baseline over the 42-week study period (P<0.001) but did not differ significantly at any measurement point (Table 2). Both groups experienced significant improvements from baseline in sleep quality, wake time after sleep onset, anxiety, depression, fatigue, pain, and quality of life (P<0.05 for all). At week 6, active acupuncture was more effective than sham control in shortening sleep onset latency, as measured by Actiwatch (P<0.001) and sleep diary (P=0.044); increasing total sleep time, as measured by sleep diary (P<0.001); and improving sleep efficiency, as measured by Actiwatch (P=0.049) and sleep diary (P=0.005). However, the two groups did not differ significantly in changes in Pittsburgh Sleep Quality Index. The active acupuncture group showed a greater reduction in anxiety at week 10 (P=0.016) and in both anxiety and depression at week 42 (P≤0.001), as well as greater improvement in quality of life at week 14 (P=0.024) and week 42 (P<0.001).

Treatment-related adverse effects were mild. Two serious adverse effects unrelated to treatment (pneumonia) were reported in the active acupuncture group. The most common adverse effect was bruising (n=6). Four participants in the sham acupuncture group experienced auricular skin allergic reactions. No participants discontinued treatment due to adverse effects.

Discussion

Compared with the sham acupuncture group, the active acupuncture group demonstrated significantly greater improvements in sleep onset latency, total sleep time, and sleep efficiency. However, the two groups did not differ significantly in changes in ISI scores or the Pittsburgh Sleep Quality Index. This discrepancy may be because (1) the short-term efficacy of acupuncture in alleviating insomnia is more apparent than its long-term efficacy, and (2) the Actiwatch and sleep diary exhibit greater sensitivity in detecting insomnia improvements compared with other measures.

Our sham control group showed a greater improvement in ISI scores at 6 weeks, compared with other sham-controlled acupuncture trials. This may have contributed to the smaller effect size and the lack of significant differences between groups. Nonetheless, the active acupuncture group experienced greater reductions in anxiety and depression and greater improvements in quality of life during both treatment and follow-up periods. Additionally, during weeks 18 to 20, a greater proportion of participants in the active acupuncture group discontinued the use of sleeping medications. The present study had several limitations. First, Streitberger placebo needles may have exerted modulatory effects on multiple levels of the central nervous system by stimulating mechanoreceptors beneath the skin. Second, the active acupuncture regimen included both acupuncture at body acupoints and auricular acupressure. It remains unclear whether the beneficial effects arose from the two acupuncture modes acting individually or synergistically. Finally, the Actiwatch was the only objective measure used; discrepancies were observed between Actiwatch and sleep diary results. Additional objective measures such as polysomnography are needed to validate the findings from Actiwatch and clinical instruments.

TABLE 2. Comparisons of changes in outcomes from baseline between and within groups

Outcome	Change from baseline*		Between-group difference*	P value
	Active acupuncture (n=69)	Sham acupuncture (n=69)		
Insomnia Severity Index				
Week 3	-4.4 (-5.4 to -3.5)†	-3.6 (-4.6 to -2.6)†	-0.8 (-2.2 to 0.6)	0.265
Week 6	-5.9 (-6.9 to -4.9)†	-5.5 (-6.6 to -4.5)†	-0.4 (-1.8 to 1.1)	0.609
Week 10	-6.5 (-7.5 to -5.5)†	-6.6 (-7.6 to -5.5)†	0.1 (-1.4 to 1.6)	0.894
Week 14	-7.0 (-7.9 to -6.0)†	-6.7 (-7.8 to -5.6)†	-0.2 (-1.7 to 1.2)	0.736
Week 18	-7.6 (-8.6 to -6.6)†	-7.2 (-8.2 to -6.1)†	-0.5 (-1.9 to 1.0)	0.541
Week 30	-6.8 (-7.8 to -5.8)†	-5.9 (-7.0 to -4.8)†	-0.9 (-2.3 to 0.6)	0.249
Week 42	-7.5 (-8.5 to -6.5)†	-6.7 (-7.7 to -5.6)†	-0.8 (-2.3 to 0.6)	0.265
Actiwatch at week 6				
Sleep onset latency, min	-7.5 (-9.8 to -5.3)†	1.5 (-0.9 to 3.9)	-9.0 (-12.3 to -5.7)	<0.001
Wake after sleep onset, min	-7.2 (-12.1 to -2.4)†	-8.2 (-13.5 to -2.9)†	1.0 (-6.2 to 8.2)	0.784
Total sleep time, min	2.7 (-4.2 to 9.6)	2.3 (-5.3 to 9.9)	0.4 (-9.8 to 10.6)	0.943
Sleep efficiency, %	2.8 (1.8 to 3.8)†	1.3 (0.3 to 2.4)	1.5 (0.0 to 2.9)	0.049
Sleep diary at week 6				
Sleep onset latency, min	-11.4 (-18.9 to -3.9)†	-3.3 (-11.1 to 4.6)	-8.1 (-16.1 to -0.2)	0.044
Wake after sleep onset, min	-9.2 (-16.2 to 2.2)	-13.5 (-21.2 to -5.8)†	4.3 (-6.1 to 14.8)	0.413
Total sleep time, min	42.8 (32.2 to 53.3)†	13.5 (1.9 to 25.1)	29.2 (13.5 to 44.9)	<0.001
Sleep efficiency, %	8.6 (6.5 to 10.6)†	4.1 (1.8 to 6.4)†	4.4 (1.3 to 7.5)	0.005
Pittsburgh Sleep Quality Index				
Week 3	-2.3 (-3.0 to -1.5)†	-2.1 (-2.9 to -1.4)†	-0.1 (-1.2 to 0.9)	0.808
Week 6	-3.4 (-4.2 to -2.7)†	-3.3 (-4.2 to -2.5)†	-0.1 (-1.2 to 1.0)	0.894
Week 10	-4.1 (-4.8 to -3.3)†	-3.9 (-4.7 to -3.1)†	-0.2 (-1.3 to 0.9)	0.742
Week 14	-4.6 (-5.3 to -3.8)†	-3.7 (-4.5 to -2.9)†	-0.9 (-2.0 to 0.2)	0.123
Week 18	-5.0 (-5.7 to -4.2)†	-4.5 (-5.3 to -3.7)†	-0.5 (-1.6 to 0.7)	0.408
Week 30	-4.9 (-5.6 to -4.1)†	-4.0 (-4.9 to -3.2)†	-0.8 (-2.0 to 0.3)	0.148
Week 42	-5.2 (-6.0 to -4.4)†	-4.2 (-5.0 to -3.3)†	-1.0 (-2.1 to 0.1)	0.084
Hospital Anxiety and Depression Scale				
Anxiety				
Week 3	-1.0 (-1.6 to -0.4)†	-0.5 (-1.1 to 0.1)	-0.5 (-1.3 to 0.3)	0.250
Week 6	-2.0 (-2.5 to -1.4)†	-1.2 (-1.9 to -0.6)†	-0.7 (-1.6 to 0.1)	0.098
Week 10	-2.1 (-2.7 to -1.5)†	-1.0 (-1.7 to -0.4)†	-1.1 (-1.9 to -0.2)	0.016
Week 14	-1.9 (-2.5 to -1.3)†	-1.3 (-2.0 to -0.7)†	-0.6 (-1.4 to 0.3)	0.213
Week 18	-2.3 (-2.9 to -1.7)†	-1.8 (-2.4 to -1.1)†	-0.5 (-1.4 to 0.4)	0.256
Week 30	-2.1 (-2.7 to -1.5)†	-1.8 (-2.5 to -1.2)†	-0.2 (-1.1 to 0.6)	0.593
Week 42	-2.6 (-3.2 to -2.0)†	-1.0 (-1.7 to -0.4)†	-1.6 (-2.4 to -0.7)	0.001
Depression				
Week 3	-0.7 (-1.4 to -0.1)†	-0.8 (-1.5 to -0.1)†	-0.1 (-0.9 to 1.0)	0.889
Week 6	-1.3 (-1.9 to -0.6)†	-1.5 (-2.2 to -0.8)†	0.2 (-0.7 to 1.2)	0.613
Week 10	-2.0 (-2.6 to -1.3)†	-1.5 (-2.2 to -0.8)†	-0.5 (-1.4 to 0.5)	0.354
Week 14	-2.1 (-2.8 to -1.5)†	-1.7 (-2.4 to -1.0)†	-0.4 (-1.4 to 0.5)	0.382
Week 18	-2.2 (-2.9 to -1.6)†	-2.2 (-2.9 to -1.5)†	-0.0 (-1.0 to 0.9)	0.932
Week 30	-2.1 (-2.8 to -1.5)†	-1.5 (-2.3 to -0.8)†	-0.6 (-1.6 to 0.4)	0.227
Week 42	-3.2 (-3.9 to -2.5)†	-1.3 (-2.0 to -0.6)†	-1.9 (-2.9 to -0.9)	< .001
Brief Fatigue Inventory				
Week 3	-1.0 (-1.5 to -0.6)†	-1.1 (-1.5 to -0.6)†	0.0 (-0.6 to 0.7)	0.917
Week 6	-1.7 (-2.2 to -1.3)†	-1.7 (-2.2 to -1.2)†	-0.0 (-0.7 to 0.6)	0.907
Week 10	-2.1 (-2.6 to -1.7)†	-1.6 (-2.1 to -1.1)†	-0.5 (-1.2 to 0.1)	0.117
Week 14	-2.5 (-2.9 to -2.0)†	-2.1 (-2.6 to -1.6)†	-0.4 (-1.0 to 0.3)	0.261
Week 18	-2.6 (-3.1 to -2.2)†	-2.2 (-2.7 to -1.7)†	-0.4 (-1.1 to 0.2)	0.189
Week 30	-2.4 (-2.9 to -2.0)†	-1.9 (-2.4 to -1.4)†	-0.5 (-1.2 to 0.1)	0.110
Week 42	-2.7 (-3.2 to -2.2)†	-2.1 (-2.6 to -1.6)†	-0.5 (-1.2 to 0.2)	0.134

* Data are presented as mean (95% confidence interval)

† Adjusted P<0.05

TABLE 2. (cont'd)

Outcome	Change from baseline*		Between-group difference*	P value
	Active acupuncture (n=69)	Sham acupuncture (n=69)		
Brief Fatigue Inventory-Short Form				
Pain severity				
Week 3	-0.7 (-1.2 to -0.2)†	-0.5 (-1.0 to 0.0)†	0.2 (-0.9 to 0.5)	0.578
Week 6	-0.6 (-1.1 to -0.1)	-0.6 (-1.2 to -0.1)†	0.0 (-0.7 to 0.8)	0.914
Week 10	-1.0 (-1.5 to -0.5)†	-1.2 (-1.7 to -0.6)†	0.2 (-0.6 to 0.9)	0.642
Week 14	-1.0 (-1.4 to -0.5)†	-1.0 (-1.5 to -0.5)†	0.0 (-0.7 to 0.8)	0.917
Week 18	-0.7 (-1.2 to -0.2)	-1.2 (-1.7 to -0.6)†	0.4 (-0.3 to 1.2)	0.232
Week 30	-1.0 (-1.5 to -0.5)†	-1.2 (-1.8 to -0.7)†	0.3 (-0.5 to 1.0)	0.470
Week 42	-1.1 (-1.6 to -0.6)†	-0.7 (-1.2 to -0.2)†	0.4 (-1.1 to 0.4)	0.285
Pain interference				
Week 3	-0.8 (-1.3 to -0.3)†	-0.5 (-1.0 to 0.0)†	-0.3 (-1.0 to 0.4)	0.375
Week 6	-0.9 (-1.4 to -0.4)	-0.8 (-1.3 to -0.3)†	-0.1 (-0.8 to 0.6)	0.817
Week 10	-1.2 (-1.7 to -0.7)†	-1.0 (-1.5 to -0.5)†	-0.2 (-0.9 to 0.5)	0.528
Week 14	-1.5 (-2.0 to -1.0)†	-1.3 (-1.8 to -0.8)†	-0.2 (-0.9 to 0.5)	0.530
Week 18	-1.2 (-1.7 to -0.7)†	-1.5 (-2.1 to -1.0)†	0.4 (-0.4 to 1.1)	0.331
Week 30	-1.2 (-1.7 to -0.7)†	-1.6 (-2.1 to -1.1)†	0.4 (-0.3 to 1.1)	0.300
Week 42	-1.6 (-2.1 to -1.1)†	-1.2 (-1.7 to -0.6)†	-0.5 (-1.2 to 0.3)	0.210
Functional Assessment of Cancer Therapy-Breast Cancer				
Week 3	6.3 (3.3 to 9.4)†	6.8 (3.6 to 10.0)†	-0.4 (-4.9 to 4.0)	0.842
Week 6	10.6 (7.5 to 13.7)†	9.8 (6.5 to 13.1)†	0.8 (-3.8 to 5.3)	0.742
Week 10	14.2 (11.1 to 17.3)†	10.5 (7.1 to 13.9)†	3.7 (-0.9 to 8.3)	0.118
Week 14	14.7 (11.6 to 17.9)†	9.4 (6.0 to 12.8)†	5.3 (0.7 to 9.9)	0.024
Week 18	15.8 (12.6 to 18.9)†	12.3 (8.9 to 15.7)†	3.5 (-1.2 to 8.1)	0.141
Week 30	14.4 (11.3 to 17.6)†	12.6 (9.2 to 16.0)†	1.8 (-2.8 to 6.5)	0.441
Week 42	19.1 (15.9 to 22.3)†	10.1 (6.6 to 13.5)†	9.0 (4.3 to 13.7)	<0.001

Conclusion

The active acupuncture regimen could be considered for the management of chemotherapy-associated insomnia. It has the potential to taper and even replace the use of sleeping medications in patients with breast cancer.

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1. Zhang J, Qin Z, So TH, et al. Acupuncture for chemotherapy-associated insomnia in breast cancer patients: an assessor-participant blinded, randomized, sham-controlled trial. Breast Cancer Res 2023;25:49.
2. Zhang J, Yang M, So TH, et al. Electroacupuncture plus auricular acupressure on chemotherapy-related insomnia in patients with breast cancer (EACRI): Study protocol for a randomized, sham-controlled trial. Integr Cancer Ther 2021;20:15347354211058695.
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