


The Feasibility and Effects of Qigong Intervention (Mind-Body Exercise) in Cancer Patients With Insomnia: A Pilot Qualitative Study

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Sara L. K. Low, MRes^{1,2} , Birinder S. Cheema, PhD^{1,3},
Hsiewe Ying Tan, PhD¹ , Yoann Birling, MMed^{2,3},
and Xiaoshu Zhu, PhD^{1,2,3}

Abstract

Background: Up to 80% of cancer patients experience insomnia that significantly affects their quality of life. This pilot qualitative study investigated the feasibility and effects of a 3-week Qigong (mind-body exercise) intervention with a 1-week follow-up in cancer patients experiencing insomnia. **Methods:** Cancer patients with insomnia who had completed radiotherapy or chemotherapy treatment and/or were at least 8 weeks post-cancer-related surgery were recruited. Primary outcomes were feasibility outcomes, which included recruitment, retention, attendance, completion of assessment, adverse events and participant feedback via a questionnaire and focus group/individual interview. Secondary outcomes on insomnia severity and sleep quality were measured using the Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index (PSQI) at baseline, mid, post-intervention and follow-up. **Results:** Seven participants were recruited and two withdrew from the study. The participant retention rate was 71.4% with an overall attendance rate of more than 84% and participants were able to complete all required assessments. An adverse event relating to the worsening of existing musculoskeletal condition was reported. Qualitative analysis of participant feedback identified 4 emerging themes: (1) experience from Qigong intervention; (2) class preferences; (3) barriers to participation; and (4) recommendation for improvement. Participants reported increased relaxation, improved sleep and energy level, better upper body flexibility and reduced stress. Both ISI and PSQI scores improved significantly ($P < .05$). **Conclusion:** This study demonstrated that it is feasible to employ the current clinical trial design using Qigong intervention on insomnia in cancer patients. Preliminary data suggest that the intervention may improve sleep outcomes, however, these findings need to be confirmed by future robust randomized controlled trials. **Trial registration:** The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618001670268) <http://www.ANZCTR.org.au/ACTRN12618001670268.aspx> on 10 October 2018.

Keywords

Qigong, cancer, insomnia, sleep, feasibility study, mind-body exercise

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Background

Cancer is currently the second leading cause of death worldwide,¹ and the incidence is expected to increase by 63% over the next 2 decades.² Medical advancements have increased the 5-year survival rate of all cancer to 67%.³ However, many cancer patients experience cancer-related side effects both during and well beyond the completion of cancer treatments.⁴⁻⁶

Insomnia is characterized by dissatisfaction with sleep quality, trouble falling and/or staying asleep, early waking,

¹School of Health Science, Western Sydney University, NSW, Australia

²Chinese Medicine Centre, Western Sydney University, NSW, Australia

³NICM Health Research Institute, Western Sydney University, NSW, Australia

Corresponding Authors:

Xiaoshu Zhu, School of Health Science, Western Sydney University, Penrith South, NSW 2751, Australia.
Email: X.Zhu@westernsydney.edu.au

Sara LK Low, School of Health Sciences, Western Sydney University, Locked Bag 1797, Penrith, NSW 2751, Australia.
Email: 8848sara@gmail.com



and non-restorative sleep.⁷ The condition affects up to 80% of cancer patients⁴⁻⁶ and can often worsen other cancer-related symptoms.⁸⁻¹² Furthermore, prolonged insomnia is associated with poor adherence to medical treatments¹³ and increased morbidity and mortality.^{14,15} While cognitive behavioral therapy for insomnia (CBTI) is recommended as a first-line treatment for insomnia in cancer patients,¹⁶⁻¹⁹ its usage is relatively low due to feasibility issues in clinical practice²⁰⁻²² and the lack of high-quality evidence.¹⁶ As such, there is a need to look for alternative management strategies, including mind-body therapies.

Qigong, when translated from the Chinese language, refers to the practice of skills to cultivate Qi. According to Chinese medicine, Qi can be considered as an inherent life force or vital energy²³ or intelligence²⁴ within the body^{25,26} and the universe.²⁷ Qigong is a mind-body exercise that incorporates coordinated regulation of the mind and body through simple, slow, gentle-flowing, low impact, integrated exercise, meditation, mind adjustment, and breath regulation.^{25,28} By evoking mind-body integration, Qigong practices are thought to activate neurohormonal pathways and other physiological mechanisms that support health.^{28,29} Moreover, Qigong is easy to learn³⁰ and can require low physical effort which would suit those with lower performance status.²⁵

There are consistent reports of the benefits of Qigong for treating cancer-related fatigue and improving quality of life.^{25,31-33} Other benefits of Qigong in this cohort include the improvement of depression, anxiety,^{12,33-37} cognitive function,³⁸ immune system markers,³⁸⁻⁴⁰ and potentially survival.^{41,42} Among the various styles of Qigong studied in cancer patients,²⁵ those involving Tai Chi,^{32,40,43-45} Chan Chuang⁴⁶ and Six Healing Sound Qigong⁴⁷ have reported significant improvement of sleep outcomes following the intervention.⁴⁸ By contrast, one study of breast cancer survivors participating in 5 weeks of Guolin Qigong during radiotherapy did not detect any significant change in sleep.³³ Despite some inconsistent findings in the literature, a recent meta-analysis indicated that Qigong has a beneficial effect on sleep difficulty in cancer patients.³²

Several studies also suggest that Qigong has the potential to mediate the inflammatory response,^{38-40,42} with growing evidence that Qigong and other mind-body training reduced the expression of inflammation-related genes and the activity of pro-inflammatory transcription factor Nf-kB.⁴⁹ As studies have shown a connection between chronic inflammation and immune suppression on sleep,^{16,50-52} the aforementioned findings suggest that Qigong may present significant clinical potential in the immunoprevention of insomnia in cancer patients.

As mental health is strongly associated with sleep,⁵³ Zhineng Qigong was employed in the current study as it emphasizes a healthy, positive and optimistic mental state that can extend beyond practice time⁵⁴ and this change in mental outlook may contribute to improved sleep. According

to the holistic concept of Chinese Medicine, human must live in harmony with nature to achieve total health.⁵⁵ Zhineng Qigong is different from other forms of Qigong studied for insomnia in cancer patients, as the practice of Zhineng Qigong integrates the Qi of nature and the Qi of human^{12,24} to synchronize the human body system with nature including the human circadian rhythm that affects sleep.^{53,56-58}

Therefore, this study aimed to investigate the feasibility and potential effects of a 3-week Zhineng Qigong intervention for insomnia in cancer patients. Feasibility outcomes included recruitment, retention, attendance, completion of assessment, adverse events, and participant feedback via a questionnaire and focus group/individual interview, and clinical outcomes included insomnia severity and sleep quality measured using the Insomnia Severity Index (ISI) and Pittsburgh Sleep Quality Index (PSQI). The findings of this study would provide preliminary data to support the design of a rigorous randomized controlled trial in the future.

Methods

Study Design

This was a single treatment group with repeated-measures design study. The Human Research Ethics Committees of Western Sydney University (H12870) approved all procedures, and the trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618001670268). Written informed consent was obtained from all participants.

Given the nature of this study (pilot), a prospective sample size calculation was not performed. Rather, a sample size of $n=15$ was planned, allowing for a drop-out rate of 20% ($n=3$) to meet the requirements for a pilot study, that is, $n=12$.⁵⁹

Participants and Recruitment

Participants were recruited from September 2018 to April 2019, using study flyers, from the Liverpool Hospital Wellness Centre and various cancer support groups. Eligibility criteria included: (1) age ≥ 18 years old; (2) diagnosed with cancer, completed chemotherapy and/or radiotherapy and/or at least 8 weeks post-surgery; (3) Insomnia Severity Index (ISI)⁶⁰ score ≥ 11 ; (4) not involved in any mind-body therapy for at least 3 months; (5) body mass index <35 kg/m²; (6) English language abilities sufficient to understand study procedures and provide informed consent; (7) no signs or diagnosis of severe depression, neurological diseases, cognitive decline or any other medical condition that would make assessment and intervention potentially hazardous or any of the outcomes impossible to assess. Potential participants were initially pre-screen via telephone or in-person by the principal investigator (SLKL)

for criteria #1-6, and those meeting eligibility criteria underwent medical screening for criteria #1-7 by their general practitioner (GP) or oncologist. Those satisfying all entry criteria were enrolled in the study.

Qigong Intervention

Participants were prescribed 5 supervised sessions of Qigong practice per week for 3 weeks. The intervention was delivered by SLKL, who is a registered Chinese Medicine Practitioner with the Australia Health Practitioner Regulation Agency and has more than 15 years of experience in teaching Qigong. The frequency and duration of the intervention were based on previous research of Qigong in cancer patients.^{45,46,61} Two sessions per week were delivered face-to-face at the Western Sydney University Liverpool campus, either on an individual basis or in a small group, while 3 sessions per week were delivered using an online video conferencing application (Zoom Video Communications Inc., 2012-2019, Version: 4.3.2) with participants logging on from their own homes. The Zoom online video conferencing application was downloaded on participants' mobile devices and tested to ensure that it worked before the actual virtual session. The first two face-to-face introductory sessions lasted approximately four hours per session where participants were briefed on the overall program details, logistics and administration information and taught the Qigong protocol, while the remainder of sessions lasted approximately 60 minutes and were mainly practice and sharing sessions. Participants were given a simplified copy of Qigong instruction with diagrams and two *YouTube* video links^{62,63} of the Qigong demonstrations.

The Qigong protocol consisted of mild level mind-body exercise that included the standing (or seated) Lift Qi Pour Qi (LQPQ) method and two seated, simple, repetitive non-strenuous movements—Kai He La Qi (lateral movement of arms in synchrony with mind intent) and Rou Fu (massaging stomach). Kai He La Qi and Rou Fu are very relaxing and calming methods that can also be performed while lying down. The Qigong protocol selected for this study focused on relaxation and is modifiable according to individual limitations without much impact on the effects.²⁶ Participants were advised to stop or take a rest whenever they feel tired or uncomfortable. They were also asked to report any adverse events to SLKL.

Outcome Measures

Primary outcomes—Feasibility outcomes

Recruitment and retention. The source of participant recruitment was recorded. The retention rate was calculated as the number of participants who completed the Qigong intervention over the number recruited. Reasons for drop-out were obtained from participants who withdrew.

Attendance. Attendance to Qigong intervention including additional home practice sessions were recorded by participants using the practice diary provided. Attendance was computed as the number of sessions attended divided by the number of sessions offered multiplied by 100%.

Adverse events. Any adverse events including changes in health status were recorded by the participants or SLKL in the practice diary.

Completion of assessments. The completion of clinical outcome assessments was computed as the number of assessments completed over the total number of assessments.

Feedback on trial participation. Participants' experience of the Qigong study was obtained through the completion of a questionnaire (Appendix I) followed by a focus group/individual interview (Appendix II) at the trial site on the last face-to-face Qigong session (Week 3). Both the questionnaire and interview questions were designed by SLKL, reviewed by three experienced researchers and revised. They covered key concepts identified through prior literature review and focused on understanding participants' beliefs, preferences, experience and barriers to Qigong intervention to assess the feasibility of the study and to provide recommendations and insight on how to design and execute future studies. The questionnaire and the interview were semi-structured and participants were encouraged to provide feedback verbally or in writing at any time of the trial.

Secondary outcomes—Clinical outcomes. Clinical outcomes were assessed at baseline (Week 0), mid-intervention (Week 2), post-intervention (Week 3), and follow-up (Week 4) by the participants at the university campus.

Insomnia severity and sleep quality were measured using the ISI and the PSQI, respectively. The ISI is recommended for cancer populations.¹⁶ It is a Likert-type scale composed of seven items ranging from 0 (no problem) to 4 (very severe problem) and is devised to evaluate insomnia severity. The reliability and validity of the ISI are acceptable.^{60,64} The PSQI is a 19-item scale measuring seven aspects of the sleep quality and disturbances, that is, subjective sleep quality, sleep latency, duration, efficiency, disturbances, use of sleep medication, and daytime sleep dysfunction, each weighted equally on a 0 to 3 scale. The total score ranges between 0 and 21, with increasing scores indicating worse sleep quality.⁶⁵ It has a sensitivity of 89.6% and a specificity of 86.5% to detect insomnia cases and is a useful first-line, easy-to-handle, and time-efficient questionnaire to evaluate sleep quality.⁶⁶ The PSQI was reported to be a stable measure of sleep quality with high test-retest reliability and construct validity.^{66,67}

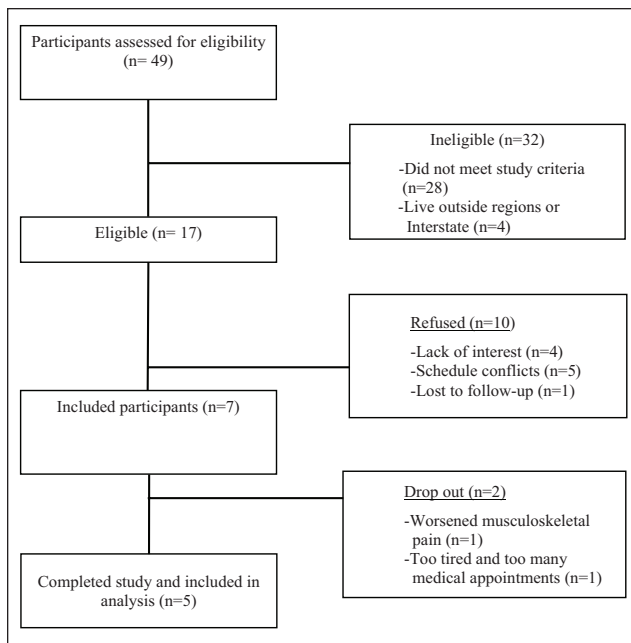


Figure 1. Flow chart of participants recruitment.

Data Analysis

Quantitative analyses were performed using SPSS Version 25. One-way repeated measures analysis (ANOVA) was used to compare the ISI and PSQI scores over the four time-points. Contrast tests were performed to compare Week-0 with Week-2, Week-3, and Week-4. Additionally, to overcome the issue of small sample size we conducted a Monte Carlo simulation of 10000 replicates to increase the sample size. Intent-to-treat analysis was not used due to missing data and the impossibility to conduct multiple imputation techniques with our sample size.

A content analysis was conducted to synthesize the response of the participants to the open-ended questions of the survey to report the perspective of the participant as directly as possible. As theories concerning the benefits and limitations of Qigong for cancer patients living with insomnia are lacking, we used an inductive approach.⁶⁸

Results

Primary Outcomes—Feasibility Outcomes

Recruitment and retention. Of the 49 cancer patients who made contact (Figure 1), 32 were deemed ineligible, including 28 (n=28) who did not meet the study eligibility criteria mainly due to lack of capacity to give informed consent with medical conditions that preclude participation and 4 (n=4) who lived outside regions or interstate. Seventeen (n=17) were deemed eligible but 10 (n=10) did not consent to participate: 4 (n=4) were not interested, 5 (n=5)

could not commit to study due to schedule conflicts and 1 (n=1) did not respond to further contact. Seven participants took part in the study. Two dropped out in Week-1, one due to worsening of existing musculoskeletal pain, while another one due to fatigue with too many medical appointments respectively. Five completed the study and were included in the analysis. The retention rate in this study was 71.4% (5/7 participants).

The age of the seven female participants ranged from 43 to 65 (Table 1). One participant had lung cancer while the other six were breast cancer patients of which one had breast cancer with bone metastases. All the breast cancer participants had radiotherapy and other treatments while the lung cancer patient had only targeted therapy. All the participants reported fatigue and insomnia as the main complaints. The mean ISI at Week-0 (baseline) was 21.4 (clinical moderate severity level).

Attendance. Attendance to face-to-face sessions was $90\% \pm 14.9\%$ (5.4/6) while attendance to online sessions was $80\% \pm 18.2\%$ (7.2/9). The overall attendance rate was $84\% \pm 15.3\%$ (12.6/15) (Table 2). The attendance rate was highest for Week-1, followed by Week-2 and lowest in Week-3. The reasons for missing attendance were due to illnesses or family obligations.

However, it should be noted that, in addition to the 84% attendance rate, most participants conducted additional self-practice sessions individually at home as shown in Table 3.

Adverse events. There was one incident of worsening of existing musculoskeletal pain after the third Qigong session reported by a participant with bone and breast cancer who was immediately advised to rest and consult her GP. The participant informed SLKL three days later that she decided to drop out of the study without further explanation despite further contact.

Completion of assessments. All participants who completed the study (n=5) complied with baseline testing and completed the relevant data collection procedures.

Feedback of trial participation. Analyses of participants feedback identified the following four emerging themes:

1. Experience from Qigong intervention. All participants associated Qigong with emotional and physical wellbeing. They reported improved sleep, reduced stress, increased sense of calm and relaxation from as early as after the first introduction session. One participant who had hot flushes at night was able to sleep well without hot flushes after the Qigong intervention. Other benefits reported include increased energy level, improved flexibility in the upper body and relief at having “Time Out.” Participants indicated

Table 1. Participants Baseline Characteristics.

Participant #	Race	Age	Marital status	Employment	Cancer type	Cancer treatment	Three most common cancer side effects	ISI score
1	Caucasian	65+	Married	Retired	Breast	R, C, S	Fatigue, insomnia, lymphedema	24
2	Caucasian	40-55	Married	Full employment	Breast	R, S, HT	Fatigue, insomnia, heat sensitivity/flushes	14
3	Caucasian	40-55	Separated	Full employment	Breast	R, C, S, HT	Fatigue, insomnia, pain	23
4	Asian	65+	Widowed	Retired	Breast	R	Fatigue, insomnia	21
5	Asian	40-55	Married	Retired	Lung	TT	Fatigue, insomnia	24
6	Asian	65+	Married	Retired	Breast	R, C, S	Fatigue, insomnia	24
7	Caucasian	40-55	Divorced	Retired	Breast, Bone	R, HT	Fatigue, insomnia, pain	20

Abbreviations: R, radiotherapy; C, chemotherapy; S, surgery; HT, hormone therapy; TT, targeted therapy; ISI, Insomnia Severity Index.

Table 2. Descriptive Statistics of Mean Attendance, ISI and PSQI Values.

Time point	N	Combined attendance % (SD)	F2F% (SD)	Online % (SD)	ISI# (SD)	ISI % change	P* value	PSQI [§] (SD)	PSQI % change	P* value
Baseline	5	NA	NA	NA	21.2 (4.2)	NA	NA	14.8 (1.8)	NA	NA
Week 1	5	92 (10.9)	100 (0)	86 (18.3)	NA	NA	NA	NA	NA	NA
Week 2	5	84 (21.9)	90 (22.3)	80 (29.3)	15.6 (4.6)	26	P=.040	9.7 (3.5)	34	P=.018
Week 3	5	76 (32.8)	80 (27.4)	73 (43.3)	13.4 (4.8)	36	P=.010	9.4 (3.3)	36	P=.011
Week 4	5	NA	NA	NA	15.2 (3.9)	28	P=.036	10.1 (2.9)	32	P=.011
Total attendance		84 (15.3)	90 (14.9)	80 (18.2)	NA	NA	NA	NA	NA	NA

Abbreviations: SD, standard deviation; F2F, face to face attendance; Online, online attendance

*Denotes significant difference of P values compared to baseline (Week 0).

#Significant improvement over the 4 measurement points, P=.031.

§Significant improvement over the 4 measurement points, P=.009.

that they enjoyed practicing Qigong and would continue practicing after the study period and would recommend it to other cancer patients.

2. Class preferences. Factors that would influence participation included referral by medical staff, the quality of instructor, the duration, frequency and location of class. Preferences for Qigong class included scheduled 30 to 60 minutes, small group, supervised, online practice from home with the presence of an instructor, two to three times a week before sleep time as participants felt this is a more stress-free time to practice to help them relax and promote sleep. Participants also indicated a preference to start the Qigong intervention after completion of primary cancer treatment. Traveling within 10 km from home to attend class was acceptable while the response on paying for Qigong class was mixed.

3. Barriers to participation. Barriers to participation included patient-reported lack of self-discipline, availability and safety of parking facility, lack of information about available studies, and competing work and family demands. For example, one participant recounted that she

was only informed of the current study by another cancer patient while waiting for consultation in a hospital and suggested that hospitals should assign health care personnel to inform cancer patients of the availability of relevant studies as most cancer patients are overwhelmed with many flyers and would not read them.

4. Recommendation for improvement. Reimbursement of expenses incurred, bigger class sizes and more time allocated for social support were suggested. Two working participants felt that the initial two face-to-face introduction classes were too long and the frequency of face-to-face class of twice a week for Week-2 and Week-3 was too much; one non-working participant felt that it was just right while another participant felt that more time was needed.

Secondary Outcomes—Clinical Outcomes

Significant improvements were observed in ISI and PSQI scores between Week-0 (baseline) and the other study measurement time-points (Table 2).

Repeated measures ANOVA showed significant improvement in ISI ($F(1.963, 7.852)=5.606, P=.031$) and

Table 3. Additional individual home practice.

Participant	Week 1	Week 2	Week 3
1	30 minutes × 1 session	-	30 minutes × 1 session
2	20 minutes × 1 session	30 minutes × 1 session	-
3	30 minutes × 5 sessions	30 minutes × 1 session	30 minutes × 4 sessions
4	20 minutes × 7 sessions	30 minutes × 3 sessions	15 minutes × 2 sessions
5	40 minutes × 2 sessions	30 minutes × 2 sessions	30 minutes × 2 sessions

PSQI values ($F(1.229, 4.915)=16.508, P=.009$) over the four time points. Contrasts tests (Table 2) revealed a significant reduction in ISI score between Week-0 (baseline) compared to Week-2 (mean=5.6, $\eta^2_p=.694, P=.040$), Week-3 (mean=7.8, $\eta^2_p=.838, P=.010$) and Week-4 (mean=6, $\eta^2_p=.709, P=.036$). The contrast tests also reported a significant reduction in PSQI score between Week-0 (baseline) compared to Week-2 (mean=5.1, $\eta^2_p=.841, P=.018$), Week-3 (mean=5.4, $\eta^2_p=.833, P=.011$) and Week-4 (mean=4.7, $\eta^2_p=.835, P=.011$). The results of the Friedman Test revealed statistically significant median differences in rank of 4 (Week 0), 2.4 (Week2), 1.4 (Week3), and 2.2 (Week 4) and with ($P=.006$) for ISI and statistical significant median differences in rank of 3.9 (Week 0), 2.1 (Week2), 1.5 (Week3), and 2.5 (Week 4) with ($P=.007$) for PSQI.

The highest improvement in ISI (36%) and PSQI (36%) was recorded in Week-3 but these effects deteriorated in the follow-up Week-4 (Table 2). Overall, our results indicated that at least one week of Qigong practice could reduce the ISI and PSQI of participants.

Discussion

In this study, we found that a 3-week intervention and 1-week follow-up Qigong clinical trial on cancer patients experiencing insomnia was feasible in terms of maintaining participant retention, attendance, and completion of assessments, low risk of adverse events and overcoming perceived barriers. We successfully recruited seven participants, among which five completed the whole study, resulting in a retention rate of 71%. The participants were able to attend 84% of scheduled sessions, followed instructions, practiced at home and complied with all assessment procedures. No serious adverse events were encountered and the barriers perceived by the participants were relatively manageable. We also found that the current 3-week Qigong intervention was able to improve the sleep of cancer patients experiencing insomnia. Moreover, the participants reported feeling less stressed, calmer and more relaxed.

The retention rate of 71% in this study is high when compared to the 48% retention rate reported in another study of Qigong for breast cancer patients⁶⁹ and comparable to another study reporting 67% retention rate.³⁵ These two

studies have longer intervention periods, more data collection procedures involving participants and more rigorous Qigong training compared to the simplified Qigong intervention and data collection process in this study thereby reducing the burden on participants which may have resulted in a better retention rate reported^{70,71} in the current study.

The total attendance of 84% to in-person and online Qigong sessions is comparable to attendance rates of 63.5% to 96% in other Qigong studies for which sleep was significantly improved.^{43,44,47,61} As reported in a study of pulmonary rehabilitation for patients with chronic obstructive pulmonary disease, the use of online home practice may have encouraged retention and attendance as it is convenient and also contributes to a confidence boost in participants from the availability of support.⁷² Instructor presence, even virtually, seems to play a role in attendance rates, as the attendance rate of the supervised online sessions in this study (80%) was higher than two other studies which reported a 78% and 51% attendance rate, respectively, for unsupervised home-based sessions.^{47,73} Prescribing online, supervised practice via Zoom is a novel approach for delivering Qigong to cancer patients and our study suggests that such intervention may contribute positively to motivation and adherence to scheduled practice sessions.

In line with findings reported in a previous review,⁷⁴ our qualitative analysis revealed that most participants were stressed by the cancer experience. However, they were motivated to attend sessions and even conducted additional home practice due to the ease of the Qigong style, as well as the effects of increased inner calm and improved sleep experienced, especially from the La Qi and Rou Fu methods which emphasize on meditation and relaxation. Considering that stress is one of the main causes⁷⁵⁻⁷⁷ and aggravators of insomnia⁴ in cancer patients and that previous studies have noted improvements in stress levels with mind-body exercises such as yoga⁷⁴ and Qigong,^{78,79} though not objectively evaluated in this study, the stress reduction reported by participants may have contributed to the sleep improvements. Further studies are warranted to investigate the relationship between Qigong, the perception of stress and one's state of wellbeing.

The significant improvement in sleep in this study post-intervention was consistent with previous findings.^{43-47,61} However, the deterioration in improvement after

discontinuation of Qigong practice at follow-up (Week 4) was contrasted with other studies, which reported continuous improvement.⁴³⁻⁴⁵ It should be noted that the other studies had an intervention period of three months or longer, with indications that the continuation of Qigong practice during the follow-up period contributed to the ongoing effects.⁴³⁻⁴⁵

Aside from the insomnia clinical outcomes, during participant feedback, other effects reported include improved energy levels, reduced stress, increased sense of calm and relaxation, improved upper body flexibility and reduced hot flushes. The improved energy level reported by participants is consistent with other Qigong studies reporting significant reduction in fatigue in cancer patients.^{25,31,32,46,47,61} Fatigue and insomnia in cancer patients have been strongly correlated in the literature.^{6,10,32} It has also been established that insomnia affects mood, pain and other aspects of quality of life.^{11,44,80} Previous reports have suggested that Qigong is a multi-component mind-body intervention that benefits various clinical presentations.^{25,31,32} It was also suggested that each of the multi-component elements could potentially affect multiple cancer-related outcomes.²⁵ In view of the prevalence of cancer patients experiencing fatigue, depression and pain^{31,32,81-83} and the association of fatigue,^{6,80,84} depression^{77,84,85} and pain^{11,84} with sleep, further investigation of the physiological effects of Qigong may provide a better understanding of its direct and/or indirect impact on sleep and other health aspects, thereby guiding better Qigong study designs.

As hot flushes have a significant mediating effect on sleep in cancer patients who had radiotherapy and/or hormone therapy,⁴ future studies should also explore the potential beneficial effect of Qigong on hot flushes as reported by one participant.

Qigong intervention was well-tolerated by cancer patients with insomnia. There was only one adverse event of worsening of existing musculoskeletal pain. This was consistent with a systematic review of the adverse events of Qigong, reporting that the intervention may be associated with minor musculoskeletal aches and pains.⁸⁶ In view of the risk of skeletal fractures and musculoskeletal morbidities in patients with bone cancer, future studies of Qigong involving this patient group should incorporate more stringent medical assessments and modifications of the Qigong intervention, and provide increased supervision.⁸⁷

Limitations

One of the main flaws of this study included the lack of a control group and blinding procedures, therefore deterring firm conclusions to be made. The small sample size and limited geographical reach may also limit the generalization and interpretation of the feasibility and clinical outcomes of this study. As this was only a pilot study with a primary

focus on study feasibility, it is expected that these shortcomings will be addressed in a full-scale clinical study in the near future.

Recruitment is a major challenge in clinical trials.⁸⁸ In this study, we recruited 7 participants instead of the planned sample size of 15. The main barriers identified were lack of support from clinicians and patient issues,^{89,90} which may be related to poor Qigong literacy, skepticism, unclear referral process and inadequate integration of complementary medicine therapies, such as Qigong, as part of integrative oncology.^{71,91} The timing of our recruitment, which overlapped with the year-end holiday season, also played a part, as most people were in festive moods or preparing for the holidays and were unable or unwilling to commit to the study. Therefore, future clinical trial recruitment plans should avoid the year-end holiday season period. Finally, outcomes related to sleep such as fatigue, mood or pain level^{11,44,80} were not assessed quantitatively in this study.

The Implication for Future Research

The issue of recruitment may be addressed in future studies by increasing literacy and awareness of Qigong as a mind-body exercise in hospitals and cancer support groups, as well as giving co-authorship incentives on papers to professionals.^{70,71} Qigong-promoting initiatives such as writing Qigong articles in periodical health journals, conducting free Qigong workshops and presentations of Qigong-related studies supported by local hospitals, government and communities should be organized to provide a better understanding of the nature of Qigong and encourage the involvement of clinical practitioners, nurses, allied health professionals and all interested parties in every phase of the study.⁷¹

Conclusion

This Qigong clinical trial design for cancer patients experiencing insomnia is feasible and can be beneficial for participants. The promising improvements in terms of sleep found in this study will have to be confirmed by a future large-scale randomized-controlled trial.

Appendix I

Project Title: Can Qigong (Mind-Body Exercise) Improve Insomnia in Cancer Survivors

Qigong Survey Questionnaire

- (1) Have you heard of Qigong (pronounced: Chee Gong) before this study?
 - Yes
 - No

- (2) If yes, which are the benefits you think Qigong (mind-body exercise) may be associated with?
- Improve physical well being
 - Improve emotional well being
 - Boost immune system
 - Reduce the side effects associated with cancer treatment
 - Prevent cancer relapse
 - Assist in treating cancer
 - Reduce symptoms associated with cancer
 - Others—please specify _____
- (3) If no, what was your motivation to participating in this study apart from hoping for improvement of sleep?
- (4) Which of the following, if any, could have increased your willingness to participate in Qigong (mind-body exercise)/how important are the following aspects in your decision to participate in Qigong? (Tick all that apply)
- Referral by GP or oncologist
 - Quality or reputation of the instructor
 - Location of classes
 - Time of classes
 - Duration of classes
 - Frequency of classes
 - Access to parking
 - Access by public transport
 - Price
 - Availability of information
 - Other (please specify): _____
 - None
- (5) How would you have wanted to take part in Qigong (mind-body exercise) as part of cancer care for insomnia?
- a. When do you think would be the optimal time to introduce Qigong (mind-body exercise) when you experience insomnia? (Tick all that apply)
- as soon as insomnia occur while not receiving cancer therapy
 - as soon as insomnia occurs while receiving cancer therapy
 - after completion of all cancer therapy
- b. If Qigong (mind-body exercise) is offered in cancer care, how long the duration, how many sessions per week and how much time per session do you think is the optimum level?
Eg. _____ minutes/session _____ times/week _____ weeks/months
- c. What would be your preferred time of Qigong (mind-body exercise) practice/class? (Tick all that apply)
- Morning
 - Afternoon
 - Evening
 - Night
 - Doesn't matter
 - Other _____
- d. How would you prefer to attend the Qigong (mind-body exercise) intervention? (Tick all that apply)
- In a group led by an instructor
 - One to one with an instructor
 - Own practice at home
 - Web-based group video conferencing from home
- e. If Qigong (mind-body exercise) is offered in cancer care for insomnia, how far are you willing to travel to attend the class?
- Less than 5 km
 - 5 km-10 km from home
 - >10 km from home
 - Does not matter
- f. If Qigong (mind-body exercise) is offered in cancer care for insomnia, are you willing to pay for the service?
- Yes, how much per session _____
 - No
- g. If you were taught the basic steps of Qigong (mind-body exercise) and recommended to continue practicing at least 2 times a week, how likely/willing are you to continue practicing on your own?
- Very likely
 - Likely
 - Unlikely
 - Very unlikely

Appendix II

Focus Group Question

- (1) How do you feel about these 3 weeks of Qigong study?
- (2) Have you had other benefits from this Qigong study? For example, energy level, attention, emotional state, relationship, work productivity
- (3) What did you like about this Qigong program? For example, shared worry and support, meeting others with the same worries, instructor
- (4) What are the difficulties you face in adherence to this Qigong program during the 3-weeks period?
- (5) What could be improved?
- (6) Would you recommend it to other cancer survivors?

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Authors' Contributions

SLKL conceived and designed the study, was involved in the acquisition of data, delivery of intervention and assessments, and drafted the manuscript. XZ, BSC, and HYT provided consultation regarding the design of the study and contributed to drafting the manuscript. XZ, BSC and YB provided clinical and research expertise, interpretation of results, and drafted the manuscript. BSC and HYT conducted editing and proofreading of the manuscript. All authors read and approved the final manuscript.

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Ethical Approval and Consent to Participate

This study has been approved by the Human Research Ethics Committees of Western Sydney University (H12870) and written informed consent was obtained from all participants.

ORCID iDs

Sara L. K. Low  <https://orcid.org/0000-0001-6296-6052>
Hsiewe Ying Tan  <https://orcid.org/0000-0003-1289-3646>

Availability of Data and Materials

The data and materials can be made available on request by contacting the corresponding authors.

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