

Study title: Assessing the effect of a mind-body exercise, qigong Baduanjin, on sleep disturbance among women experiencing intimate partner violence and possible mediating factors: a randomized-controlled trial

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Abstract

Study Objectives: To evaluate the effects of a mind-body exercise, qigong Baduanjin, on sleep disturbances in women experiencing intimate partner violence and explore the mediating role of depressive symptoms, perceived stress, and inflammation in producing the effects.

Methods: A subgroup of a parent randomized controlled trial, were randomized for a 22-week Baduanjin intervention (n=94) or wait-list control (n=92). Questionnaires including the General Sleep Disturbance Scale, Perceived Stress Scale, and Beck Depression Inventory version II were administered at baseline, post-training (6 weeks), and post-intervention (22 weeks), and blood samples were collected to assess tumor necrosis factor and interleukin 6 levels at baseline and post-intervention only.

Results: Of the 186 participants, 170 completed the study. Results indicate that the total sleep disturbance scores for the intervention group were significantly lower than those for the wait-list control group at Week 6 (difference = -7.96; 95% CI, -13.63 to -2.30; $P = 0.006$) and Week 22 (difference = -7.17; 95% CI, -12.58 to -1.76; $P = 0.01$). Mediation analysis showed a statistically significant indirect effect of the intervention on sleep improvement through reducing depressive symptoms ($\beta=2.58$, 95% CI, 0.69 to 5.09), while the mediating effects of perceived stress and inflammation were not significant.

Conclusions: Qigong Baduanjin can be recommended for women who experience intimate partner violence and report sleep disturbances. More research is needed to understand the clinical significance of the observed sleep improvements.

Keywords: Intimate partner violence, sleep, randomized control trial, qigong, Baduanjin, mind-body, complementary and alternative medicine, non-pharmacological intervention

Brief Summary

Current Knowledge/Study Rationale: Women experiencing intimate partner violence often report sleep disturbances. Although qigong Baduanjin has demonstrated benefits in improving sleep among patients with physical illnesses, its effects in abused women, a population whose sleep problems may be associated with chronic stress, have not been examined in the literature.

Study Impact: Our research shows that qigong Baduanjin, compared to wait-list control, resulted in improvement in self-reported sleep disturbances. More research is needed to understand the clinical importance of the observed improvement in sleep.

1 INTRODUCTION

Intimate partner violence (IPV), encompassing physical, psychological and sexual abuse, is a serious public health problem which affects women worldwide. Globally, nearly one third (30%) of women who have been in an intimate relationship have experienced physical or sexual abuse inflicted by their intimate partners.¹ Psychological violence is more prevalent than are other forms of IPV, affecting up to 43% of the women². IPV victimization has been associated with numerous adverse mental and physical health outcomes among women.¹ However, sleep disturbance is an area that has received limited attention in the IPV literature.

A systematic review has shown that sexually abused women were more likely to experience sleep disturbances than were individuals who had not been abused.³ Approximately half of IPV victims had clinically significant insomnia.⁴ Specifically, a majority of women reported moderate to severe sleep initiation insomnia, middle of the night insomnia, nightmares that replayed elements of their abusive events, and early morning awakening.⁴ IPV may be more salient in causing enduring sleep disturbances than are other stressors and life events because the abused victim's sleep environment may be the venue where the violence took/takes place and it thus represents past/present danger. Also, the sleep environment may be accessible to the perpetrator, causing the woman to experience heightened vigilance during sleep. The feelings of threats and chronic stress inhibit sleep and may contribute to the persistence of sleep disturbances, even if abuse has terminated.⁵

Sleep disturbance in IPV victims has been associated with other mental health issues, including depression, anxiety, suicidality, social dysfunction, and post-traumatic stress disorder.^{4, 6} Another study has found that sleep disturbance partially mediates the relationship between IPV and mental/physical health.⁵ Therefore, sleep interventions may potentially mitigate the negative effects of IPV. Despite the well-documented prevalence and impacts of sleep disturbance resulting from IPV, interventions addressing this problem are scarce. Long-term use of conventional pharmacotherapies has uncertain efficacy and is associated with drug abuse, dependence, and increased mortality.⁷ Psychological and behavioral therapies are effective, but they have remained largely

underused in primary care, probably due to the high costs and extensive behavioral changes required.⁸ Because sleep disturbance is often chronic in abused women, long-term and safe non-pharmacological interventions are warranted. In this connection, qigong may hold promise as such an intervention.

Qigong is a mind-body intervention rooted in a Traditional Chinese medicine (TCM) concept and is a preferable complementary and alternative medicine for insomnia in the Chinese population.⁹ Qi refers to the vital energy flowing within the body along the meridian. Qigong exercises are practiced with a combination of body posture and movement, breath control, and mindful meditation, all designed to promote qi flow for healing, preventing disease, and promoting psychological and physical health.¹⁰ The most commonly studied form of qigong is Baduanjin. This consists of eight easy-to-follow movements and thus is suitable for a wide range of participants. A meta-analysis has demonstrated an overall significant result of qigong Baduanjin in improving sleep among patients with physical illnesses.¹¹ However, the results were not conclusive because the heterogeneity of the included studies was high (83%). Among the three studies reporting significant findings, the one presenting the greatest effect size also included educational lessons for reducing hypertension in the intervention.¹² It is speculated that if Chen et al.'s study were not included, the overall effect estimate might not be significant.¹¹ More research is therefore needed to examine the specific effects of Baduanjin for improving sleep in different populations including those without chronic physical illnesses.

In addition to studying the effects of qigong on sleep, it is crucial to explain the mechanisms by which the intervention is successful. Cytokines in the inflammatory system have long been suggested to participate in the central nervous system regulation of physiological sleep.¹³ A meta-analysis has revealed that sleep problems were associated with increases in markers of inflammation.¹⁴ In addition, mental health comorbidities such as depression may have a negative impact on sleep.¹⁵ Given that inflammation, perceived stress, and depression have been found to be amenable to modification through qigong,^{16, 17} we hypothesize that they are potential mediators able to produce the intervention effects. Analyses that elucidate mediators of the qigong

impact on sleep will provide an important next step for guiding clinical interpretations of trials and informing the design and targeting of future interventions.

The effects of qigong for improving sleep disturbance in abused women, a population whose sleep problems may be associated with chronic stress related to IPV, have not been examined in the literature. The aim of the study is to evaluate the effect of qigong Baduanjin intervention on sleep disturbance in abused women and explore the mediating role of depressive symptoms, perceived stress, and inflammation in producing the effects.

2 METHODS

2.1 Design

The dataset was a subset from a two-group, parallel randomized controlled trial (RCT) comparing the effects of a qigong Baduanjin intervention on telomerase activity among abused women with a wait-list control. From a qualitative evaluation of the first phase of the study ($n = 85$), a substantial number of participants highlighted sleep improvements after the intervention as shown in the following narrative comments, for example: “It feels like I can go into deeper sleep at night. During daytime, I feel less fatigue and more energetic.” “My sleep quality at night has become better, so I wake up feeling more rested and cheerful. My husband sleeps better as well and we fight less.” “In the past, my mind was active and worked continuously from day to night. During qigong practice, the master taught us to focus our mind on the present moment. My mind has become calmer and I can fall asleep more easily.” “I have had trouble remaining asleep during the night. Whenever I was awake in the middle of night, I became very anxious that I could not sleep again. After practicing qigong, I have learnt how to relax and breathe slowly. I am now less worried and often able to return to sleep.” Hence, sleep measure was added in the quantitative evaluation in subsequent phases ($n = 186$). A complete description of the design and methods of the parent study, without the sleep measurement described herein, has been published previously.^{16, 18} The parent study was conducted between March 12, 2014 and May 26, 2016.

2.2 Participants

The inclusion criteria were as follows: participants were Chinese women, 18 years of age

or older, willing to undertake the qigong intervention, available for all of the data collection points, receptive to random allocation, and determined to be positive for IPV, using the Abuse Assessment Screen,¹⁹ in the preceding 1-2 years. Individuals were excluded if they had participated in qigong training within the previous 6 months, were pregnant, or had serious medical conditions that might limit their participation in qigong.

2.3 Intervention and control conditions

The intervention lasted 22 weeks and was comprised of (i) group training – qigong sessions provided by a qigong master twice per week for 6 weeks (24 hours), (ii) weekly group follow-up – qigong follow-up sessions with reinforcement of practice by the same qigong master once per week for 16 weeks (16 hours), and (iii) self-practice - participants were encouraged to practice qigong 30 minutes per day for the entire intervention period. To monitor the self-practice of qigong, each participant entered on a record card the duration and frequency of qigong undertaken every day, and this card was submitted to a research assistant at the weekly group follow-up sessions to verify compliance.

Participants in the wait-list control group received monthly health education sessions unrelated to qigong and could choose to receive qigong training after data collection had been completed.

2.4 Procedure

Ethical approval for the study was obtained from the Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB: UW 12–555). Participants were recruited from the catchment area of a large community center that provides diversified health and social services for users of all ages in Hong Kong. Flyers promoting the study were posted on the notice boards of the host community center and its outreach sites. Interested clients contacted center staff members to make an appointment for further screening. To confirm a woman's eligibility, a face-to-face interview was conducted by a trained research assistant in a private area without the presence of the participant's partner. All participants provided written informed consent.

Eligible participants were randomly assigned to the intervention or the wait-list control group (1:1) based on a list of random permutations prepared by block randomization. The list was computer generated, recorded by an investigator not involved in subject recruitment, and placed in numbered sequential sealed envelopes. The list was also centrally controlled to avoid any bias in selection.

2.5 Data collection

Data were collected at the following time points: baseline, post-training (week 6, i.e., upon completion of the 6-week group training), and post-intervention (week 22, i.e., upon completion of the entire qigong intervention). At each time point, questionnaires including the General Sleep Disturbance Scale (GSDS), Perceived Stress Scale (PSS), and Beck Depression Inventory version II (BDI-II) were administered to participants in both groups. The Abuse Assessment Screen and Demographic Questionnaire were administered only at the baseline point. For measurements of the plasma levels of proinflammatory cytokines, tumor necrosis factor (TNF) and interleukin 6 (IL-6), 10 mL of peripheral blood was collected from each participant at baseline and after 22 weeks. Research assistants who administered the questionnaires and entered data were blinded. The nurse who collected the blood and laboratory technicians who processed the blood samples and measurements were also blinded to the group assignment.

2.6 Study measures

The Abuse Assessment Screen was used to screen potential participants for IPV. Participants were required to respond “yes” or “no” to five items addressing physical, psychological, and sexual abuse and fear toward the partner. The Chinese version demonstrated satisfactory screening accuracy.¹⁹

The GSDS was used to assess symptoms of sleep disturbance exhibited in the past week (ranging from 0 (“not at all”) to 7 (“everyday”). The instrument includes 21 items related to a number of general sleep issues, which are summed to form 7 subscales: 1) difficulty getting to sleep; 2) waking up during sleep; 3) early waking; 4) quality of sleep; 5) quantity of sleep; 6) daytime sleepiness, and; 7) self-medication to assist sleeping. Each subscale has a range from 0-7, with scores 3 or higher indicating significant sleep

problems on 3 or more nights per week. The 21 items were also summed to yield an overall sleep disturbance score ranging from 0 (“no disturbance”) to 147 (“extreme disturbance”); scores ≥ 43 represented poor sleep. Among various sleep measures, the GSDS covers a comprehensive assessment of both daytime impairment (seven items) and nighttime sleep experience (five items), while other commonly used instruments such as the Pittsburgh Sleep Quality Index (two items on daytime functioning) and Insomnia Severity Index (one item on daytime functioning) focus more on nighttime sleep disturbances. Indeed, daytime assessment is equally important because people experiencing insomnia symptoms generally report daytime consequences.²⁰ Therefore, the GSDS was selected as the outcome measure in the present study. The GSDS has been used with a variety of clinical groups, including post-partum women²¹ and cancer patients.²² The internal consistency and construct validity of the Chinese GSDS has been proven satisfactory.²³

The PSS was used to measure perception of stress during the past month. It consists of 10 items, for which respondents rate the degree to which life situations are perceived as stressful on a 4-point Likert-type scale ranging from 0 (never) to 4 (very often). The total scores range from 0 to 40, with higher scores representing higher stress. The Chinese PSS has shown satisfactory internal consistency in Chinese adults.²¹

The BDI-II was used to assess depressive symptoms exhibited in the past two weeks. It assesses cognitive, affective, and somatic components of depression, including, for example, concentration problems, suicide ideation, and sleep disturbances. It consists of 21 items rated on a 4-point Likert-type scale. The total score ranges from 0 to 63, with higher scores indicating more severe depressive symptoms. The Chinese BDI-II has exhibited construct validity and reliability for Chinese populations.²⁴

For measuring levels of proinflammatory cytokines (TNF and IL-6), plasma was first separated from the blood sample. Levels of the cytokines in plasma were then measured with ELISA kits (Bio-Station Limited) in the laboratory.

The Demographic Questionnaire was designed by the research team to elicit background, lifestyle, and health-related information.

2.7 Selected mediators

We chose mediators based on the literature report that qigong practice reduces depressive symptoms, perceived stress,¹⁶ and inflammation,¹⁷ which in turn reduces sleep disturbance in abused women. Therefore, changes in levels of perceived stress (measured by the PSS), depressive symptoms (measured by the BDI-II), and inflammation (measured by TNF and IL-6) occurring between baseline and post-intervention periods were hypothesized to be the mediators of the relationship between the qigong intervention and changes in sleep (measured by the GSDS).

2.8 Sample size

A meta-analysis has reported that the effect size of Baduanjin for improving sleep quality among healthy individuals and patients with physical health problems compared to usual care was 0.55.¹¹ Taking into account the chronicity of sleep disturbance experienced by abused women relative to the general population,³ a conservative estimate of effect size of 0.45 was utilized. Using the statistical program G*Power and assuming a type I error rate of 5%, $n = 158$ is needed to achieve power greater than 80%. Allowing for an attrition rate of 10%, a sample size of at least 176 is needed.

2.9 Data analysis

Descriptive statistics included participants' background characteristics, adherence, and baseline sleep profile. A t-test and chi-square test were performed to identify the heterogeneity of the between-group baseline data.

Intervention effects on sleep were tested on an intention-to-treat (ITT) basis using mixed-effects models, which can accommodate missing observations in the follow-up data and does not require imputation, providing a natural way to deal with missing values or dropouts. All tests involved a two-sided significance level of $\alpha = 0.05$. A linear mixed-effects model was conducted using SPSS, in order to compare the mean changes in the GSDS total and subscale scores between the intervention and control groups at different time points (as compared with baseline). The analyses were repeated by including poor sleepers at baseline only (baseline GSDS scores ≥ 43) and using the per-protocol approach (using data of adherents only). The adherents in this study were defined as

follows: (a) in the intervention group, those who attended over 80% of the training sessions and completed all measurements; (b) in the control group, those who completed all measurements. All analyses were repeated while adjusting for potential covariates including age²⁵ and type of IPV²⁶ (psychological abuse only, physical/sexual abuse combined with psychological abuse, and physical abuse plus sexual abuse plus psychological abuse).

The mediation model of the intervention effect on sleep was tested using the PROCESS function V3.4.1 in SPSS (model 4).²⁷ Only participants without missing data in the respective variables were included in the analysis. Changes in perceived stress, depressive symptoms, and inflammation were entered as mediators; the qigong intervention was the independent variable, and change in sleep was the outcome variable. To test the significance of the indirect effects (IEs), the macro generated bias-corrected bootstrapped 95 % confidence intervals (CIs). Mediation was significant if the upper and lower bound of the bias corrected CI for the IE did not include zero.²⁷ The proportion of the total effect that was mediated was also calculated.

3 RESULTS

The sample available for the current analysis was comprised of 186 participants (94 in the intervention group and 92 in the wait-list control group). Figure 1 shows the study flow. The study was completed by 89% (84 of 94) of the participants in the intervention group and 94% (86 of 92) of those in the wait-list control group. Overall, 16 (9%) participants withdrew from the study, frequently because of a lack of time. Of the participants in the intervention group, 71% attended $\geq 80\%$ of training sessions (n=60). No adverse effects resulted.

Insert Figure 1

At baseline, sociodemographic characteristics (Table 1) for the intervention and wait-list control groups did not differ significantly. All participants' data were analyzed by the original assigned groups.

Insert Table 1

Table 2 shows the intervention effect on sleep. The decrease in GSDS total scores in the intervention group from baseline was significant at 6 weeks (-7.06; 95% confidence interval [CI], -11.20 to -2.93; $P < 0.001$) and 22 weeks (-8.57; 95% CI, -12.56 to -4.58; $P < 0.001$). In the wait-list control group, the decrease in GSDS total scores from baseline was not statistically significant at 6 weeks (-1.56; 95% CI, -5.66 to 2.54; $P = 1.000$) or 22 weeks (-3.86; 95% CI, -7.80 to 0.09; $P = 0.06$). There were differences between the groups, and the GSDS total scores of the intervention group were significantly lower than were those of the wait-list control group at Week 6 (difference = -7.96; 95% CI, -13.63 to -2.30; $P = 0.006$; effect size = -0.40) and Week 22 (difference = -7.17; 95% CI, -12.58 to -1.76; $P = 0.01$; effect size = -0.38). There was a significant change in the between-group difference in the GSDS total scores over time, as indicated by the group \times time interaction effect ($P = 0.045$).

Regarding subscales, the scores of intervention group were significantly lower than those in the wait-list control group at Week 6 in terms of difficulty in getting to sleep (-0.93; 95% CI, -1.55 to -0.32; $P = 0.003$; effect size = -0.44), quality of sleep (-0.69; 95% CI, -1.17 to -0.21; $P = 0.005$; effect size = -0.47), and daytime sleepiness (-0.43; 95% CI, -0.83 to -0.03; $P = 0.04$; effect size = -0.30). At Week 22, only the daytime sleepiness data for the two groups still exhibited a significant difference (-0.51; 95% CI, -0.88 to -0.14; $P = 0.008$; effect size = -0.40), and waking during sleep was found to be significantly lower in the intervention group (-0.72; 95% CI, -1.40 to -0.04; $P = 0.04$; effect size = -0.30). In the analysis including poor sleepers at baseline only ($n=124$; Supplementary material 1), the between-group differences that were insignificant at week 6 and week 22 in the total sample analysis remained insignificant, suggesting that the null findings for those subscales were not due to ‘ceiling effect’ at baseline.

Insert Table 2

The results of analyses controlling for potential covariates (age and type of IPV) remained similar. In addition, per-protocol analysis was performed on adherents (intervention group: $n = 60$; wait-list control group: $n = 86$). The baseline characteristics were comparable between the two study groups. The results of the per-protocol analysis

(Supplementary material 2) were similar to those of ITT, with two exceptions: (i) the reduction from baseline to Week 6 in early waking in the intervention group became significant ($p = 0.04$; vs 0.09 in ITT), and (ii) the between-group difference in quantity of sleep at Week 6 changed from marginally nonsignificant to significant ($p = 0.04$; vs 0.06 in ITT).

Results of the mediation analyses for improved sleep ($n=169$ after removing missing data) are presented in Figure 2 and Table 3. The total effect of qigong intervention on sleep was significant ($\beta_{\text{total}} = 4.91$; 95% CI, 0.24 to 9.57; $P = 0.04$). Significant overall IEs ($\beta_{\text{overallIE}} = 3.03$, 95% CI, 0.59 to 5.79) were exhibited, while the direct effect was not significant ($\beta_{\text{direct}} = 1.87$; 95% CI: -2.55 to 6.29; $P = 0.40$). Specifically, there is a statistically significant IE, in that the intervention improved sleep through depressive symptoms ($\text{IE}_{\text{depression}} = 2.58$, 95% CI: 0.69 to 5.09), such that participants who received the qigong intervention were more likely, relative to control group participants, to exhibit improvements in the effects of depressive symptoms, and were, therefore, more likely to report improvements in sleep disturbance. However, reductions in perceived stress, IL-6, and TNF did not mediate the relationship between the intervention and improved sleep ($\text{IE}_{\text{stress}} = 0.72$, 95% CI: -0.19 to 2.06; $\text{IE}_{\text{IL-6}} = -0.47$, 95% CI: -1.51 to 0.34; $\text{IE}_{\text{TNF}} = 0.21$, 95% CI: -0.32 to 0.79). Overall, the indirect paths explained 62% of the total effect observed ($3.03/4.91$) and the mediating effect of depressive symptoms was found to account for 53% of the total intervention effect ($2.58/4.91$). The significance of the mediation pathways remained unchanged after controlling for potential covariates (age, duration of relationship, and type of IPV).

Insert Figure 2

Insert Table 3

4 DISCUSSION

Our findings indicate that Baduanjin qigong resulted in a statistically significant improvement in sleep among abused women, relative to the wait-list control group. Specifically, significant benefits were observed from relieving difficulty in sleep initiation, improving quality of sleep, and reducing daytime sleepiness. Mediation

analysis reveals that women who received the qigong intervention were more likely to exhibit reductions in depressive symptoms, and, through this, participants were more likely to experience improved sleep.

To the best of our knowledge, this is the first RCT to examine the effect of qigong on reducing sleep disturbances among women experiencing IPV. Although relocating to a shelter may be efficacious in reducing re-abuse and psychological distress of abused women, sheltered women may still experience disturbed sleep and daytime fatigue probably due to environmental factors.²⁸ Also, many women may not leave their partner due to such barriers as fear, cultural values for maintaining a two-parent family, financial dependence, religious beliefs, and increased vulnerability to stalking and homicide.²⁹ Interventions directed toward improving sleep for abused women are crucial. However, research on interventions for sleep disturbance experienced by abused women is scarce. The existing literature only includes: (i) a study reporting significant benefits from music therapy for improving insomnia in 28 abused women using a pre-post design,³⁰ and (ii) one study protocol of an RCT targeting survivors of interpersonal violence using cognitive-behavioral therapy, with results not yet published.³¹ Compared to these two interventions, qigong is more culturally appropriate for Chinese people, because Chinese abused women were receptive to engaging in health-promoting behaviors based on the concepts of Chinese medicine.³² Also, qigong is inexpensive, safe, and can be practiced at home without equipment, making treatments accessible to IPV survivors from a wide range of sociodemographic backgrounds.³³ Most importantly, the current study uses a rigorous design to confirm the sleep benefits experienced by subjects in an abused population.

Though not within the context of IPV, the effects of qigong Baduanjin for improving sleep have been investigated with patients having chronic physical illnesses such as hypertension,¹² diabetes,³⁴ and Parkinson's disease.³⁵ Unlike chronic physical illnesses in which insomnia may be caused by physical symptoms arising from the illness or the side effects of treatment (e.g., nocturia in diabetes)³⁶ or nocturnal cramping in Parkinson's disease,³⁷ insomnia in abused women is more likely attributable to psychological issues such as feelings of threats and chronic stress.⁵ In our study, the effect size of sleep

improvement post intervention in abused women was -0.40 (Cohen's *d*), while that of a meta-analysis which covered 6 RCTs conducted among patients with physical illnesses was -0.55 (Hedge's *g*).¹¹ Although our effect size is somewhat smaller, our study provides new information indicating that the benefits of qigong for sleep are not limited to populations with physical illnesses but are also effective for populations experiencing psychological stress (such as abused women).

In order to explore the mechanism by which qigong benefits sleep, we performed additional analyses to identify mediators. To date, diverse non-pharmacological interventions have been proposed to be effective in altering sleep in various populations⁸; however, whether the benefits are mediated in part by psychological, physiological, or neurobiological changes remains largely unknown. Contrary to speculation that the alterations in sleep promoted by exercise are mediated by cytokines,³⁸ IL-6 and TNF did not exhibit mediating effects in our study. However, this negative finding does not exclude other possible biological mechanisms such as C-reactive protein modulation,^{39, 40} which can be explored in future studies. Data from this study showed that the effect of qigong in improving sleep was mediated by reductions in depressive symptoms. A multi-country population-based study has shown that depression is a strong predictor of sleep problems.¹⁵ A plausible explanation to the mediating effect of depression on sleep outcomes is the ability of qigong, as a mind-body exercise, to counteract intrusive thoughts, foster relaxation states, and reduce body tension.³³ In addition, the neurobiological pathways (monoamine neurotransmitters in the brain, the hypothalamic-pituitary-adrenal axis, and brain-derived neurotropic factors) that have been proposed to explain the anti-depressive effects of qigong practice⁴¹ may constitute a partial explanation for the observed improvement in sleep. Further investigation is needed to understand fully the psychobiological mechanisms underlying the mediating effects of depression on sleep in qigong interventions. On the other hand, researchers have sought to conceptualize the sleep-depression relationship as bi-directional⁴²; thus, caution must be taken when interpreting the results. Additionally, other plausible mediators, such as self-efficacy, cortisol, and C-reactive protein could be assessed in future studies.

4.1 Limitations

A limitation of the present study is the absence of objective forms of outcome measurement on sleep and psychological well-being. The reliance on self-reported measures of sleep and psychological well-being risks responses of participants being subject to retrospective reporting biases. Second, other conditions that may contribute to participants' sleep problems such as shift work were not excluded. This may have increased heterogeneity of the sample. Third, we focused on outcomes immediately post-intervention and are unable to assess the sustainability of the effects on sleep. Fourth, our mediation modeling was not derived from an experimental design, and the data were not specifically powered for mediation analysis. Although we have emphasized the indirect effects of qigong on sleep mediated by depression, there might be a bidirectional component to the relationship between depression and sleep which was not evaluated in the present study. Fifth, given that qigong was practiced in a group on a regular basis, social interactions with other participants and attention from research personnel may have contributed partly to the intervention effect and cannot be isolated. Finally, our measure of depression (i.e., BDI-II) incorporates one item assessing sleep symptoms. However, this item accounts for only a small proportion of the total scale score, so the chances that changes in this item alone could account for the observed mediating effect are minimal.

4.2 Implications

In practice settings, service providers may recommend Qigong Baduanjin for abused women who report sleep disturbances. It is safe, free, and can be practiced at any time. Specifically, the observed effects included (i) reduced difficulty in sleep initiation, (ii) reduced daytime sleepiness, and (iii) improved sleep quality. To enable the wide adoption of qigong as a complementary intervention in service settings, more efforts are needed to increase programming availability and to enhance the awareness of the benefits of qigong among the public and service communities.

In terms of research, our findings add to the information on underlying mechanisms that can explain the effects of non-pharmacological interventions on sleep by demonstrating the possible mediating effect of depressive symptoms. In the context of IPV, a number of psychological interventions have proved to be effective for improving depressive symptoms⁴³ and may also improve sleep outcomes. It is recommended that future

interventional trials should include both depression and sleep in the outcome evaluations. Particularly, trials should report item-level data or use depressive measures that do not include items assessing sleep symptoms, so as to enable investigations of the association among the intervention, non-sleep depressive symptoms, and sleep. Also, further research is needed to understand the clinical importance of the observed sleep improvements. Findings complemented by standard sleep outcome measures such as sleep diary can provide a more complete picture of the intervention effect. Particularly, actigraphy, a non-invasive device which allows for continuous sleep monitoring for days to weeks, could be used as an objective sleep measurement in future studies. Of note, IPV researchers should consider the safety of participants when designing the measurement, as wearing actigraphy devices may lead to heightened suspicion of perpetrators. In addition, discrepancies between self-reported and objective sleep assessment have been reported in previous studies^{44,45}. Given the subjective nature of sleep complaints and rising importance of evaluating treatment effectiveness from the patient's perspective⁴⁶, self-reported sleep measures could be prioritized in the context of IPV. An active control group such as simple stretching can be used to control for the non-specific effects of social gathering and light physical activity.

4.3 Conclusions

In this study involving abused women, as compared with results for a wait-list control group, qigong Baduanjin resulted in improvement in self-reported sleep disturbances based on its effect on reducing depressive symptoms. More research is needed to understand the clinical importance of the observed improvement in sleep.

Abbreviations

BDI-II is the Beck Depression Inventory, version II; CI is confidence interval; GSDS is General Sleep Disturbance Scale; IE is indirect effect; IL-6 is interleukin 6; IPV is intimate partner violence; PSS is the Perceived Stress Scale; TNF is tumor necrosis factor.

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Figure 1. Study flow

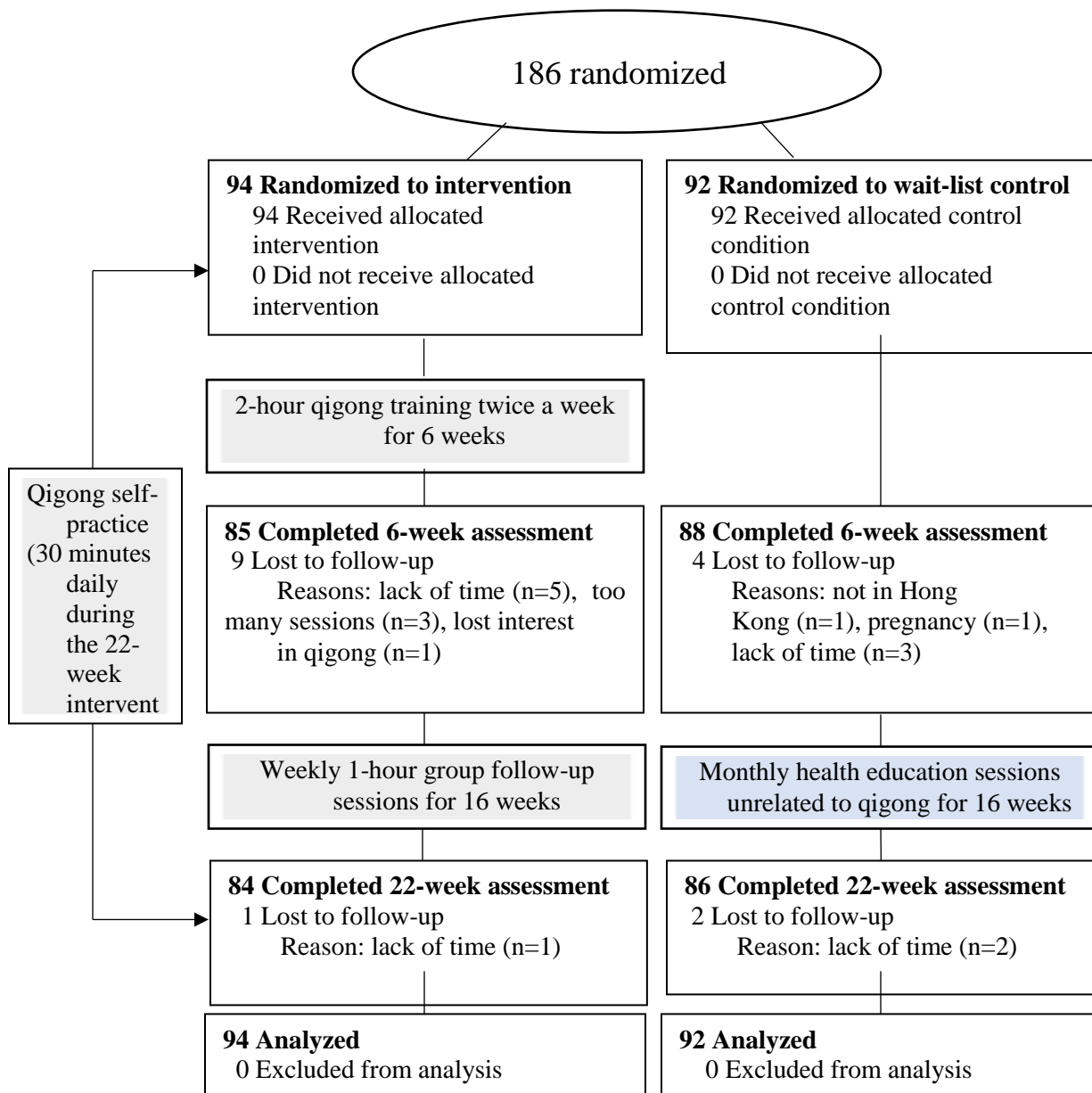
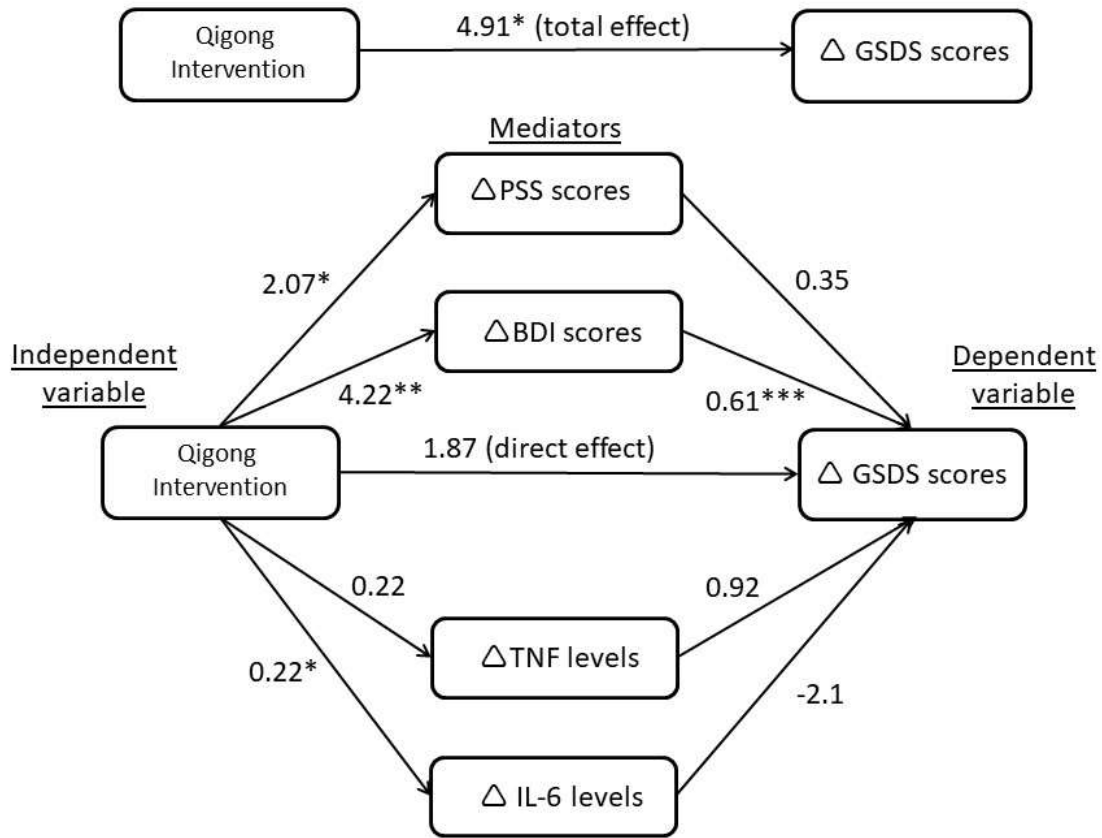


Figure 2. Diagram showing the mediation pathways (n = 169)



Notes.

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

Values on pathways represent unstandardized regression coefficients.

Δ Denotes the change from T0 to T2, such that positive numbers indicate decrease in sleep disturbance/ stress/ depressive symptoms/ TNF/ IL-6 levels from T0 to T2 (i.e., improvement).

Abbreviations. BDI-II is the Beck Depression Inventory, version II; GSDS is General Sleep Disturbance Scale; IL-6 is interleukin 6; PSS is the Perceived Stress Scale; TNF is tumor necrosis factor.

Table 1. Baseline Characteristics

	Group, Number (%)		P value obtained by Chi-square test or T-test
Characteristics	Intervention (n=94)	Control (n=92)	
Age, mean±SD, years			0.972
self	41.63±8.89	41.67±9.00	
partner	47.29±9.39	47.47±10.16	
Education			0.488
≤6 years	15 (16%)	10 (11%)	
7–13 years	71 (76%)	76 (83%)	
Tertiary	8 (9%)	6 (7%)	
Place of birth			0.796
Hong Kong	17 (18 %)	18 (20%)	
Mainland China	77 (82%)	74 (90 %)	
Years of marriage, mean±SD	20.19±23.64	19.04±20.45	0.725
Marital status			0.250
Married/cohabiting	85 (90%)	88 (96%)	
Single / Divorced	9 (10%)	4 (4%)	
≤1 child	36 (38 %)	39 (42%)	0.654
Chronic illness			
Self	15 (16%)	14 (15%)	1.000
Partner	10 (11%)	12 (13%)	0.655
Employed			0.142
Self	23 (25%)	14 (15%)	
Partner	77 (83%)	79 (87%)	
Experiencing financial hardship	62 (67%)	61 (66%)	
Regular exercises	32 (34%)	25 (27%)	0.342
Daily smoking	4 (4%)	3 (3%)	1.000
Alcohol drinking	4 (4%)	4 (4%)	1.000
Postmenopausal	17(18%)	15(16%)	0.749
Illness			
Diabetes	2(2%)	1(1%)	0.576
Cardiovascular disease	1(1.1%)	0(0%)	0.324
Cancer	0(0%)	1(1%)	0.313
Hypertension	3(3%)	7(7%)	0.184
Body mass index			0.410
<18.5 (underweight)	10(11%)	8(9%)	
18.5-22.9 (normal)	55(59%)	47(51%)	
>22.9 (overweight/obese)	29(31%)	37(40%)	
Type of abuse experienced			0.506
psychological abuse only	54 (57%)	45(49%)	

physical/sexual abuse combined with psychological abuse	28 (29%)	33 (36%)	
physical abuse plus sexual abuse plus psychological abuse	12 (13%)	14 (15%)	
Baseline PSS scores, mean±SD	20.93±6.44	20.47±5.23	0.596
Baseline BDI scores, mean±SD	19.33±12.16	17.32±10.43	0.227
Baseline TNF levels, mean±SD	1.68±1.84	1.63±1.73	0.834
Baseline IL-6levels, mean±SD	0.33±1.06	0.16±1.02	0.246

Abbreviations. BDI-II is the Beck Depression Inventory, version II; CI is confidence interval; GSDS is General Sleep Disturbance Scale; IL-6 is interleukin 6; PSS is the Perceived Stress Scale; SD is standard deviation; TNF is tumor necrosis facto

Table 2. Intention to treat analysis of outcomes at baseline and at the end of weeks 6 and 22

	Intervention (n=94)			Control (n=92)			Between-group difference at each time point			Group × time interaction effect <i>P</i> value
	Mean (95% CI)	Within-group change from baseline (95% CI)	<i>P</i> value	Mean (95% CI)	Within-group change from baseline (95% CI)	<i>P</i> value	Mean (95% CI)	<i>P</i> value	Effect size ^a	
GSDS total score										0.045
Baseline	49.66 (45.72, -53.60)	/	/	52.12 (48.13, 56.11)	/	/	-2.46 (-8.07, 3.15)	0.39		
Week 6	42.60 (38.58, 46.61)	-7.06 (-11.2, -2.93)	<0.001	50.56 (46.56, 54.56)	-1.56 (-5.66, 2.54)	1.000	-7.96 (-13.63, -2.30)	0.006	-0.40 (-0.69, -0.11)	
Week 22	41.09 (37.26, 44.93)	-8.57 (-12.56, -4.58)	<0.001	48.26 (44.45, 52.07)	-3.86 (-7.80, 0.09)	0.06	-7.17 (-12.58, -1.76)	0.01	-0.38 (-0.67, -0.09)	
GSDS subscale scores										
Difficulty getting to sleep										0.03
Baseline	2.47 (2.04, 2.90)			2.60 (2.16, 3.03)			-0.13 (-0.74, 0.48)	0.67		
Week 6	1.74 (1.31, 2.18)	-0.72 (-1.24, -0.21)	0.002	2.68 (2.25, 3.11)	0.08 (-0.43, 0.59)	1.000	-0.93 (-1.55, -0.32)	0.003	-0.44 (-0.73, -0.15)	
Week 22	1.76 (1.36, 2.16)	-0.71 (-1.25, -0.17)	0.005	2.31 (1.91, 2.70)	-0.29 (-0.83, 0.26)	0.57	-0.55 (-1.11, 0.01)	0.05	-0.28 (-0.57, 0.01)	
Waking up during sleep										0.47

Baseline	3.73 (3.28, 4.19)			4.02 (3.56, 4.48)			-0.29 (-0.93, 0.36)	0.38		
Week 6	3.34 (2.85, 3.83)	-0.40 (-0.98, 0.19)	0.31	3.84 (3.36, 4.33)	-0.18 (-0.75, 0.40)	1.000	-0.50 (-1.19, 0.18)	0.15	-0.21 (-0.50, 0.080)	
Week 22	2.89 (2.40, 3.37)	-0.85 (-1.46, -0.24)	0.003	3.61 (3.13, 4.09)	-0.41 (-1.02, 0.19)	0.30	-0.72 (-1.40, -0.04)	0.04	-0.30 (-0.59, -0.01)	
Early waking										0.83
Baseline	2.97 (2.49, 3.45)			3.54 (3.06, 4.03)			-0.58 (-1.26, 0.11)	0.10		
Week 6	2.36 (1.87, 2.85)	-0.61 (-1.29, 0.07)	0.09	2.76 (2.28, 3.24)	-0.78 (-1.45, -0.11)	0.02	-0.41 (-1.09, 0.28)	0.24	-0.17 (-0.46, 0.12)	
Week 22	2.36 (1.89, 2.83)	-0.61 (-1.29, 0.07)	0.10	3.01 (2.54, 3.48)	-0.53 (-1.21, 0.14)	0.17	-0.65 (-1.31, 0.02)	0.06	-0.28 (-0.57, 0.01)	
Quality of sleep										0.001
Baseline	4.57 (4.23, 4.91)			4.28 (3.93, 4.62)			0.29 (-0.19, 0.78)	0.24		
Week 6	3.83 (3.48, 4.17)	-0.74 (-1.18, -0.31)	<0.001	4.52 (4.18, 4.86)	0.24 (-0.19, 0.67)	0.55	-0.69 (-1.17, -0.21)	0.005	-0.47 (-0.76, -0.18)	
Week 22	3.88 (3.56, 4.21)	-0.69 (-1.13, -0.25)	0.001	4.03 (3.71, 4.36)	-0.25 (-0.68, 0.19)	0.52	-0.15 (-0.61, 0.31)	0.52	-0.10 (-0.39, 0.19)	
Quantity of sleep										0.42
Baseline	2.28 (2.00, 2.56)			2.39 (2.11, 2.67)			-0.11 (-0.51, 0.28)	0.57		
Week 6	1.91 (1.60, 2.21)	-0.37 (-0.76, 0.01)	0.06	2.32 (2.02, 2.61)	-0.08 (-0.46, 0.31)	1.000	-0.41 (-0.83, 0.01)	0.06	-0.27 (-0.56, 0.02)	

Week 22	2.05 (1.75, 2.35)	-0.23 (-0.64, 0.19)	0.57	2.35 (2.06, 2.65)	-0.04 (-0.45, 0.37)	1.000	-0.30 (-0.72, 0.12)	0.16	-0.21 (-0.50, 0.08)	
Daytime sleepiness										0.32
Baseline	2.96 (2.68, 3.24)			3.21 (2.93, 3.50)			-0.25 (-0.65, 0.15)	0.22		
Week 6	2.64 (2.35, 2.92)	-0.33 (-0.63, -0.02)	0.03	3.07 (2.78, 3.35)	-0.15 (-0.45, 0.16)	0.74	-0.43 (-0.83, -0.03)	0.04	-0.30 (-0.59, -0.01)	
Week 22	2.49 (2.23, 2.75)	-0.47 (-0.77, -0.18)	<0.001	3.00 (2.74, 3.26)	-0.22 (-0.51, 0.08)	0.22	-0.51 (-0.88, -0.14)	0.008	-0.40 (-0.69, -0.11)	
Self-medication to assist sleeping										0.96
Baseline	0.25 (0.12, 0.37)			0.31 (0.18, 0.43)			-0.06 (-0.24, 0.12)	0.51		
Week 6	0.20 (0.07, 0.33)	-0.05 (-0.16, 0.07)	1.000	0.28 (0.15, 0.41)	-0.03 (-0.14, 0.08)	1.000	-0.08 (-0.26, 0.11)	0.41	-0.13 (-0.41, 0.16)	
Week 22	0.21 (0.07, 0.35)	-0.03 (-0.15, 0.08)	1.000	0.26 (0.12, 0.41)	-0.04 (-0.16, 0.07)	1.000	-0.05 (-0.25, 0.15)	0.62	-0.07 (-0.36, 0.22)	

Abbreviations. CI is confidence interval; GSDS is the General Sleep Disturbance Scale

^acomputed by dividing the difference between group means by the pooled standard deviation

Table 3. Results of mediation analyses

Potential mediators	Intervention effect on change in potential mediators ^a (A)		Association between change in potential mediators and change in GSDS scores ^a (B)		Indirect effect (AB)
	β Coefficient (95% CI)	P value	β Coefficient (95% CI)	P value	β Coefficient (95% CI)
PSS	2.07 (0.37, 3.76)	0.02	0.35 (-0.05, 0.74)	0.09	0.72 (-0.19, 2.06)
BDI-II	4.22 (1.31, 7.12)	0.005	0.61 (0.38, 0.84)	<0.001	2.58 (0.69, 5.09)
TNF	0.22 (-0.11, 0.55)	0.18	0.92 (-1.04, 2.88)	0.36	0.21 (-0.32, 0.79)
IL-6	0.22 (0.01, 0.44)	0.04	-2.10 (-5.15, 0.95)	0.18	-0.47 (-1.51, 0.34)

Notes. Total effect (C): β Coefficient=4.91; 95% CI = 0.24, 9.57; P=0.04

Direct effect (C'): β Coefficient=1.87; 95% CI = -2.55, 6.29; P=0.40

Overall indirect effect: β Coefficient=3.03; 95% CI = 0.59, 5.79

Abbreviations. BDI-II is the Beck Depression Inventory, version II; CI is confidence interval; GSDS is General Sleep Disturbance Scale; IL-6 is interleukin 6; PSS is the Perceived Stress Scale; TNF is tumor necrosis factor.

^aDenotes the change from T0 to T2, such that positive numbers indicate decrease in sleep disturbance/ stress/ depressive symptoms/ TNF/ IL-6 levels from T0 to T2 (i.e., improvement)