International Journal of Medical Science and Clinical Research Studies

ISSN(print): 2767-8326, ISSN(online): 2767-8342

Volume 05 Issue 02 February 2025

Page No: 359-370

DOI: https://doi.org/10.47191/ijmscrs/v5-i02-30, Impact Factor: 8.188

Qigong Improves Quality of Life in Lung Cancer Patients: A Randomised Controlled Trial

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ABSTRACT

Background: Qigong is used by cancer patients, but its effect has not been adequately evaluated. Lung cancer is a widespread and lethal malignant disease.

Objective: The current study aimed to explore the effect of Qigong on quality of life, in lung cancer patients.

Methods: A total of 156 lung cancer patients were randomly assigned, at a 1:1 ratio, to receive a 6-week Qigong training (intervention group) or usual care (waitlist control group). The outcome was a composite score of the quality of life assessed through the European Organization for Research and Treatment of Cancer, Core Quality of Life questionnaire, and Lung Cancer module was evaluated at baseline, the end of treatment, and at 12 weeks.

Results: Between groups, statistically significant improvements from baseline to 12th week were observed in global health status (p = 0.021), functional quality-of-life score (p = 0.001), and the symptom subscale of the quality-of-life scale (p = 0.002).

Conclusion: Qigong was effective and safe on the alongside core quality of life indicators.

KEYWORD: Lung cancer, Qigong, QOL, QLQ-C30, LC13

ARTICLE DETAILS

Published On:
24 February 2025

Available on:
https://ijmscr.org/

INTRODUCTION

Lung cancer is a widespread and lethal malignant disease. Lung cancer causes more than 1.6 million deaths annually (1). It is known that lung cancer has been the most common cancer worldwide for several decades, resulting in nearly 20% of all deaths from cancer during that period (2). The survival rate of patients with lung cancer in developing countries is only 9% (3). Annually, there are 20,000 newly diagnosed cases and 17,000 deaths in Vietnam due to lung cancer (4). According to the national survey in Vietnam, lung cancer is ranked as the 4th highest cause of death in males and the 7th highest cause in females (5).

A complementary and alternative modality of traditional Chinese medicine such as Qigong is often used by cancer patients to manage their symptoms and quality of life (QOL)(6). Qigong has been developed and used in cancer treatments (7). Qigong consists of a series of simple, performed in synchrony, repeated practices including body posture or/and movements, breathing practice, and meditation (8). It consists mostly of gentle movements (with some vigorous and shaking movements in addition to quiet, stillness practice) designed to attain a deeply relaxed state.

A burgeoning literature has examined the effects of Qigong on supportive care outcomes in people with cancer including physical function, physical symptoms, psychological symptoms, and quality of life (9). Many positive health-related impacts from the use of Qigong have been reported in the literature, such as improving depression, fatigue and anxiety (10), appetite, nausea and vomiting (11), and decreasing heart rate, blood pressure, lipid levels and levels of circulating stress hormones, and improving immune function (12, 13). Systematic reviews and meta-analyses have concluded that Qigong interventions during and after cancer therapies often result in meaningful and reliable improvements in several supportive care outcomes (14, 15). These benefits include observed changes in physiological measures, objective performance indicators, self-reported functioning and symptoms, psychological well-being and overall QOL. However, these studies did not include people with advanced lung cancer.

Qigong could be highly beneficial because cancer symptoms are chronic, thus requiring patients to have long-term self-management of their symptoms. Therefore, this approach seems to be suitable the Vietnamese context, in which the majority of cancer patients stay at home due to the overloading of oncology hospitals. Normally, Vietnamese cancer patients are only hospitalised for active treatments of the cancer. Most of the time, they stay in the community without or with very limited palliative care (16). The separation from healthcare facilities, as is happening in Vietnam, could be a risk for the insufficient control of symptoms and QOL. Therefore, Qigong could be highly beneficial for lung cancer patients in the Vietnamese population.

Moreover, the literature suggests that Qigong would be an appropriate approach to ease patients' symptoms. Several studies with Qigong interventions have been conducted to reduce cancer-related physical and psychological symptoms. The results are promising. However, the findings from those studies still require further affirmation due to their shortcomings in research designs such as small sample sizes, differences between control and experimental groups, and high attrition rates. The aim of this study is to explore the effect of Qigong on QOL in lung cancer patients. The hypothesis of this study is that patients with lung cancer who receive Qigong training intervention will show greater improvement in QOL than those who receive usual care, as assessed immediately after the completion of Qigong intervention, and at 6-weeks follow-up.

MATERIALS AND METHODS

2.1 Study design

The design of this study was a randomized controlled trial (RCT) with two parallel groups in a 1:1 allocation ratio, allocation concealment, and assessor blinding. Participants from the National Lung Hospital and Nam Dinh General Hospital were enrolled and randomized to the 6-week Qigong intervention or the 6-week wait-list control group to explore the effects of Qigong with the intervention compared to a wait-list control group. The lung cancer patients' QOL was measured as primary outcomes. The intervention in this study was based on a protocol that was enacted by Chulalongkorn University, Thailand (17). All outcomes were measured at baseline before randomization, at the 6th week (at the end of intervention), and at the 12th week (after the 6-week follow-up period). The data collectors were blinded to the group assignments.

2.2 Subjects and Setting

2.2.1 Study population

The study population included patients with a diagnosis of lung cancer at the National Lung Hospital and Nam Dinh General Hospital, Vietnam.

Eligibility criteria

The inclusion criteria of subjects were:

(a) Age 18 or above

(b) Diagnosis of invasive lung cancer [Non-small cell lung cancer (NSCLC) or Small cell lung cancer (SCLC)].

(c) Patients with NSCLC or SCLC who have completed treatment with chemotherapy and/or radiotherapy for a minimum of 4 weeks prior to commencing the study.

(d) Medically fit to participate in general well-being and activities of daily life, as two or smaller on a 0 - to 5-point numeric rating scale at the time of recruitment, as determined by The Eastern Cooperative Oncology Group (ECOG) score.

(e) With no clinically confirmed recurrence or occurrence of other cancers; and

(f) Patients report all three symptoms (dyspnoea, fatigue, and anxiety) in the previous week and ranked the severity of at least two of the three symptoms as three or more on a 0 - to 10-point numeric rating scale at the time of recruitment, as determined by dyspnoea, fatigue, and anxiety intensity rating scales.

Exclusion criteria

1) Known history of clinically diagnosed with major psychiatric illness.

2) Presenting with criteria associated with risk during physical activity: severe cachexia; frequent dizziness; bone pain; or severe nausea.

3) Having had past or current regular experience with mind-body practices that blend movement with meditative practices, such as Yoga, Tai Chi, or Qigong.

4) Life expectancy is estimated to be less than 6 months (as determined by their physicians).

5) Visual problems or deafness.

2.2.2 Sample size

The sample size was calculated based on relevant published literature (Loh, 2015). A sample size of 130 participants has been calculated to be sufficient to detect the effect size of relevant study with a type 1 error of 5% (α=0.05) and 80% power (β=0.20) by Gpower 3.1.9.2 software (http://www.gpower.hhu.de). Therefore, a sample size of 130 subjects is necessary for this study. Considering a 20% attrition rate, 156 subjects are necessary for the total sample size, with 78 subjects in each group.

2.2.3 Withdrawal criteria and management

There were no subjects required to withdraw from the trial based on the following: (1) development of a serious disease or deteriorated health preventing continuation in the trial; (2) adverse events related to the Qigong intervention.

2.2.4 Settings and Time Frame

Vietnam is divided into three main parts: the north, the center, and the South. The country's population is approximately 90 million people, with almost half of the population being found in the north (18). Data collection was conducted in the north because this region demonstrated a significantly higher prevalence of lung cancer than other areas (19). The National Lung Hospital and Nam Dinh General Hospital are two hospitals in the north of Vietnam; on average, those hospitals have 180 to 200 lung cancer

patients receiving treatment in inpatient and outpatient departments per day (20). This study was conducted from January 2017 to December 2017.

2.3 Randomisation and blinding

2.3.1 Randomisation

To avoid the potential bias in the allocation of patients to receive Qigong intervention group or usual care group, neither the investigator, the patient themselves nor their physician could decide that a given person should receive the Qigong intervention or the standard usual care. Randomization tends to balance two groups concerning characteristics that could influence the development of an outcome. To randomize patients to receive Qigong intervention or another guaranteed that the two groups were well balanced and comparable concerning all risk factors that could influence the outcome at study completion (21).

After the completion of baseline measurements, eligible patients were randomly assigned to either the Qigong group or the wait-list control group following blocked randomization procedures with a 1:1 allocation according to the computer-generated randomization list based on ID assigned in the order of enrolment (www.sealedenvelope.com). The blocked randomization refers to what the investigators decide to enrol participant into the study sequentially. The investigators were treated people who were being consecutively enrolled in a series called a block (22). Due to the research setting and patient's characteristics, the block size of six subjects (the next six subjects who are going to be enrolled in study) was used for this study.

Patients in the intervention groups received Qigong training and post-intervention data were collected at the end of completion of the 6 weeks of intervention, and again at the 6 weeks' follow-up. For the control group, the schedules for data collection and following up were the same as for the intervention group. Due to patients being recruited from the same hospital, patients receiving Qigong intervention were asked not to share information with other patients. Similarly, the Qigong Master was requested not to discuss the intervention with research assistants involved in different phases of the trial.

2.3.2 Blinding

In the current study, based on nature of intervention, blinding was not feasible with the researcher, statistician, or Qigong Master who were responsible for the recruitment of subjects, randomisation, and delivering the intervention, respectively. However, the investigators who collect the outcome information were blinded to the allocation sequence. Blinding of the data collectors to group assignment is necessary to ensure objectivity and avoid the risk that assessors record more responses that are favourable when treatment status is known or may assume that improved performance is evidence of treatment status.

2.4 Intervention method

2.4.1 Control group

The wait-list control group received the usual care provided by the hospitals or caregivers and received Qigong training after the follow-up period. The usual care of this study comprised a mandatory individual briefing of the lung cancer care procedure (nursing care after completion of medical treatment) and about a five to a ten-minute individual discussion focusing on symptom management (such as using oxygen when patients have dyspnoea) by a staff nurse before discharge. Patients were also invited to attend an optional group talk given by a registered nurse and a medical social worker about general care before and/or after they returned to the community (23). Patients in both intervention and control groups were offered this usual care.

2.4.2 Intervention group

Qigong training was delivered at the National Lung Hospital and Nam Dinh General Hospital to subjects in the intervention group. One professional coach, who had been engaged in teaching Qigong to clients at the UNESCO Centre for Supporting Community's Heath for at 12 years, was employed to guide the participants' training. The training scheme of Qigong was planned according to the 'Qigong Standard' enacted by the Chulalongkorn University, Thailand (17), and consists of seven postures. This Qigong protocol produced small-to-large effects on symptom management in various populations and medical conditions (24). Qigong is generally reported to be safe in the general population when practiced according to standard moderate principles and when learned under the guidance of a qualified teacher. However, Qigong should not delay the time of diagnosis or replace more established treatments (17).

Subjects in the intervention group (6 patients in each Qigong training section) received a 90 minutes' Qigong training, meeting twice a week for the first 2 weeks to intensify proper learning of the Qigong intervention. Thereafter, subjects were asked to practice at home for at least 30 min a day, 5 days per week, over 4 weeks and to keep a log of the frequency, minutes of practice, and level of skills. The home exercises were the same as those learned in the training sessions and an instructional DVD and guidebook were also given to subjects. The DVD was modified from original Thai version with the performances of Qigong master with music, and Vietnamese description in the background.

2.4.3 Follow-up

After the 6-week intervention period, all participants stopped practice Qigong and started an additional 6-week unsupervised follow-up practice. During the follow-up period, all participants were required to record their daily activity information at 8 and 12 weeks.

2.4.4 Adherence measures

All subjects were advised not to seek any other regular exercise during the trial period. The researcher supervised the training to guarantee the quality of Qigong delivery. In order to observe any impact of the usual physical

activity, the researcher required all subjects to record information about their usual daily physical activity at 3 and 6 weeks of the intervention period on a daily activity log.

The researcher assessed the subjects' compliance with the home program by asking and testing them every week though phone calls to encourage participants to practice and ensure that the training dose is adequate by recording in a diary logbook. If a subject missed a phone call, the researcher made an additional phone call to prevent loss-to-follow-up. To incentivize the completion of the data collection, 50,000 VND gift cash was provided at the baseline collection, 150,000 VND gift cash at the post-intervention data collection, and 150,000 VND gift cash at the 12-week follow-up data collection time point. Subjects were reminded that the gift would be given to them upon completion of data collection. All participants can stop practicing Qigong during the follow-up period. The wait-list control group received usual care during the first 12 weeks of the study and participants then received the same Qigong training after the follow-up period.

2.4.5 Safety assessment

There were no side effects from practicing Qigong in the intervention group in this study.

2.5 Outcome measures

Baseline characteristics

The investigator using the printed questionnaires collected participants' demographic characteristics (e.g., age, sex, education, marital status, and occupation) and history of the disease, disease status, and current treatments.

Quality of life

QOL was measured by the European Organisation for Research and Treatment of Cancer - Quality of life questionnaire - Core (EORTC-QLQ-C30) and Lung module (LC-13 subscale) (25). The Cronbach's alpha coefficient of EORTC QLQ-C30 and QLQ-LC13 in this study were 0.83 and 0.75, respectively.

2.6 Data analysis

Data analysis was performed according to the procedures of the SPSS version 23. The GEE was used to analyse the effect of the effect of the Qigong on QOL. In each model, the independent variables are the group (Qigong group and wait-list control group), time (different measurement time points, such as baseline, post-intervention, and post-follow-up), confounding factors (e.g., age, gender) and any inequality factors among groups at the baseline assessment. All tests involved a two-sided significance level of $\alpha = 0.05$.

2.7 Ethical issues

The principles of this study was following the declaration of Helsinki Principles that included: (1) Protection of life, health, dignity, integrity, right to self-determination, privacy, and confidentiality by using an individual code with each subject only known by the researcher; (2) Acceptable scientific principles; (3) Described in a protocol; (4) Protocol must be reviewed by an ethics committee; (5) Consideration of local laws and regulations; (6) Assessment of predictable risks, burdens, and importance; (7) appropriate training and qualifications of investigator; (8) Participation must be voluntary; and (9) Participants were give consent (World Medical Association, 2013). Therefore, the study information and consent form were approved by the Research Ethics Committee of the Hong Kong Polytechnic University, Hong Kong and the hospital in Vietnam.

RESULTS AND DISCUSSION

3.1 Characteristic of the subjects

The mean age of the patients was 56.84 ± 9.45. This finding is similar to other studies (20, 26), in that most lung cancer patients are diagnosed at a late adult age. The majority (74.4 %) of patients were male. The high prevalence of lung cancer in Vietnamese males may be "associated with their smoking behaviour-one of the most important causes of lung cancer" (20). It was reported that smoking is highly prevalent in Vietnam, with 56.7% of males aged from 25-44 years, and 59.5% of males aged from 45-64 years being smokers (27).

With regard to stage of cancer, the most prevalent was stage IV (61.5%), followed by stage III (29.5%). Patients with stage I accounted for the smallest proportion of the sample (2.6%). These findings reflect the fact that most patients were diagnosed in advanced stages. Many patients came to hospital for treatments when the tumour had grown and spread widely (28). Most of the lung cancer patients in Vietnam (65-80%) are diagnosed in the hospital in advanced stages (29). The reason for this situation is the poor knowledge and awareness of the public and general practitioners at the community levels of the Vietnamese healthcare system (20). The number of chemotherapy cycles received for the treatment of lung cancer among subjects varied from 4 to 14 cycles (equally 4 to 20 months) with the mean of 5.67 ± 2.62 cycles; subjects with 4 cycles accounted for the highest prevalence (55.1%). It can be said that the subject of the current study was at the middle steps of the treatments as well as their lives with the cancer (Table 1).

3.2 Descriptive data relating to the baseline outcome data

There were significant between-group differences at baseline in diarrhoea (Qigong 6.41 and control 9.4; p = 0.024), as depicted in Table 2. At baseline, patients in both groups reported similar levels of QOL in most domains. There were no clinically relevant differences (MD) ≥10 points. Small differences of 5–10 points were encountered in dyspnoea, peripheral neuropathy LC13, and alopecia LC13 (MD – 7.29; -5.13; and -5.37 respectively), (Table 2).

3.3 Effect of Qigong on QOL in lung cancer patients.

3.3.1 Quality of life – global health status domain

A significant difference was observed at the 6th week between-groups of the Qigong and waitlist control groups with a mean difference of -5.69 (p = 0.021) (Table 3a, 3b and Figure 1). Furthermore, the mean global health status scores

within group of the Qigong group increased from baseline to the 6th week with a mean difference of 5.29 (p = 0.010). In contrast, the mean global health status scores within group of waitlist control group gradually changed at the 6th week and then decreased slightly at 12th week although these changes revealed no statistical significance in scores. As indicated by statistically significant within-group changes, there was variation in the Qigong group in the first 6 weeks that need further exploration.

3.3.2 Quality of life - functional scales

The functional scales were the scoring of physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning. A significant difference was only observed at the 6th week between-groups of the Qigong and waitlist control groups with a mean difference of –6.02(p = 0.001) (Table 4b). Furthermore, there were no significant differences in mean functional scores within both the Qigong and control groups. This means that Qigong did not improve functional scores across time (Table 4a and Figure 2).

3.3.3. Quality of life - symptom scales

The symptom scales were the scoring of fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties. A significant difference was observed at the 6th week and 12th week between-groups of the Qigong and waitlist control groups with a mean difference of 5.81 (p = 0.002) and 5.54 (p = 0.034), respectively (Table 5a,5b and Figure 3). Furthermore, the mean symptom scores within group of the Qigong group declined from baseline to the 6th week, with a mean difference of -3.45 (p = 0.035), and then marginally increased at the 12th week; these changes revealed no statistical significance in these scores. In contrast, the mean symptom scores within the waitlist control group gradually changed at the 6th week and then increased slightly at the 12th week, although these changes revealed no statistical significance in these scores. As indicated by statistically significant within-group changes, there was variation in the Qigong group in the first 6 weeks and Qigong needed more than 6 weeks to improve symptom scores.

3.3.4. Quality of life – LC13 scales

The mean LC13 total scores of the Qigong group marginally increased from baseline to the 6th week with a mean difference of 1.16 (p = 0.448) and then increased at the 12th week with a mean difference of 7.23 (p = 0.001); these changes across time revealed statistical significance in these scores. The mean LC13 total scores of control group gradually increased at the 6th week with a mean difference of 3.27 (p = 0.024) and then continue increased at 12th week, these changes revealed statistical significance in these scores with a mean difference of 7.83 (p = 0.000). In addition, no significant differences were observed at the 6th week and 12th week between the Qigong and waitlist control groups. Furthermore, there was no significant interaction (group x time) of the model across time (Table 6a, 6b and Figure 4).

The results from this study suggested that Qigong has a positive influence on QOL of lung cancer patients. Qigong intervention improved while the control group had little improvement or even a reduction of QOL. There was a significant difference within and between groups on global health status at the 6th week with p = 0.01 and p = 0.021, respectively. There was also a significant difference between groups on function score at the 12th week with p = 0.01. With regard to symptom scales, there was a significance difference within, between groups at the 6th week, and across time with p = 0.035; p = 0.002; and p = 0.038, respectively. The results of this study are consistent with those of other studies. Multiple studies confirm that Qigong significantly improves QOL (12, 30-34). In addition, Byeongsang, Butow (35) found that the Qigong intervention group reported clinically significant improved global QOL scores pre- and post-intervention. Another similar study of a Tai Chi intervention reported improvement in health-related QOL of patients with breast cancer (36).

Regarding minimal clinically important differences, changes to global health status in the Qigong group at post-intervention was 5.29. This finding provides estimates of MCIDs for lung cancer patients when using the EORTC QLQ-C30. The estimates generally agree with the estimates of 5–10 units of the QLQ-C30 scales we considered and as proposed by Osoba, Rodrigues (37) and King, Bell (38). This change can be useful for clinicians to determine the proportion of patients benefiting from Qigong treatment. The change could also be used as guidance for classification of patients by changes in QOL and symptoms over time. Furthermore, the estimates may be useful in sample size determination and design for future clinical trials.

Regarding typical symptoms of lung cancer symptom related to QOL, there were LC13 scores increased in both the Qigong and control groups. There was no statistically significant difference between the two groups for this increase. However, symptoms in the control group increased more and heavier than those of the Qigong group. At the 6th week, mean difference of LC13 score of control and Qigong group were 11.10 and 7.23, respectively. It can be said that Qigong does not directly reduce the typical symptoms of lung cancer related to QOL, but Qigong had helped to slow the severity of the characteristic symptoms. This result is consistent with the conclusions of the previously published systematic review (39, 40).

According to Anant, Guleria (41), several factors such as age, associated co-morbidities, and quality of medical and palliative care provided to the patients influence many aspects of QOL. In addition, the short-term survival of lung cancer, rapid deterioration of performance status, and dropouts due to treatment-related side effects may cause difficulty in collecting data and following-up the patients for a long period of time. This problem of "missing data" causes difficulties in making accurate assessments and drawing conclusions from many studies. It has been suggested that

comparative analysis of QOL should be stopped when less than 30% of the data is available (42). In the current study, over 50% of the data are available, therefore, the results can provide meaningful information to clinicians in addition to the clinical diagnosis (e.g. the history, the physical examination and other diagnostic and laboratory test) and it may also influence clinical decision making as well as improving QOL of patients (43).

The repeated QOL assessment may train patients, thus influencing their scores, which could weaken the effects of the study intervention. Furthermore, the use of semi-structured interviews contributes meaning to individual patient scores (44) and adds information about perceived problems (45). In the course of the disease, patients´ perception of their health status usually changes due to deterioration as a tumour progresses, but also because of adaptation, as patients often adopt new internal standards. This phenomenon is known as response shift and is not easily observed by physicians (46, 47).

Limitations of the current study

There are several notable features to this study, including the recruitment of adequate numbers, the inclusion of two cohorts (immediate, delayed training groups) which allows for assessment of reproducibility between groups, the use of standardized measures to determine outcomes, and attention to adherence to protocol with the amount of practice. In addition, there is also a consideration of those who attain outcomes that are considered to represent clinically meaningful changes. Although our results are promising, several limitations of the current study should be noted: *Firstly*, the subjects were mainly recruited from the two hospitals from the Northern part of Vietnam, which may limit the generalisability of our results. The male subjects outnumbered the female subjects in our study. The demographic characteristics (e.g., age) of the drop group were quite different from the active group. It might be better if we could identify more subjects and then allocate them to either group. All of these limitations might affect the generalisability of the present findings; *Secondly*, the rate of drop out was high at the sixth week of intervention and the 12th week follow-up (38%, 60.2% in the Qigong group and 15%, 40% in the waitlist control group). The main reason was that many subjects voluntarily withdrew from the study process. In addition, there was no fixed time to "enter static" and practice. There were also some patients who reported that their perspective was "letting go", so they were not able to achieve the complete Qigong achievement. This may explain why the differences between the two groups were more significant at six weeks than at 12 weeks; *Thirdly*, blinding the subjects to their treatment allocation was not possible due to the nature of the intervention. The inclusion of a control group was nonetheless important to compare changes between those who did and did not receive Qigong intervention and to control for changes in self-reported QOL that may occur over time without an intervention; *Fourthly*, although the Qigong protocol was developed by Chulalongkorn University, Thailand that agreed that it was suitable for Vietnamese lung cancer patients to practice, we did not have an objective assessment tool to indicate how much the subjects could master the exercise; *Fifthly*, although we tried to deal with the problem of non-specific effect by introducing the block randomisation, we still faced the possibility of the experimenter-expectancy effect; *Sixthly*, Qigong learning process was lacked checklist for two weeks training at hospitals, missed follow-up assessment and qualitative information about perfective of subjects to Qigong practicing; *Finally*, when investigating characteristics between the active subjects and the dropout subjects, due to a significant difference in age and gender, baseline values of fatigue, etc., we could not apply the LOCK and per-protocol approach to deal with missing data forms. For comparisons between the qigong group and waitlist group subjects, computation variables were also used in some outcome variables such as cluster symptom, functional scales, symptom scales, and LC 13 total scores. Conducting multiple tests probably increased the probability of Type I error. Therefore, caution should be used when interpreting the findings.

CONCLUSIONS

The aim of this study was to explore the effect of Qigong on QOL in lung cancer patients. To achieve the study's aim, the theory of unpleasant symptom management was utilised to guide the intervention of this study. The subject was recruited by purposive sampling into intervention and control groups followed by randomisation assignment of subjects were conducted through in Nation Lung Hospital and Nam Dinh General Hospital in North of Vietnam. The sample consisted of 156 lung cancer patients. The collection of data was conducted at three time points: baseline, 6th week, and 12th week for the two groups from January 2017 to December 2017. The attrition rate in the Qigong group at the end of the intervention and at the end of the follow-up was 38.5% and 60%, respectively. The attrition rate in the control group at the end of the intervention and the end of the follow-up were 15% and 40%, respectively. The effects of Qigong on the QOL were investigated in the RCT. There was a trend in improvement within the group of the Qigong intervention on QOL. The improvement in LC13 of the Qigong group was also better than that of the control group. The results of the current study suggest that Qigong was effective on improving patients' QOL.

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Table 1. Demographic data and disease characteristics for all participants in Qigong and control groups (n = 156)

Variables	All N = 156	Qigong groups n = 78	Control group n = 78	*p-value**
Age (years)				
Mean (SD)	56.84(9.45)	57.62 (9.63)	56.06 (9.25)	0.429
Gender (n, %)				
Male	116(74.4)	59 (75.6)	57 (73.1)	0.714
Female	40 (25.6)	19 (24.4)	21 (26.9)	
Cancer type (n, %)				
NSLCC	152 (97.4)	78 (100)	74 (94.9)	0.43
SLCC	4 (2.6)	0 (0)	4 (5.1)	
Stage (n, %)				
I	4 (2.6)	4 (5.1)	0 (0)	0.28

II	10 (6.4)	4 (5.1)	6 (7.7)	
III	46 (29.5)	23 (29.5)	23 (29.5)	
IV	96 (61.5)	47 (60.3)	49 (62.8)	
Current treatment (n, %)				
Chemotherapy	64 (41)	31 (39.7)	33 (42.3)	0.73
Chemotherapy & Radiotherapy	60 (38.5)	29 (37.2)	31 (39.7)	
Chemotherapy & Operation	32 (20.5)	18 (23.1)	14 (17.9)	
Number of Chemotherapy Cycles				
Mean (SD)	5.67 (2.62)	5.33 (2.46)	6.01(2.73)	0.636
Education (n, %)				
Primary	16 (10.3)	10 (12.8)	6 (7.7)	0.508
Secondary	83 (53.2)	42 (53.8)	41 (52.5)	
High school	43 (27.6)	18 (23.1)	25 (32.1)	
Vocational school	3 (1.9)	1 (1.3)	2 (2.6)	
University and higher	11 (7.1)	7 (9.0)	4 (5.1)	
Religion (n, %)				
Non-religion	154 (98.7)	78 (100)	76 (97.4)	0.363
Buddhism	1 (0.65)	0	1 (1.3)	
Christian	1 (0.65)	0	1 (1.3)	
Employment (n, %)				
Current worker	25 (16)	16 (20)	9 (11.5)	0.095
Unemployment	131 (84)	62 (80)	69 (88.5)	
Marital status (n, %)				
Married	154 (98.7)	78 (100)	76 (97.4)	0.115
Single	2 (1.3)	0	2 (2.6)	

(The p-value are based on χ^2 analysis for categorical variables and t-tests for continuous variables)*

NSLCC: Non-Small Cell Lung Cancer

SLCC: Small Cell Lung Cancer

Table 2. Description of studied variables at baseline (N = 156) * $p \leq 0.05$

	Mean (SD)			***p***
	All (n = 156)	Control (n = 78)	Qigong (n = 78)	
Quality of life				
Global health status	48.39(13.12)	46.79(12.75)	50.00(13.36)	0.803
Physical functioning	63.37(14.81)	63.68(13.99)	63.07(15.66)	0.388
Role functioning	56.62(18.51)	57.05(17.71)	56.19(19.38)	0.520
Emotional functioning	66.44 (12.94)	64.42(12.43)	68.47(13.19)	0.567
Cognitive functioning	61.08(21.18)	57.88(20.22)	64.29(21.75)	0.781
Social functioning	48.29(19.59)	47.22(18.49)	49.35(20.70)	0.647
Fatigue	44.23 (14.95)	44.30(13.57)	44.17(16.30)	0.080
Nausea and vomiting	14.31(20.16)	15.17(19.95)	13.46(20.46)	0.888
Pain	31.10(20.40)	28.66(19.35)	33.54(21.23)	0.847
Dyspnoea	31.39(15.72)	35.04(15.09)	27.75(15.57)	0.082
Insomnia	45.29(28.32)	43.58(29.08)	47.00(27.62)	0.641
Appetite lose	44.87(25.01)	46.15(24.75)	43.58(25.37)	0.671
Constipation	10.25(17.60)	11.53(18.47)	8.97(16.70)	0.111
Diarrhoea	7.90(15.66)	9.40(16.90)	6.41(14.27)	**0.024***
Financial difficulties	55.12(27.21)	56.83(25.82)	53.41(28.59)	0.179
Quality of life – LC13				
Dyspnoea	40.01(15.49)	40.00(14.37)	40.02(16.63)	0.363

Coughing	40.38(15.61)	40.59(16.68)	40.17(14.57)	0.594
Haemoptysis	5.15(13.19)	5.18(12.09)	5.12(14.29)	0.859
Sore mouth	14.23(23.02)	14.79(23.72)	13.67(22.43)	0.548
Dysphagia	30.55(26.22)	29.91(25.53)	31.19(27.04)	0.746
Peripheral neuropathy	35.89(28.97)	38.46(27.43)	33.33(30.38)	0.452
Alopecia	48.83(31.51)	51.52(30.17)	46.15(32.77)	0.133
Pain in chest	28.63(25.24)	29.48(24.60)	27.77(25.99)	0.176
Pain in arm or shoulder	25.85(26.38)	27.35(26.17)	24.35(26.68)	0.346
Pain in other parts	21.97(25.88)	20.04(24.59)	23.89(27.13)	0.405

Table 3a. Results of GEE on global health status of QOL (N = 156)

	Mean (Std. Error)		**Group*Time**		
	Qigong	**Control**	**β**	**95% CI**	*p- value*
Baseline	50.00(1.50)	46.79(1.44)			
6 weeks	55.29(1.89)	49.61(1.57)	2.481	-2.94; 7.90	0.369
12 weeks	51.76(3.21)	45.80(2.28)	2.754	-5.55; 11.06	0.516

Global health status score ranges from 0 to 83.33 *(Higher score indicates better QOL)*

Table 3b. Pairwise Comparisons on global health status (N = 156)

	Baseline – 6th week		**Baseline – 12th week**		**6th week - 12th week**	
	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*
Qigong	**5.29 (1.26; 9.32)**	**0.010***	1.76 (-5.15; 8.67)	0.618	-3.53 (-9.27; 2.20)	0.128
Control	2.81 (-0.81; 6.44)	0.128	0.99 (-5.60; 3.62)	0.673	-3.81 (-8.63; 1.02)	0.122
Qigong & Control	-3.21 (-7.28; 0.87)	0.123	**-5.69 (-10.50; -0.87)**	**0.021***	-5.96 (-13.67; 1.75)	0.130
	Baseline		**6th week**		**12th week**	

Table 4a. Results of GEE on functional score of QOL (N = 156)

	Mean (Std. Error)		**Group*Time**		
	Qigong	**Control**	**β**	**95% CI**	*p- value*
Baseline	60.28(1.42)	58.05(1.14)			
6 weeks	62.08(1.36)	56.06(1.22)	3.788	-0.52; 8.10	0.085
12 weeks	59.42(2.21)	55.49(1.71)	1.701	-4.38; 7.78	0.583

Functional score ranges from 18.33 to 92.33 *(Higher score indicates better function)*

Table 4b. Pairwise Comparisons on functional score (N = 156)

	Baseline – 6th week		**Baseline – 12th week**		**6th week - 12th week**	
	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*
Qigong	1.80 (-1.48; 5.08)	0.283	-0.86 (-5.82; 4.10)	0.733	-2.66 (-6.92; 1.60)	0.221
Control	-1.99 (-4.79; 0.81)	0.163	-2.56 (-6.08; 0.95)	0.153	-0.57 (-4.27; 3.13)	0.762
Qigong & Control	-2.23 (-5.80; 1.35)	0.222	**-6.02 (-9.60; -2.44)**	**0.001***	-3.93 (-9.41; 1.55)	0.160
	Baseline		**6th week**		**12th week**	

Table 5a. Results of GEE on symptom scales of QOL (N = 156)

	Mean (Std. Error)		**Group*Time**		
	Qigong	**Control**	**β**	**95% CI**	*p- value*
Baseline	30.93(1.36)	32.30(1.20)			

6 weeks	27.48(1.42)	33.29(1.20)	-4.440	-8.63; -0.25	**0.038***
12 weeks	29.54(2.15)	35.08(1.49)	-4.164	-9.87; 1.55	0.153

Symptom scales score range from 2.47 to 75.31 *(Higher score indicates more severe)*

Table 5b. Pairwise Comparisons on symptom scales (N = 156)

	Baseline – 6th week		**Baseline – 12th week**		**6th week - 12th week**	
	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*
Qigong	**-3.45 (-6.65; -0.24)**	**0.035***	-1.39 (-6.15; 3.38)	0.569	2.06 (-2.20; 6.32)	0.343
Control	0.99 (-1.71; 3.70)	0.471	2.78 (-0.37; 5.93)	0.083	1.79 (-1.39; 4.96)	0.270
Qigong & Control	1.37 (-2.17; 4.92)	0.448	**5.81 (2.18; 9.45)**	**0.002***	**5.54 (0.41; 10.67)**	**0.034***
	Baseline		**6th week**		**12th week**	

Table 6a. Results of GEE on LC13 total score of QOL (N = 156)

	Mean (Std. Error)		**Group*Time**		
	Qigong	**Control**	**β**	**95% CI**	*p- value*
Baseline	28.57(1.38)	29.74(1.24)			
6 weeks	29.73(1.55)	33.01(1.28)	-2.114	-6.23; 2.00	0.314
12 weeks	35.80(2.05)	40.83(1.58)	-3.868	-9.34; 1.60	0.166

LC13 total score range from 2.22 to 63.33 *(Higher score indicates more severe the symptoms)*

Table 6b. Pairwise Comparisons on LC13 total score (N = 156)

	Baseline – 6th week		**Baseline – 12th week**		**6th week - 12th week**	
	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*	Mean difference (95%CI)	*p-value*
Qigong	1.16 (-1.83; 4.14)	0.448	**7.23 (2.91; 11.55)**	**0.001***	**6.07 (1.86; 10.29)**	**0.005***
Control	**3.27 (0.44; 6.10)**	**0.024***	**11.10 (7.74; 14.45)**	**0.000***	**7.83 (4.63; 11.02)**	**0.000***
Qigong & Control	1.17 (-2.47; 4.80)	0.530	3.28 (-0.67; 7.23)	0.104	5.03 (-0.03; 10.10)	0.051
	Baseline		**6th week**		**12th week**	

** $p \leq 0.05$*

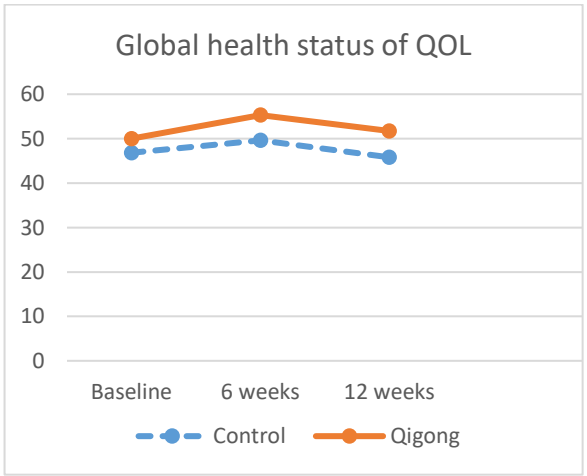

Figure 1. Changes in global health status scores across time

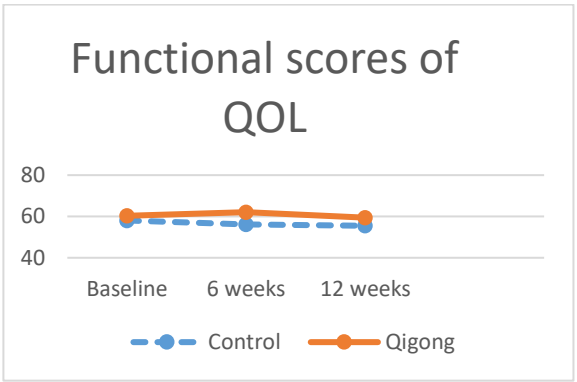

Figure 2. Changes in functional scores across time

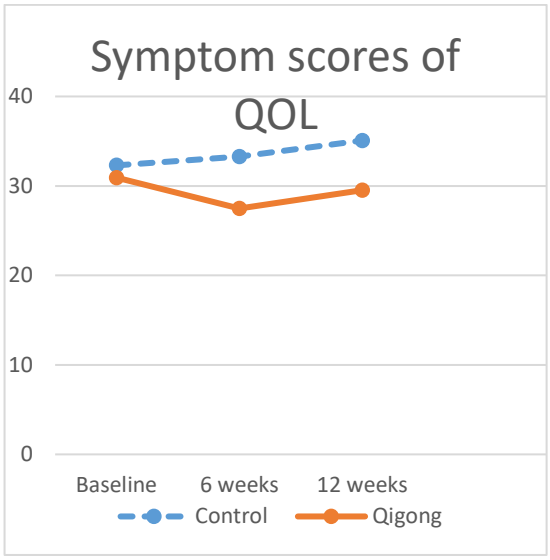

Figure 3. Changes in symptom scores across time

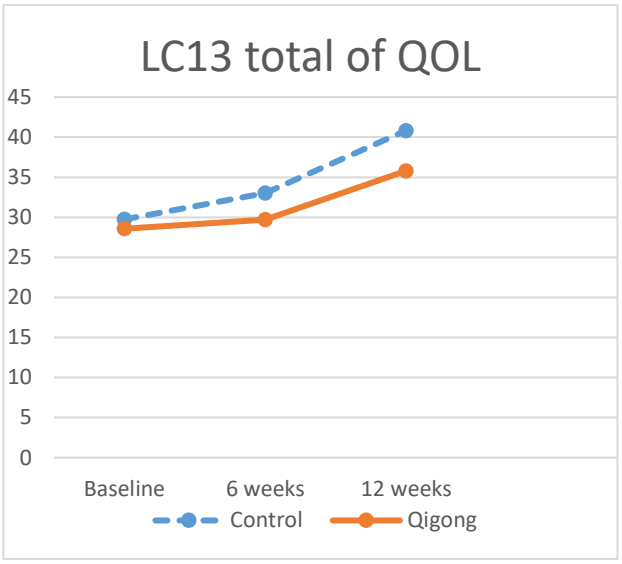

Figure 4. Changes in LC13 total scores across time