

The Challenges of Conducting a Randomized Controlled Trial in Vietnamese lung cancer population

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ABSTRACT

Background: Clinical Randomized Control Trial (RCT) on lung cancer subjects has one of the highest dropout rates. The aim of this report is to examine the challenging issue that arises with conducting an RCT in lung cancer with the title “Effects of Qigong on symptom clusters of dyspnea, fatigue, and anxiety in Vietnamese lung cancer patients: A randomized control trial” and to suggest possible resolutions.

Materials and Method: One hundred and fifty-six patients were recruited and randomly assigned to either the Qigong group (n=78) or the wait-list control group (n=78). A 6 week Qigong practice program was conducted that comprised of 2 weeks training at a hospital then home-based practice 30 min per day for 5 days per week. A DVD, a logbook and weekly phone calls were provided to the Qigong group.

Results: Multiple challenging issues were identified and were regrouped as the patients at hospitals in Vietnam are not familiar with research study or RCT. The intervention is complex involving attending a workshop and practices Qigong with many steps and over a period with home practice. Heavy disease burden of lung cancer patients have some affect exercising significantly such as, breathless and fatigue Patients’ cultural belief in self-care and taking care of the family, ‘No’ comfortable place for patients during data collection, hospitals administrations are too busy, do not have time to cooperate and lack of support for research project.

Conclusions: A clinical trials must pay considerable attention to the recruitment process and it should even be piloted to identify potential challenging and facilitators to reduce attrition rate in trials, have a realistic timeline, define a clear objective and precise endpoints, balance the study with correct randomization are key elements that help us assuring a strong study’s validity.

KEYWORDS: RCT challenge, Lung cancer, Qigong, Clinical trials

INTRODUCTION

The aim of this report is to examine the challenging issue that arises with conducting an RCT in lung cancer with the title “*Effects of Qigong on symptom clusters of dyspnea, fatigue, and anxiety in Vietnamese lung cancer patients: A randomized control trial*” and to suggest possible resolutions. This is a randomized control trial to explore the effect of Qigong on managing dyspnea, fatigue and anxiety (as a cluster) in lung cancer patients and on cough which was another common symptom linked with dyspnea, fatigue and anxiety as a cluster, and QOL in lung cancer patients.

Overview of the Original Study

This study was conducted in lung cancer population. Effectiveness of existing interventions for fatigue, dyspnea

and anxiety is currently modest, resulting in the need to design new interventions for these symptoms.

Patients with lung cancer experience a variety of symptoms and most of them are at a moderate level of severity. Dyspnea, fatigue and anxiety are often the most problematic symptoms of lung cancer. Non-pharmacological approaches to manage symptoms among lung cancer patients showed either no or mild effects. Qigong is used by cancer patients, but its effects are not adequately evaluated, all past related trials focus on a single symptom, none have been done with lung cancer patients and many trials have methodological limitations.

The study had two objectives:

1. To assess the effect of Qigong on managing dyspnea, fatigue and anxiety (as a symptom cluster) in lung cancer patients.

- To explore the effect of Qigong on cough, this is another common symptom, linked with dyspnea, fatigue and quality of life, in lung cancer patients.

METHODOLOGY

One hundred and fifty-six patients were recruited and randomly assigned to either the Qigong group (n=78) or the wait-list control group (n=78). A 6 week Qigong practice program was conducted that comprised of 2 weeks training at hospital then home-based practice 30 min per day for 5 days per week. Qigong consists of two words: “Qi” and “Gong”. The word “Qi” means ‘breath’ or ‘vital essence’ or ‘energy’.

The word “Gong” means ‘daily effort’ or ‘self-discipline’ or ‘mastery’ or ‘power’. Qigong in this study was founded by the Faculty of Nursing, Chulalongkorn University, Thailand [1]. A DVD, a logbook and weekly phone calls were provided to the Qigong group. The primary outcome was a composite score of the Functional Assessment of Cancer Therapy-Fatigue (FACT-F), Cancer Dyspnea Scale (CDS) and Depression Anxiety Stress Scales 21 subscale anxiety (DASS21-A). While the secondary outcomes included the three symptoms of the cluster individually, cough assessed with the Manchester Cough in Lung Cancer Scale (MCLCS), and quality of life assessed through the European Organization

Table 1: Demographic data, disease characteristics and symptoms 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)	
Types of 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)	
Fatigue (range 6 -42)	27.25(5.9)	27.71(5.13)	26.78(6.58)	0.039*
Dyspnoea (range 9 -30)	17.28(3.46)	17.29(3.44)	17.26(3.5)	0.723
Anxiety (range 4 - 36)	13.5(5.43)	13.39(5.21)	13.31(5.68)	0.658
Cough (range 12 -39)	21.06 (5.23)	20.71(5.36)	21.41(5.10)	0.870

* p ≤ 0.05

for Research and Treatment of Cancer (EORTC) Core Quality of Life questionnaire (QLQ-C30), and Lung Cancer module (LC13). All outcomes were assessed at baseline, post-intervention and post 6-weeks of follow-up. Generalized estimating equation methods were used to analyze the effects of Qigong on primary and secondary outcomes.

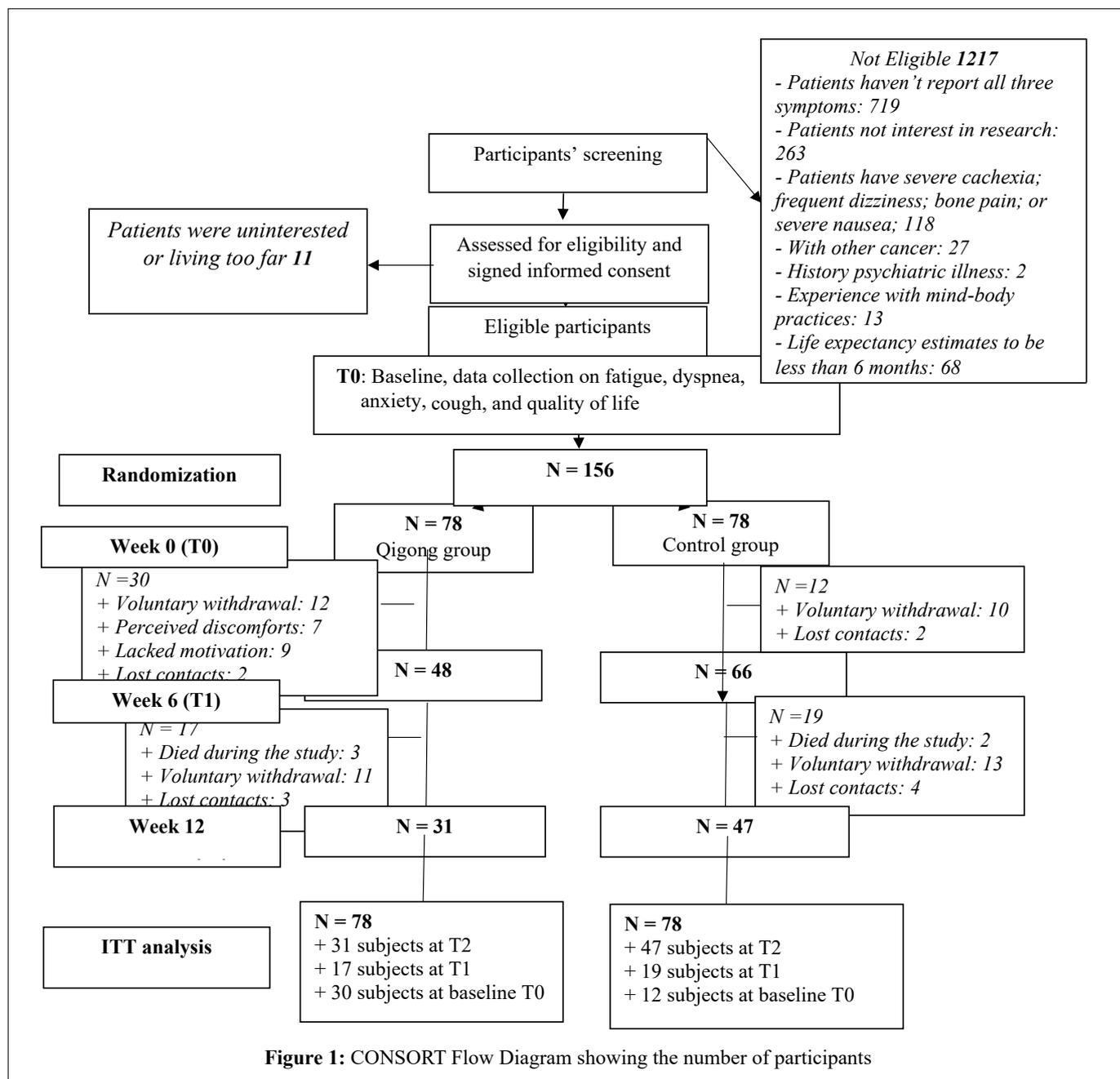
RESULTS

The sample included 156 lung cancer patients. Most of them were male (74.4%) and the mean age was 56.84 ± 9.45 years. Most of the subjects had completed secondary

school (53.2%). The mean duration of treatment with lung cancer was 5.67 ± 2.62 cycles and the majority had received 4 cycles of chemotherapy (55.1%). Most of the sample was at stage IV (61.5%) and III (29.5%) (Tables 1 and 2). Of the 78 subjects in the Qigong group, 48 (61.5%) completed the 6 week intervention program, and 66 (84.6%) completed at least half of the 6-week intervention. Based on face-to-face meetings during follow-up at hospitals and telephone check-ups, the practice adherence rate was 61.5% (Figure 1). No Qigong-related adverse reactions were reported by the subjects in the intervention group.

Table 2: Description of Patients’ Symptoms at Baseline between Those Who Dropped out and Completed the Study (i.e. active) in Both Intervention and Control Groups.

Variables	Drop out n = 78	Active n = 78	All subjects	p-value*
Age (years)				
Mean (SD)	57.94 (7.21)	55.74 (11.19)	56.84 (9.45)	0.004
Gender (n, %)				
Male	67 (85.9)	49 (62.8)	116 (74.4)	0.002
Female	11 (14.1)	29 (37.2)	40 (25.6)	
Cancer type (n, %)				
NSLCC	77 (98.7)	75 (96.1)	152 (97.4)	0.620
SLCC	1 (1.3)	3 (3.9)	4 (2.6)	
Stage (n, %)				
I	2 (2.5)	2 (2.5)	4 (2.5)	0.226
II	2 (2.5)	8 (10.3)	10 (6.4)	
III	22 (28.3)	24 (30.8)	46 (29.5)	
IV	52 (66.7)	44 (56.4)	96 (61.6)	
Types of treatment (n, %)				
Chemotherapy	35 (44.9)	29 (37.2)	64 (41)	0.138
Chemotherapy & Radiotherapy	32 (41)	28 (35.9)	60 (38.5)	
Chemotherapy & Operation	11 (14.1)	21 (26.9)	32 (20.5)	
Number of Cycles				
Mean (SD)	5.6 (2.65)	6.18 (3.04)	5.89 (2.86)	0.216
Education (n, %)				
Primary	11 (14.1)	5 (6.4)	16 (10.3)	0.394
Secondary	43 (55.1)	40 (51.3)	83 (53.2)	
High school	19 (24.4)	24 (30.8)	43 (27.6)	
Vocational school	1 (1.3)	2 (2.6)	3 (1.9)	
University and higher	4 (5.1)	7 (8.9)	11 (7)	
Religion (n, %)				
Non-religion	78 (100)	76 (97.4)	154 (98.7)	0.363
Buddhism	0	1 (1.3)	1 (0.65)	
Christian	0	1 (1.3)	1 (0.65)	
Employment (n, %)				
Current worker	9 (11.5)	21 (26.9)	30 (19.2)	0.024
Non-current worker	69 (88.5)	57 (73.1)	126 (80.8)	
Marital status (n, %)				
Married	78 (100)	76 (97.4)	154 (98.7)	0.497
Single	0	2 (2.6)	2 (1.3)	
Symptom outcomes				
Fatigue	28.44 (5.87)	26.42 (6.08)	27.25(5.9)	0.036
Dyspnea	17.05 (3.53)	16.93 (2.88)	17.28(3.46)	0.525
Anxiety	13.35 (5.17)	11.94 (6.34)	13.5(5.43)	0.034
Cough	20.39 (5.23)	20.37 (6.12)	21.06 (5.23)	0.080



There was no improvement on the symptom cluster, fatigue or anxiety, between the two groups across time. However, the subjects in the Qigong group showed a trend towards an improvement in symptoms in within-group analysis in the fatigue, dyspnea and anxiety from baseline to 6th week ($p=0.004$, 0.002 and 0.049 , respectively). Between group statistically significant improvements were observed in cough ($p=0.001$), dyspnea ($p=0.014$), global health status ($p=0.021$), functional quality of life score ($p=0.001$) and the symptom subscale of the quality of life scale ($p=0.002$) (Table 3).

Partial conclusion of the original study: Qigong was not a promising treatment for relieving the symptom cluster. However, Qigong was effective and safe on the single symptom of dyspnea and cough alongside core quality of life indicators.

In addition, Qigong needed more than 6 weeks to improve dyspnea and the intervention was more effective in managing respiratory symptoms in males more than in females. Qigong may be useful in managing respiratory symptoms rather than a symptom cluster that includes fatigue and anxiety. Symptom cluster research should carefully target appropriate symptom combinations in the future.

Challenges of the Original RCT

This part critically discusses challenges encountered by researchers in delivering a Qigong intervention for people with lung cancer in the Vietnamese population. The RCT was conducted to test the effectiveness of the intervention on managing dyspnea, fatigue and anxiety (as a cluster) in

Table 3: Generalized Estimating Equations (Gee) Analysis in the Trial Outcomes

Symptom Cluster ¹	Mean (Std. Error)		Group*Time		
	Qigong	Control	β	95% CI	<i>p</i> -value
Baseline	41.36 (1.11)	40.61(0.90)			
6 weeks	37.58(1.06)	38.76(0.97)	-1.926	-5.31; 1.46	0.264 ^a
12 weeks	36.26(2.04)	40.10(1.20)	-4.584	-9.46; 0.30	0.066 ^a
Fatigue²					
Baseline	26.79(0.74)	27.72(0.58)			
6 weeks	29.04(0.67)	28.54(0.58)	1.426	-0.81; 3.66	0.062
12 weeks	29.49(1.15)	27.68(0.76)	2.745	-0.14; 5.63	0.211
Dyspnea¹					
Baseline	17.27(0.39)	17.29(0.39)			
6 weeks	15.84(0.33)	16.99(0.33)	-1.122	(-2.45;0.20)	0.097
12 weeks	16.04(0.55)	17.54(0.38)	-1.472	(-3.19;0.25)	0.094
Anxiety¹					
Baseline	13.62(0.64)	13.40(0.59)			
6 weeks	11.92(0.74)	12.03(0.72)	-0.322	-2.74; 2.10	0.794
12 weeks	10.61(1.31)	12.46(0.77)	-2.065	-5.21; 1.08	0.198
Cough¹					
Baseline	21.41(0.57)	20.72(0.60)			
6 weeks	17.21(0.67)	20.28(0.69)	-3.766	-5.962; -1.569	0.001*
12 weeks	18.68(1.07)	21.51(0.85)	-3.519	-6.409; -0.629	0.017*
Global Health Status³					
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
Functional health³					
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
QOL symptoms scale¹					
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

¹ Higher score indicate higher symptom burden;

² Higher score indicates less fatigue.

³ Higher score indicates better quality of life indicators

^aAlpha level of 0.017.

lung cancer patients. This experimental design study also explored the effect of Qigong on cough, which is another common symptom linked with dyspnea, fatigue, and anxiety as a cluster, and quality of life in lung cancer patients. RCTs involving Qigong interventions can be challenging to implement with vulnerable subjects, including those with a lung cancer diagnosis.

Patients and Hospitals in Vietnam are Not Familiar with Research Study

Randomized Controlled Trials (RCT) which have superior status amongst experimental design studies, are widely

regarded as the gold standard for evaluation of health care programs [2], and are considered the most appropriate way to evaluate the impact of such an intervention in clinical practice [3]. The reputation of rigorously conducted RCTs enables the findings of a well-developed and applied study to be considered high-level evidence on which future practice in healthcare is based [4,5].

The protocol of this study contains detail of background, objective, rationale and the importance, as well as the design, the methodology, the University Review Board approval, the informed consent and the statistical considerations of

the current RCT. In addition, the selection criteria for patient eligibility (i.e., inclusion and exclusion) and the concrete organization of the RCT (e.g., recruitment, baseline data collection, randomization, treatment administration, control visits and follow-up) were described in the document. The procedures manual contained study definitions, descriptions and instructions of each procedure and each task/item of data collection process. The manual was written in detailed along with figure and diagrams to elucidate and forecast possible problems in procedures finalization.

Regard to number of RCT, there are many RCTs that were conducted and considered as high-level evidence for research outcome in developed countries. However, in Vietnam as a developing country, there are many limitations in the health care system in term of research and assessment of health outcomes, and including RCT that were conducted. Remarkably, there are lack of understanding about clinical trials such as recruitment criteria, randomization & blinding among the patients, doctors, nurses and hospitals' manager. They often have doubts and worries about non-pharmacological trials. Because of these problems, during the data collection patients and staffs asked many questions whenever researcher introduced the study to them. The recruitment rate was low during near first 3 months. In addition, there are some social, cultural issues related to trial participation and patients' cultural belief. Patients prefer to work with a doctor rather than work with a nurse because of Vietnamese people believe that nurses are specialists in the care of patients in the hospital, under the direction of the doctor [6]. Since the subjects in this study are lung cancer patients at stage III and stage IV, some of patients' perspective that anyway, "after all, I will die so do not want to practice Qigong".

In response to patients and hospitals in Vietnam are not familiar with research study issue, the researcher adopted the following strategies: Knowledge-based information such as overview of the study, kind of Qigong intervention and benefits were conveyed to the patient to increase their interest to participate in a physical activity based on clinical trials. Educating subjects on clinical trial by researcher during routine both in and outpatient department visits at the convenience room in the hospitals. Subjects were educated about the objective of the study, study design, the intervention, outcomes measurement, implication of the study, and the right of the patients. Moreover, creating positive understanding about clinical trials among hospitals' manager, staffs and patients through meeting and discussion. Researcher explained to doctors and nurses that the RCT can provide data and evidence about supportive and palliative care for lung cancer patients which may help to write the book "supportive and palliative care for lung

cancer patients" under the requirement of hospitals director. In addition, based on outcomes of the RCT, department's manager may re-structure of patient's room, or usual care routine to support more for patients.

Providing an adequate, clear and concise explanation about trial procedures to study patients during the informed consent process. Training was a focus on addressing common misconceptions about RCTs, particularly equipoise and informed consent. Allowing time for the patients to talk to the researcher about their concerns of participating in the trial. In addition, researcher also spent the time to explore patients' and their family members' concern. Therefore, patients and clinical staffs were understood more about clinical trials. However, some patients still preferred to work with a doctor rather than work with a nurse.

Regard to patients' perspective that anyway, "after all, I will die so do not want to practice Qigong". Researcher talked about cancer patients in Thailand and Vietnam that they practiced Qigong and believed on Buddhism then their health status might improve. The story somehow helped patients feel better and encouraged them practice Qigong.

We learnt that this issue of the study provides important insights into contextual and cultural issues that need to be considered in the development of cancer interventions in the Vietnamese context. Therefore, the future study should prepare in advance a detailed study protocol including cultural issues such as the belief of the patients with serious illness and the concern of health care provider with non-pharmacological intervention in palliative care for cancer patients. A procedure manual with timetable for education and discussion times must be necessary according to the complexity of the RCT and of the demanded tasks to enhance understanding of the hospital staff.

Subject recruitment issue

Successful recruitment of patients is known to be one of the most challenging aspects in the conduct of randomized controlled trials. Inadequate patient retention during the conduct of trial affects conclusive results.

There was great challenge related to successful recruitment context in this study that was high dropped out because the most lung cancer patients were diagnosed at the advanced stages. Normally, patients in the advanced stage were suffering from more discomfort and physical weakness that deters them from participating in the study. Many patients came to the hospital for treatments when a tumor had growth and spread widely. [7] reported that the most lung cancer patients in Vietnam are diagnosed in the hospital at advanced stages (65-80%). 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 [8]. Moreover, some patients leave the intervention group due to patient or doctors' choices, treatment complications such as their doctors changed treatment routine due to negative results from laboratory blood test, or their doctor had an urgent duty. Some patients could not eat or too tired when received chemotherapy or radiotherapy and some patients had to transfer to other hospital or laboratory for gene test. Therefore, patients refused to continue participating in the trial.

In response to the recruitment challenge, the researcher has interacted with staff at hospitals regarding clinical trial recruitment by explaining to the staff the criteria and procedures for recruitment. To ensure the healthcare professionals and patients to understand the purpose of the study is very important to gain their participation and even retain in the study instead of dropping out. Considering the cultural belief and nature of disease when choosing the type of intervention. Qigong is suitable for Vietnamese cancer patients, in which most of cancer patients stay at home due to the overloading of oncology hospitals. Regard to the problem that doctors scheduling appointment for subjects that might clash with the intervention sessions, the researcher assessed the computer system to check the appointment date and compared with the time for intervention sessions. If the time point clashed, the researcher discussed with the doctors and found the appropriate time for both purposes.

Literature shown that in many trials very often there are not enough patients to join the study or researchers had to wait for long because there are no patients to recruit [9]. Patients did not want to join the trial because they believe they will die soon, they did not understand about the trial, and they had advanced cancer. However, in this study, we recruited from two hospitals. Therefore, the numbers of lung cancer patients are good enough for the recruitment process. Based on a survey about the number of patients and the routine of lung cancer treatment in Vietnamese context before making the research plan by the researcher.

The results are that even though patients were advised of the voluntary nature of the study and that they could choose not to participate, the high rates of study participation (low refusal) and then the high rate of drop out (low commitment) likely reflects sociocultural responses. This can explain by the finding of [6] whereby Asian patients are more likely to agree to participate in research than patients in Western countries are but also easy to withdraw (easy to join but also easy to withdraw). Remarkably, there were 11 patients refused to participate, as they were poor and long distance from their home to hospital. The dropout rate in the Qigong group and control group were 60.2% and 39.8%, respectively.

Researcher learnt that successful recruitment of subjects is critically dependent on factors such as volume/turnover of patients, realistic study protocols and stability of the patient population. The sample size needed to reach an adequate power in a study is inversely proportional to the intervention effect squared. To increase the recruitment rate, a researcher should concern and manage the cultural aspect, patients' characteristics, and the local hospitals' authority perspective.

Subjects Had Difficulty in Filling out the Data Collection Forms

Data collection forms included all crucial items to evaluate baseline characteristics and outcomes. To easily collect, to avoid interferences and to limit related cost in data collection, these forms were consistent and organized in logical order, according to the timing of procedures amongst RCTs. Data collection forms were easy to be completed properly and unnecessary secondary variables were avoided, as well as possible nonresponse and write-in responses. Baseline data collection included items needed to confirm eligibility, to permit randomization and to collect predictors for possible stratification. Follow-up data collection encompasses information on primary and secondary outcomes. In addition, another crucial element was prepared the questionnaire and other related document in advance is a realistic timeline document. Timeline document reported all the crucial steps of the starting RCT, with realistic and achievable time-objective.

The data collection forms included 12 pages of seven questionnaires scales, to assess and measure included criteria, primary and secondary outcomes, which is quite long. The contents of each questionnaire are medical terms that were difficult for patients to understand and patients need explanation in simple term because most of them had secondary school level. In addition, patients were tired and need to go back home as soon as soon after medical follow up/consultation. Moreover, distance between hospitals and patients' home is on average 150 km (range from 10 km to 1200 km) and spending about 3 to 4 h by bus that was the most challenging of the recruitment process and follow up of the RCT in this population.

To manage above issue, appropriate training of the research assistants (who responsible for data collection) on research and recruitment methods was performed. Pre-discussion on the data collection process with patients and caregivers was conducted to help patients familiarly with the questionnaires. In addition, the disease progression of lung cancer and treatments effects was explained in detail. Moreover, sometimes research assistant provided free soft drink or milk to encourage patients that help patients manage their feeling and endurance during data collection.

In the beginning, some patients had difficulty in understanding the questionnaires. Research assistants had to explain in appropriate ways to help them understand questions accurately. Then researcher and research assistant sat together to discuss about which items were difficult to understand and unified the same ways to explain to patients. Research assistants took time to explain with patients. Research assistants were asking the help from family members and explanation the questionnaires accurate, easy to understand. The data collection at baseline took longer time than that at the end of intervention and follow up points. Data collection was arranged when they are waiting before medical consultation.

Researcher had some difficulty in coordinating data collections in two hospitals that are geographically separated. Therefore, researcher and research assistants use video call to discuss the related issues during implementing research process.

After adopting these strategies, data collection was conducted in appropriate ways and most of patients can go home as they expected. Patients were able to complete the questionnaires after the strategies were adopted. In cases, patients went home before completing the questionnaire, the research assistant contacted them; give them telephone call to complete it. If there were incomplete items, we treated it as missing data.

I learnt that data collection form should be easy for subjects to read, to avoid interferences and to limit related cost in data collection. These forms should be consistent and organized in logical order, according to the timing of procedures amongst RCTs. Baseline data collection included items needed to confirm eligibility, to permit randomization and to collect predictors for possible stratification. Follow-up data collection encompasses information on primary and secondary outcomes.

In future, researcher should consider measures to facilitate the patients to fill out the questionnaires such as the avoid medical terms that are difficult to understand, begin data collection when they are waiting before consultation, arrange a more comfortable place or call patients by telephone to complete the unfinished questionnaires. In addition, researcher can help to establish trust and rapport with study patients, provide adequate explanation to facilitate data collection.

Randomization and Blinding

A key aspect of RCTs is the method of randomization. Balance the study with a correct randomization is key element that helps us assuring strong validity of the study. Random allocation of patients in the study or in the control

group assures that all subjects' known and unknown characteristics are similar and balanced between groups at the beginning of RCTs. Therefore, the study group will differ for treatments type assigned only, avoiding the selection bias. One of the most important aspects of randomization is the impossibility to determine a priori the allocation of each patient. Consequently, is mandatory to report all the aspects of the randomization process: The randomization method, personnel involved (physician, nurse and technician), randomization timing, existence of a randomizations register.

In this study, patients in both groups recruited from same hospitals. They may meet each other's and sharing Qigong practice during time stay at hospital. Despite indicating their understanding of this part of the research process prior to study commencement, some of the subjects allocated to the control group attended the Qigong group training sessions despite being allocated to the control group. Even though their allocation to the other group was explained again, they were reluctant to leave the group even when informed that they could join it at a later stage (waitlist). Blinding is the method to prevent the possible bias derivate from the knowledge of group allocation of a patient. Blinding subjects was not possible in this study. Allocation concealment is a method that can be used when blinding is not possible and conveys a strong message of bias prevention. In this study, subjects were required to learn and practice Qigong five days a week if they were allocated to the intervention group and therefore it was not possible to blind subjects to the intervention, but it was possible to conceal the intervention during random allocation.

In response to randomization and blinding issue, blinding subjects was not possible but the researcher who collects data from subjects were blinded to the group allocation of subjects to minimize bias. In the current study, subjects were randomly allocated to the control or intervention group. The process of random allocation was explained to subjects prior to entering the study. Random allocation occurred after explanation to subjects and via the use of block randomize that was selected by computer. The block of six was used to allocate the participant to one of the groups, enabling the subjects' variables to all have an equal opportunity to be randomly allocated and controlling for potential confounding bias. In addition, the strategies to prevent the patients in the two groups to communicate, such as recruiting subjects on a certain day of the week to be assigned to one group so that patients would not meet the other group who will follow up on another day of the week.

To support subject in the control group who went to the intervention session and practiced at home. Researcher

had explained to them to remain in the assigned group and remind them that intervention will be given to the control later with fully reassurance and explanation. To reduce the chance, meet and sharing Qigong practice. In addition, the study groups differ for treatments type assigned only, avoiding the selection bias and the process of random allocation was explained to subjects prior to entering the study.

We learnt that the future research should choose and report the methods of randomization correctly. Balance the study group using stratification technique if possible. At least, outcomes evaluation should be blinded. One of the most important aspects of randomization is the impossibility to determine a priori the allocation of each patient. This is factual knowledge about the strength of random allocation. That researcher had learned to do a perfect/better randomization. The control elements of RCTs enable the researcher to control for potential bias using inclusion/exclusion criteria, concealment during the randomization process and blinding.

Blinding is an important methodologic feature of RCTs to minimize bias and maximize the validity of the results. Researchers should strive to blind participants, healthcare practitioners, data collectors, outcome adjudicators, data analysts and any other individuals involved in the trial. However, this statement is not always possible, especially in a non-pharmacology trial. A single blind RCT is when the investigator but not the study participants know which treatment has been allocated.

The Intervention is Complex

Qigong could be highly beneficial for lung cancer patients in the Vietnamese population. Following the plan of intervention, subjects were required to receive a 90 minutes’ Qigong training and meeting twice a week for the first 2 weeks. Then they practiced at home for at least 30 min a day, 5 days per week, over 4 weeks and kept a log of the frequency, minutes of practice, and level of skills. This may somehow be a burden for some lung cancer patients (Table 4).

In response to the intervention that was the complex issue, educating subjects on clinical trial by researcher during routine both in and outpatient department visits. Focusing on knowledge-based information such as Qigong theory, Qigong regulation and Qigong practicing regulation were conveyed to the patient to increase their interest to participate in a physical activity and Qigong based clinical trials. Creating positive understanding about clinical trials among staffs and patients through meeting and discussion. Training session was designed and implemented base on Qigong theory, Qigong regulation, Qigong practicing regulation and time frame of patients’ treatment (Appendix 1).

During the Qigong training sessions, some subjects had some difficulties to learn the Qigong at hospitals and many of them were tired. Sometimes they got a cough or dizziness. Some patients too difficult to follow the many steps of Qigong practice. Therefore, Qigong master and researchers had to spend more time to help patients learned in appropriate ways. During the two-week Qigong training

Table 4: Qigong Training Sessions.

Session	Theme	Duration	Contents	Responsible
1	Learning the fundamental concepts of Qigong	5’	What is Qigong and briefly history, and beneficial effects	Qigong Master
	Practicing natural breathing and mindfulness	5’	Practicing natural breathing and mindfulness	Qigong Master
2	Practicing movement 1 to 4	5’	Demonstration of movement 1 to 4 by the Qigong master	Qigong Master
		5’	Practicing movement 1	Qigong Master
		5’	Practicing movement 2	
		5’	Practicing movement 3	
		5’	Practicing movement 4	Researcher
		5’	Reviewing movement 1 to 4	
		5’	Break	
3	Practicing movement 5 to 7	5’	Demonstration of movement 5 to 7 by the Qigong master	Qigong Master
		5’	Practicing movement 5	Researcher
		5’	Practicing movement 6	
		5’	Practicing movement 7	
		5’	Reviewing movement 5 to 7	
4	Reviewing movement 1 to 7	10’	Practicing and reviewing movement 1 to 7	Qigong Master
5	Learning the skills and techniques to continuing practice at home	10’	Guiding the skills and techniques to continuing practice at home	Researcher

at the hospital, researcher arranged the stereo system to play Qigong music to encourage patients practicing Qigong. Moreover, they guided to patients how to open Qigong DVD with DVD player or laptop or helped patients download it to a smartphone so that it was more convenient for subjects to watch the video. Telephone follow-up also available through the study to explain and support patients to practice during two weeks training at hospitals and at home.

We learnt that conducting interventions like Qigong trial is often challenging, particularly in trials of complex interventions which involve multiple times of practices, require behavioral changes or the involvement of engagement of multilingual, multicultural groups with varying educational level. Therefore, the researcher should encourage and facilitate the subjects to take up the intervention program.

Adherence and Attrition Issue

Adherence in this trial is defined as the extent to which the clinical trial participant's behavior coincides with the trial protocol in terms of keeping appointments, taking Qigong intervention and following the practicing at home. Attrition is defined as when individuals drop out of the control or treatment group over the course of the evaluation. Researchers have been focused on adherence and attrition to the intervention regimens in clinical trials because of the profound effect that reduced adherence has on the trial sample size [10].

Enough sample size is fundamental to detect a reliable statistical difference among the study groups. The sample size needed to reach an adequate power in a study is inversely proportional to the intervention effect squared. Consequently, considering that frequently the effect of the studied intervention is relatively small, the number of patients needed is relatively large. Research evidence suggests that age of patients is a common predictor of attrition, although the direction of the effect of age is less consistent. Among all, lack of awareness, transportation issues, family or job commitment and concerns related to the requirement and cost of the trial were the major factors inhibiting lung cancer patients and sustaining a clinical trial.

The data on those who refuse to participate or drop out are seldom available due to human subject research guidelines, and/or a lack of published reports about barriers to recruitment and adherence in trials. Although these issues are more widely recognized in developed countries since they are crucial to the success of RCTs [3,16] but this issue is often not highlighted in developing countries such as Vietnam.

Due to heavy disease burden of lung cancer patients, which

some affect exercising significantly such as breathless and fatigue. In addition, patients were at difference stage of disease that may be affect to Qigong practicing and patients were from difference provinces, urban area and rural areas. Therefore, the environment for practice may be difference.

Adherence to the protocol was determined by self-reports on the logbooks but patients did not fill out the logbook. Approximately 53% of participants (n=41/78) self-reported practice of ≥ 3 h per week at two weeks, which corresponds to 30 min per day. Unfortunately, completion of logbooks was so poor at 6 weeks that this data could not be used. Since researcher reminded them every week, it was possible that they did not want to fill it out. It may be too being demanding to fill out, too boring, too time consuming, or sometime patients were too sick.

All subjects were advised not to seek any other regular exercise during the trial period. This is desirable. In fact, sometimes patients comply with no other exercise because they used to not do exercise, or maybe they are too sick to do exercise. The dropout rate of 50% patients in the dropout patients was older (57.94 and 55.74 years, $p=0.04$) than did the non-dropout patients.

Of the 78 patients in the Qigong group, 55(70.5%) completed the 6-week intervention program, and 66(84.6%) completed at least half of the 6 week intervention. The practice adherence rate was 61.5%. The participants did not complete the intervention because of voluntary withdrawal (n=12), perceived discomforts (n = 7), lacked motivation (n=9) and lost contact (n=2). Some of the challenges that were noted as portrayed by the participant emerged from their values, belief and their experience with illness and hospital system. Some of the notable challenges mentioned by the participants/patients are: (1) when going to the hospital, doctor prescribed a lot of medicine and we will be happy, (2) It is better to work with a doctor rather than work with a nurse, and (3) anyway after all I will die so do not want to practice Qigong.

In an ideal scenario, every subject enrolled in RCT would follow instructions and complete their allocated treatment as described in the protocol and thus contribute data which were complete in all respects [9]. Nevertheless, unfortunately, one practical problem that investigators usually come across in RCT is that subjects do not always follow instructions. Moreover, in this study, drop out of the subjects is a problem [14,15].

To manage above issue, all patients in Qigong group were asked to complete logbooks of their Qigong practice at home to allow for calculation of overall practice adherence. In addition, engaging the support of family members so that

these patients can 'be released' temporarily to focus on their own health and wellbeing, without feeling guilty. There is a cultural belief among patients that they are responsible for their family and should not spare time to take care of themselves. They tried to do the best things for their family and not really care about themselves during short survivor time based on their lung cancer treatment situation [16]. Moreover, they follow the eightfold path of Buddhism that encompasses understanding of life, right motives, right speech, perfect conduct, right livelihood, self-discipline, right-mindedness and perfect meditation. Therefore, peace and quiet for meditation were appreciated. Patients also believe in reincarnation, and that actions in this life will affect the quality of life in a future reincarnation.

Remarkably, the researcher assessed the subjects' compliance with the home program by asking, testing, reminding them to practice Qigong, and filling out the logbook every week through phone calls to encourage participants to practice and ensure that the training dose is adequate by recording in a diary logbook. The researcher also received many telephone calls to ask related Qigong practice and reporting of some minor problems by patients and patients' family members during the whole study. For example, location for Qigong practice, using other music, practicing more than one time per day and sometime patients prefer to practice the exercise that familiar with them for a long time. To facilitate communication with subjects, at the beginning, researcher registered a phone number only use for the research project.

In fact, most of the patients stayed at the hospital during the time of two-week Qigong training and not many patients were required to come all the way to the hospital and attend the two-week Qigong workshop. Some subjects did not attend the workshops due to many reasons such as too tired, meeting with the family member and relative, and under treatment process. To solve these issues, the researcher had made an alternative time to help those patients following the training sections such as extending training time or additional training sessions. Therefore, researcher stayed at hospitals almost 24 h to support the subjects throughout the research process.

It may be too demanding for the patients to write about their exercise in the logbook. Consider the disease or symptom burden on lung cancer patients may be a burden to fill out the logbook. Nevertheless, the purpose of having a logbook is to manage intervention adherence. Therefore, researcher advised patients asking patients' family to fill out for them, also simplify the recording method, space out the time interval of filling out the logbook. In addition, researcher verbally asked patients when they come back for follow up during the intervention period.

Thus, we learned that, this study should prompt researchers

to consider carefully the challenges of conducting research on lung cancer patients with high dropout rate, because of debilitating nature of the symptom such as breathless, fatigue and anxiety. Moreover, since patients with Buddhist perspective much emphasis are put on the importance of having a clear mind [17]. They may be reluctant to take medications that are mind altering and will need side effects explained to them thoroughly. They may prefer the use of home remedies—for example, rice porridge (one-part rice to two parts water) may be considered beneficial for convalescence. Therefore, in the future, researcher should include cultural belief as another aspect of adherence.

Negotiation of Access and Data Collection Issues

Regard to this issue, before, during and after implementation of the trial, the researcher had to contact with hospitals authority to get permission for ethical consideration, facilities, and staff cooperation. Hospitals' administrations were too busy and did not have time to cooperate, lack of support, the facts that researcher tried to make an appointment with them but wait for a week even a month before meeting. In addition, researcher had to take time to negotiate of access and data collection issues and get permission from two research hospitals due to managers are too busy. Hospitals lacked comfortable place for patients during data collection and Qigong training due to overload situation at hospitals.

In response to negotiation of access and data collection issues, building the relationship with manager and committee based on Vietnamese culture such as communicating with them about the details of the study. Moreover, considering a different approach to communicate with the manager. Then let them understand the significance of the study and explain to them the problem of not having a suitable room to meet patients. Taking and sharing to get help from staffs and managers. Such as talk to doctors who responsibility for patients' treatment, staff nurses who responsibility for caring for patients in the departments. To do this approach, the researcher attended all briefings of the department on the morning of each day to know and take noted all key persons and related issue.

After done with above solutions, the researcher had got full permission and supposition. In addition, we got a comfortable room to talk with patients and a suitable room to teach Qigong. Regard to the ethical issue, the research management department in two hospitals and the Nam Dinh University of Nursing working together to coordinate research issues and consider the ethical application process to researcher conduct the research in appropriate ways.

We learnt that the researcher needs to be conscientious, have professional integrity, plan meticulously and develop good interpersonal skills with the hospital staffs.

Dual Identity of the Research Assistant as a Nurse and Nurse-Researcher

The research assistants faced a dilemma of dual responsibility as a nurse and as a research nurse. Nurses were supposed to provide direct care to the cancer patients as usual, but at the same time, they were supposed to help in the Qigong research. Therefore, the cooperation between the research assistant were interrupted with other staffs in usual care at hospitals sometimes. In addition, they sometimes need to do with research duties but at the same time in-charged with other patients care.

In response to the dual identity of the research assistant as a nurse and nurse-researcher, one professional coach, who had been engaged in teaching Qigong to clients at the UNESCO Centre for Supporting Community's Health for at 12 years, were employed to guide the subjects' training? To reduce the workload of the research assistant, the researcher who experiencing with Qigong theory and Qigong practicing during study in Thailand and Hong Kong had been engaged in guiding and supporting patients follow the Qigong lesson. He also supervised the training to guarantee the quality of Qigong delivery.

Nurses who help in this trial were advised to make a detail plan and timetable during the time of the trial. Such as deliver care to patients in the morning then afternoon focusing to help in research. In addition, researcher talked and negotiated with manager at the department to reduce duties and support for research assistants to help them during the research implementation at hospitals.

Research assistant faced a dilemma of dual responsibility as a nurse and as a research nurse. They were supposed to provide direct care to the cancer patients as usual. At the same time, they were supposed to help in the Qigong research. It was difficult at times to separate the two, hence posing a challenge. Therefore, in the future research, the researcher should consider getting help from research assistant who are not nurses of the hospitals to relieve the current duty such as the workload or the routine in the hospital. In addition, consider hospital culture to make the research plan and implementation reasonable.

DISCUSSION

Low compliance with protocols, lack of motivation to continue participating influence intervention impact, and can be other potential sources of bias and an indicator that the intervention is inappropriate for the recruited subjects [18,19] reported similar low adherence rate for their 10-week Qigong trial held at Sydney, which documented a dropout rate of 33%. Reasons for the dropout were not identified but with multi-ethnic population, there may be added issues of varying language, culture, social norms and group acceptance. To our best knowledge, our trial is the

first study that explores the effects of Qigong trial among lung cancer patients in Vietnamese context. Thus, the information gathered here would be useful to provide insight into the possible barriers in recruitment and adherence of an intervention based clinical trial.

Research evidence suggests that age of patients is a common predictor of attrition, although the direction of the effect of age is less consistent. Some studies report older patients whilst others reported younger patients to be at a greater risk of leaving [20]. Our study showed that patients in the dropout patients were older (57.94 and 55.74 years, $p=0.04$) than did the non-dropout patients. As Asian countries have a stronger family bonding and expected social roles, it is not uncommon for these patients to commit energy and time for the family and to put preference to family events [21] over their individual needs. This finding calls for proactive planning to be in place when recruiting Asian patients especially for trial with long-term commitment (more than two months). There may be a need to engage the support of family members so that these patients can 'be released' temporarily to focus on their own health and wellbeing, without feeling guilty.

RCTs require the researcher to take a position that is distant and focused on measurement using instruments or tools, as the objective of the experimental research is to search for truth in an objective and controlled manner [12]. Evidence indicates, however, that formation of a therapeutic alliance among the researcher, participant and health care professionals has the potential to influence the outcome of the research in the desired direction [22]. Therefore, the therapeutic alliance needs to be addressed in an RCT of a therapeutic intervention. Overall, these lessons related to recruitment-retention barriers for complex intervention clinical trials may be applicable across the Asia Pacific since there is a general lack of public awareness of cancer and/or, on the association of activity and cancer recurrence.

Conducting clinical trials in any setting is challenging. However, the lung cancer population can be particularly daunting. Implementing a Qigong-intervention adds to the investigators' anxieties. Unexpected challenges occur, regardless of the care with which the research plans and executes the study. In sharing and discussing, an investigative team can contribute to science by allowing others to learn from their experiences. There is no one faith for the Vietnamese lung cancer patients, but rich and varied religious traditions. Most of them have Buddhist perspective. Ask the patients about their faith or their needs whilst in the hospital to ensure their needs are being met. Recommending the patients following regulation of Qigong practice, however, can flexible time and duration to practice base on their real situation during the trial.

Improving the quality of symptom management delivered to lung cancer patients is an urgent health-care need.

This article describes a clinical trial designed to improve cluster of three symptoms (fatigue, dyspnea, and anxiety) and management cough, QOL in Vietnamese lung cancer population. We describe several challenges as well as to address the logistical challenges we encountered. In addition, we discuss several problems that arose during the study and the ways in which we approached these challenges. It is our hope that the insights and strategies gained from this study will assist others in designing future studies and addressing anticipated challenges.

CONCLUSION

In conclusion, it is very challenging and difficult for the researcher to conduct research study not to say RCT in Vietnam. This paper focused on several challenging that researcher faced in conducting this research project and discusses other obstacles that we had to overcome. The major challenge of conducting the RCT in Vietnamese lung cancer population is that the patients and hospitals in Vietnam are not familiar with research study or RCT. The intervention is complex involving attending workshop and practice Qigong with many steps and over a period with home practice. Heavy disease burden of lung cancer patients has some affect exercising significantly such as breathless and fatigue. Therefore, the attrition rate was high. In addition, patients' cultural belief in self-care and taking care of family, their perception about grave prognosis of lung cancer and maintaining hope to keep well. Moreover, no comfortable place for patients during data collection, hospitals' administrations are too busy, do not have time to cooperate, and lack of support for research project.

Implementations

Our aim in this report is to suggest certain lessons useful for the design of an RCT; have a realistic timeline, define a clear objective and precise endpoints, balance the study with a correct randomization are key elements that help us assuring a strong study's validity. If we aim to obtain RCT strengthening evidence for clinical practice, we must build them on strong hinges that allow us to influence the scientific literature and change the clinical decision-making activity of doctors involved in lung cancer and symptoms management.

The lesson that we learned from our work on this study should prompt researchers to consider carefully the challenges of conducting research on lung cancer patients with high dropout rate. Our experiences may guide investigators who plan future implementation trials or other trials among lung cancer patients. To ensure clinical trials can achieve high participation, low attrition rates among eligible subjects, future study should focus on these expressed challenges, and solutions are proactively sought to overcome to minimize challenges. Knowledge-

based information should be conveyed to the patient to increase their interest to participate in a physical activity based clinical trials. Greater attention should be given to the challenges faced to ensure higher successful the rate of recruitment and completion of a trial.

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Appendix 1 - A Guide to Buddhist Qigong (Thanasilp, 2013)

Before starting, stand quietly in a loose standing posture for a few minutes, allowing your body and mind to relax. Keep your head straight as you practise the form, and your shoulders relaxed. Hand movements should be coordinated with your breathing, and both should be in a continuous, fluidic movement. Breathing is very important in Qigong: In general, breathe in for yin (inward) movements, out for yang (outward), in long, controlled breaths, and allow your breath to naturally follow the movements as they change.

Buddhist	Contents
1. Harmonize breathing	Relaxing the mind, stand naturally with your legs shoulder width apart, drop and relax the shoulders. Keep the hips straight, and your gravity in the centre, and slowly raise the arms to shoulder height, when palms facing back then rising slowly breath in slowly. When the hand is raised to chin overturned waist. Then, while lowering the body and bending the knees, bring the arms down, exhaling on the downward, and inhaling on the upward. Repeat 10 times.
2. Opening the Chest	Stand naturally, with your legs straight, and raise your hands to the front of your chest. Separate your arms to your side as you open your chest and breathe in. Bring the hands back to the body in a circling motion, finishing with the hands in front of the stomach as you bend your legs and breathe out. Repeat 10 times.
3. Separating Clouds by Wheeling Arms	From a standing position, bend both knees into a horse stance. Simultaneously, place both hands in front of your body, palms towards your stomach. Raise both arms above your head and separate, breath in, as the arms come down bend the legs and straighten as they cross; the palms circle outward and upward over your head, then bring them down and around back to the front of the stomach, like the collection of energy from the sky, breath-out. Repeat 10 times.
4. Deep breathe	This position will be like the first position. But imagine the difference is keeping your feet on the ground like roots of a tree. Sucking the vitality from the ground. Focus on hand both sides. Repeat 10 times.
5. Qigong energy production	Keep your hands in front of chest put hands on opposite direction, rotate hands to focus the energy will feel pushed or hot, there is Qigong energy will feel repulsion between two hands. After practicing Qigong would observe hands will be able to feel the glare, energy has been increased. Two hands can capable cure or treatment for other people. Repeat 5 minutes.
6. Keep qigong energy	Hold the energy above the lower abdominal area in front of the umbilical. Breathing gently while relax a bit. Repeat 5 minutes.
7. Meditation	5 – 10 minutes