

**Can Qigong (body mind exercise) improve symptoms of insomnia in  
cancer survivors? A feasibility study**

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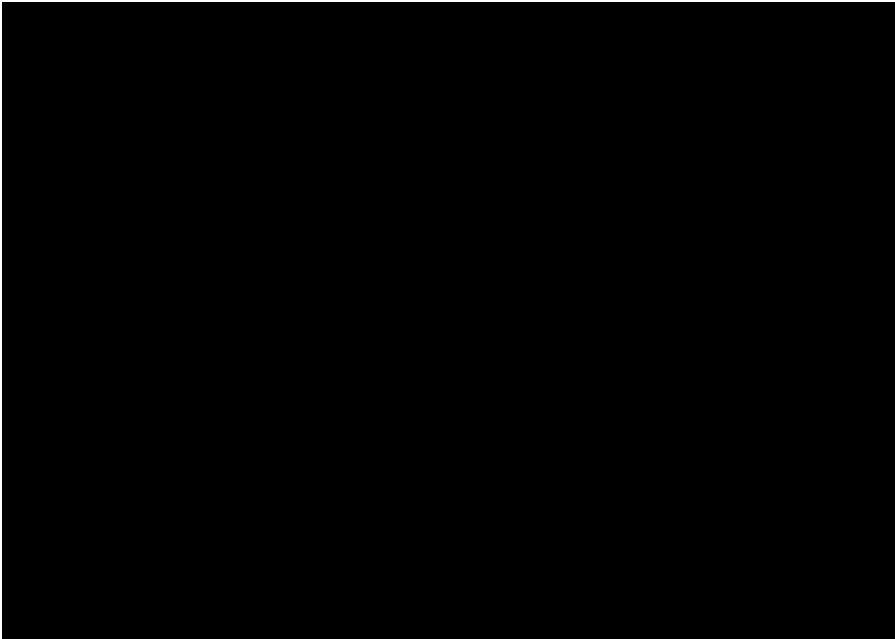
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## **Statement of Authentication**

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material either in full or in part, for a degree at this or any other institution.



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## **LIST OF ABBREVIATIONS**

<b>CBT-I</b>	<b>Cognitive behavioral therapy for insomnia</b>
<b>CAM</b>	<b>Complementary and alternative medicine</b>
<b>ISI</b>	<b>Insomnia Severity Index</b>
<b>LQPQ</b>	<b>Lift Qi Pour Qi</b>
<b>MBT</b>	<b>Mind body therapy</b>
<b>PSQI</b>	<b>Pittsburgh Sleep Quality Index</b>
<b>QOL</b>	<b>Quality of life</b>
<b>RCT</b>	<b>Randomised controlled trial</b>
<b>TCM</b>	<b>Traditional Chinese Medicine</b>
<b>ZQ</b>	<b>Zhineng Qigong</b>

## ABSTRACT

### Background:

Many cancer survivors experience insomnia that significantly affects their quality of life (QOL). Due to the limitations of the current conventional cancer care and inadequate and inconclusive studies of Qigong on insomnia-related outcomes in this population, this pilot study aims to investigate the feasibility and effect of a 3-week Qigong intervention in cancer survivors experiencing insomnia.

### Methods:

Seven cancer survivors aged 40-65, with an Insomnia Severity Index (ISI) score of  $\geq 11$ , who had completed radiotherapy or chemotherapy treatment and/or at least eight weeks post cancer-related surgery participated in the study. Participants attended face to face sessions two times per week and supervised online home practice three sessions per week for a 3-week period. Feasibility outcomes included recruitment source, compliance to data collection, adherence to Qigong intervention, serious adverse events and experience of trial. Clinical outcome measures of insomnia included subjective ISI score and Pittsburgh Sleep Quality Index (PSQI) global scores collected at Week 0 (baseline), Week 2 (mid-intervention), Week 3 (post-intervention) and Week 4 (one-week follow-up).

### Results:

Retention rate was 71% while adherence rate was 90 % for face to face sessions and 80% for online sessions. Participants reported increased relaxation, improved sleep and reduced stress. Repeated measures ANOVA reported statistically significantly difference in mean ISI values ( $F(1.963, 7.852) = 5.606, P = 0.031$ ) and PSQI values ( $F(1.229, 4.915) = 16.508, P = 0.009$ ) over the four time points. Contrasts tests revealed statistically significant reduction in

group ISI means between Week 0 (baseline) compared to Week 2 (mean=5.6,  $\eta_p^2 = 0.694$ ,  $p=0.040$ ), Week3 (mean=7.8,  $\eta_p^2 = 0.838$ ,  $p=0.010$ ) and Week 4 (mean=6,  $\eta_p^2 = 0.709$ ,  $p=0.036$ ). The contrast tests also reported statistically significant reduction in group PSQI means between Week 0 (baseline) compared to Week 2 (mean=5.1,  $\eta_p^2 =0.841$ ,  $p=0.018$ ), Week3 (mean=5.4,  $\eta_p^2 =0.833$ ,  $p=0.011$ ) and Week 4 (mean=4.7,  $\eta_p^2 =0.835$ ,  $p=0.011$ ). Non parametric tests reported significant difference in ISI ( $p=0.006$ ) and PSQI ( $p=0.007$ ).

### Conclusion

In summary, this study demonstrated that it is feasible to prescribe the current Qigong intervention with the potential to improve insomnia in cancer survivors. Potential benefits identified indicated the need for larger future trials to further evaluate the effect of Qigong on cancer survivors experiencing insomnia.

## CHAPTER 1: INTRODUCTION

Most cancer survivors experience persistent cancer and cancer treatment-related side effects that adversely affect their QOL. Among these symptoms, insomnia is a highly prevalent condition affecting 30-60% of cancer survivors (Savard, Ivers, Savard, & Morin, 2015). Sleep disturbance could worsen to fatigue and depression (Ancoli-Israel et al., 2014; Galiano-Castillo et al., 2017; Jim et al., 2013; Palesh et al., 2010). Moreover, persistent sleep disorder can increase morbidity and mortality (Ancoli-Israel, 2009; Lehrer, Green, Ramanathan, & Rosenzweig, 2013).

Cognitive behavioral therapy for insomnia (CBT-I), a psychological intervention is the current treatment of choice for insomnia but its usage is low due to issues such as availability and cost of properly trained therapists, and the commitment of time and effort required from patients (Bluestein, Healey, & Rutledge, 2011; Morin & Benca, 2012). As such most primary care providers continue to prescribe medication for insomnia that comes with a range of side effects or results in dependence on the drugs (Howell et al., 2014). Many cancer survivors, therefore, prefer to look for natural alternative treatment or complementary and alternative medicine (CAM) such as mind-body therapy (MBT) to address this problem (Buffart, Riphagen, Brug, Brown, & Chinapaw, 2012; Chan et al., 2012).

Qigong is a non-invasive mind body therapy (MBT) used for thousands of years in China for many health benefits (*Chinese Medical Qigong*, 2013; Xing & Jia, 2012). The term Qi-gong means the skill of cultivation of Qi. Qi is a Traditional Chinese Medicine (TCM) concept. The fundamental principle of TCM for a healthy body is the maintenance of a balanced and regulated Qi system to ensure smooth and clear circulation of Qi as it believes that all illnesses result from dysregulation and blockage of Qi (*Chinese Medical Qigong*, 2013; Xing & Jia, 2012).

Qigong incorporates simple, slow, gentle flowing, low impact, integrated exercise, meditation, mind adjustment, and breath regulation to bring about a deep state of relaxation that lead to a clear and smooth circulation of Qi for a better physical, mental and spiritual health (Jahnke, Larkey, Rogers, Etnier, & Lin, 2010; Klein, Schneider, & Rhoads, 2016). By evoking this mind-body integration, Qigong practices are thought to activate neurohormones and other natural health recovery mechanisms (Tiwari et al., 2014).

Studies have reported many health benefits of Qigong in non-cancer population (Jahnke et al., 2010; Yang et al., 2015). For cancer related symptoms, many studies consistently reported the benefits of Qigong in reducing fatigue and improving QOL (Klein et al., 2016; Van Vu, Molassiotis, Ching, & Le, 2017; P. Wayne et al., 2018) while other benefits reported include improvements in depression and anxiety (Campo et al., 2014; Z. Chen et al., 2013; Oh et al., 2010; R. Wang et al., 2009), cognitive function (Oh, Butow, Mullan, Clarke, et al., 2012), immune system markers (Campo et al., 2015; Irwin et al., 2014; Oh, Butow, Mullan, Clarke, et al., 2012) and a potential for increased survival (K. Chen & Yeung, 2002; R. Wang, Liu, Chen, & Yu, 2013).

Application of Qigong intervention for improving insomnia in cancer survivors has been studied and there is emerging evidence indicating its potential benefit in this area. However, in westernized countries such as Australia, there may be barriers ranging from lack of knowledge to skepticism about Qigong intervention as a form of CAM to a communication gap between health care practitioners and cancer survivors about this particular modality (Leblanc, Lodato, Currow, & Abernethy, 2013; Nipp, Hong, & Paskett, 2019; Smith et al., 2018). The lack of understanding of the mechanism of Qigong as a form of mind-body therapy by the paradigm of current medical science and lack of quality evidence in available report (Fouladbakhsh, Davis, & Yarandi, 2014; Irwin et al., 2017; Van Vu et al., 2017; P. Wayne et al., 2018) may have also contributed to the lack of awareness and study of Qigong in this area.

**Table 1 Summary of studies on Qigong for insomnia in cancer survivors**

Study	Type Cancer	Design	Sample size	Intervention	Timing of intervention	Duration (weeks)	Length, frequency (session per week)	Control condition	Outcome measures
(Irwin et al., 2017) USA	Breast	RCT	90	Tai Chi	Tx completed	12	2h, 1x	CBT-I	1. TC was non inferior to CBT-I, p=0.02 2. Sleep p<0.01
(W. Liu, Schaffer, Herra, Chollet, & Taylor, 2015) USA	Breast	NC Pilot study	8	Six Healing Sound Qigong	tx completed	6	2x/day, 7x	NA	1. Sleep Quality, p<0.01 2. ISI, p<0.01
(S. S. Fong et al., 2015) Hong Kong	Nasopharynx	Non RCT	52	Tai Chi	tx completed	24	1.5h,1x	UC	1. Sleep disturbance, p<0.037
(Chuang, Yeh, & Chung, 2017) Taiwan	Non-Hodgkin Lymphoma	RCT	100	Qigong: Chanchuang	During chemo	3	1h, 3x	UC	VSHSS (Sleep), p<0.001
Mc Quade et al, 2016 USA	Prostate	RCT	76	Qigong	During RT	6 to 8	1h, 3x	LE/WL	PSQI, p<0.05 mid-way
(M. L. Yeh & Chung, 2016) Taiwan	Lymphoma	RCT	108	Chan chuang Qigong	During chemo	3	1h,7x	UC	Sleep quality (VSHSS), p<0.01
(Z. Chen et al., 2013)  China	Breast	RCT	96	Guolin Qigong	During radiotherapy	5 to 6	1h,5x	NT	Sleep disturbances (PSQI), no significant changes
(Larkey et al., 2015) USA	Breast	RCT	101	tai Chi	Outpatient Completed primary treatment	12	1h,2x Meeting 2 weeks 1/2h,5x Practice	SQ	Sleep (PSQI) -no significant difference between groups -significant difference pre and post



To date there is no comprehensive review of Qigong for insomnia in cancer survivors nor are there adequate large scale, robustly designed RCTs. Of the available eight studies conducted, there are mixed reports on the effect of Qigong for insomnia in cancer survivors (Table 1).

There are 4 studies on breast cancer, 2 on lymphoma and 1 each on prostate and nasopharynx cancer. In breast cancer survivors, Qigong was reported to improve sleep and reduced cellular inflammatory responses and expression of gene encoding pro-inflammatory mediators (Irwin et al., 2014). A few studies also reported Qigong improved sleep in cancer survivors (Chuang et al., 2017; S. S. Fong et al., 2015; P. Wayne et al., 2018; M. L. Yeh & Chung, 2016) while one study of prostate cancer patients on radiotherapy found improvement in sleep quality mid-way through radiation only and the effect was not durable due to hot flashes and /or urinary symptoms which were not considered in the design of the intervention (McQuade et al., 2017). In another RCT study of breast cancer survivors participating in Qigong intervention and sham Qigong, there is no significant difference between the intervention and control groups as the study was designed specifically to evaluate effects on fatigue and powered accordingly (Larkey et al., 2015). However, both groups in this study reported significant improvement in sleep over the time of intervention and 3 months follow-up suggesting that gentle, low intensity exercise may be helpful for insomnia that continues past treatment. One RCT study of insomnia in breast cancer survivors participating in Guolin Qigong during radiotherapy did not find any improvement in sleep disturbance as measured by subjective Pittsburgh Sleep Quality Index (Z. Chen et al., 2013). The inconsistencies in trial results may be due to methodological weaknesses and small sample sizes. Furthermore, the differences in health status and types of cancer cohort, type of Qigong styles and intensity of Qigong intervention relative to the health level of the cohort in the various studies also contributed to the inconsistencies.

A recent study also reported that Tai Chi Chih, a modified form of Tai Chi, not only significantly improved sleep but is statistically non-inferior to CBT-I, the gold standard for behavioral treatment of insomnia in breast cancer survivors (Irwin et al., 2017). Moreover it was found that a 3 month Tai Chi Chih intervention produced significantly better results in the reduction of the level of toll-like receptor-4-activated monocyte production of IL-6 and

TNF combined, genome-wide transcriptional profiling of circulating peripheral blood mononuclear cells and expression of genes encoding proinflammatory mediators compared to CBT-I as Qigong was thought to target sleep pathways that activate inflammation while CBT-I targets sleep behaviors (Irwin et al., 2014). The results of this study promise the potential role of Qigong in regulating the immune system and inflammation which is associated not only with insomnia but the onset of cancer, death from cancer as well as recurrence and survival of cancer survivors.

While Qigong has been found to reduce sympathetic arousal (Black et al., 2014) and inflammation (Irwin et al., 2014; Irwin & Opp, 2017; Oh, Butow, Mullan, Clarke, et al., 2012; R. Wang et al., 2013), both of which influence sleep (Irwin, Olmstead, & Carroll, 2016; Manconi et al., 2010), how its mechanism contributed to improving insomnia is not known (Irwin et al., 2017).

Despite the low number of studies and mixed outcomes reported, there are emerging and encouraging evidence indicating the potential benefits of Qigong in improving insomnia. Therefore, together with the limited choice of treatment available, prevalence (Savard et al., 2015), high morbidity and mortality of insomnia in cancer survivors (Ancoli-Israel, 2009; Lehrer et al., 2013) and the lack of understanding of CAM of which Qigong is part of it especially in Australia (Smith et al., 2018), there is an urgent need to develop a more effective evidence-based intervention to address this problem. Moreover, we are not aware of any study of Qigong intervention specifically targeting insomnia in cancer survivors in Australia. Early intervention targeting sleep disorder is important as a preventive measure to provide benefits across many symptoms. This warrant further well designed and rigorous studies of Qigong to evaluate the potential of Qigong as a non-invasive and non-pharmacological option to improve insomnia in both cancer survivors and the general population.

The first step to this end is the study on the feasibility of introducing Qigong intervention to cancer survivors to improve sleep to provide preliminary data for the design of a rigorous randomized controlled trial (RCT) in the future.

Therefore, this study aims to investigate the feasibility (primary outcome) and effect (secondary outcome) of a 3-week Qigong intervention with a 1-week follow up program for cancer survivors experiencing insomnia. Feasibility will be assessed by recruitment source, compliance to data collection, adherence to Qigong intervention, serious adverse events and experience of trial feedback. The outcome effect will be measured by evaluating changes in ISI and PSQI scores over time.

## **CHAPTER 2: LITERATURE REVIEW**

### **2.1 Overview**

This chapter will provide a rationale for studying the feasibility and effect of Qigong, a MBT for insomnia in cancer survivors. It will begin with introduction of the prevalence of cancer and cancer treatment related side effects such as insomnia. Next, it will continue with an overview of insomnia and its pathophysiology from the conventional and Chinese Medicine perspectives. The current gap in management of insomnia with the search for alternative approach including Qigong will be discussed. This chapter will also summarise the literature in research of Qigong for cancer related symptoms and insomnia, highlighting potential gaps for future research and the rationale for the current study.

#### **2.1.1 Cancer**

Cancer has been reported by the World Health Organisation as the second leading cause of death worldwide and new cases of the disease are expected to increase by 70% over the next decade (World Health Organisation., 2018). Technological and medical advancements in early diagnosis, targeted treatment with aggressive interventions such as surgery, chemotherapy, radiotherapy and hormone therapy have increased the 5-year survival rate of all cancers to approximately 66% (National Cancer Institute., 2018a). With an estimated 50 million people to have cancer globally by 2030 (Mitchell, Ferguson, Gill, Paul, & Symonds, 2013), the economic impact is significant and increasing. It was estimated that the total economic cost of cancer for 2010 amounted to US\$ 1.16 trillion (Stewart & Wild, 2014). In Australia, cancer is a major cause of illness accounting for 19% of the total disease burden in 2011. It is estimated that one in every two persons will be diagnosed with cancer by age 85 and about 68% of patients will live more than 5 years after diagnosis. Increasing survival has also increased prevalence of people living with

cancer, now representing 3.5% of Australian population (Australia Institute of Health and Welfare., 2018). As such, cancer is increasingly thought as a chronic disease.

### **2.1.2 Contributing factors of cancer**

Cancer is commonly associated with aging (Mukherjee, 2010), and the largest proportion of cancer survivors (60%) are over 65 years old (Schmitz et al., 2010). A cancer survivor is defined as a person who is living with, through and beyond cancer from diagnosis through the end of life (National Cancer Institute., 2018b; National Coalition for Cancer Survivorship., 24 July 2014). Aging and serious illness such as cancer increase risk of insomnia and insomnia often aggravates other cancer side effects such as pain, fatigue, depression, or anxiety (Cancer.Net, 2019). Research has discovered that telomeres shorten with advancing age, and shortened telomeres are associated with increased risk of many diseases, including cancer, and increased mortality (Shammas, 2011). Telomeres are specific DNA–protein structures found at both ends of each chromosome involved in the replication and stability of DNA molecules. Shortened telomeres have been indicated as a risk factor for cancer and related to poor prognosis for cancer survivors (Ennour-Idrissi, Maunsell, & Diorio, 2017). However, the rate of telomere shortening which indicate pace of aging, cancer risks and prognosis can be influenced by various lifestyle factors such as stress and exercise (Shammas, 2011).

Cancer diagnosis is thought to cause intense distress and long term anxiety in cancer survivors (Mitchell et al., 2013). Psychological stress is associated with low telomerase activity and high oxidative stress in cells that will lead to accelerated telomeres shortening (Humphreys et al., 2012). Accelerated telomeres shortening inhibits DNA repair and suppresses aspects of the immune system responsible for fighting tumours. Chronic stress also leads to sustained cortisol elevations (Starr, Dienes, Li, & Shaw, 2019) such as corticoid hormone which may lead to reduction of antioxidant proteins, increased oxidative stress (Jenkins, Van Houten, & Bovbjerg, 2014) and reduced repair mechanisms, resulting in increased risk of DNA mutations and carcinogenesis (Jenkins, Van Houten, et al., 2014). The effect of stress on DNA damage was reported in laboratory test on human breast epithelial

cell line (Jenkins, Zeher, Van Houten, & Bovbjerg, 2014). Other animal studies and laboratory tests also suggested that environmental stressors are co-factors in tumour formation (Henning, Jenkins, & Bovbjerg, 2014). A RCT study of chronic fatigue in general population in a four-month Qigong intervention reported significant improvement in telomerase activity pre and post intervention within the Qigong group compared to control group (Ho et al., 2012).

Notably, cancer-related distress is associated with (Morin & Benca, 2012), and exacerbated by insomnia (M. Irwin, 2013; Mosher & Duhamel, 2012; Sharma et al., 2012) (Savard et al., 2015).

### **2.1.3 Cancer related symptoms and side effects**

Most cancer survivors experience persistent cancer and treatment-related side effects or symptoms such as insomnia (Savard et al., 2015), fatigue (Miaskowski et al., 2008; M. L. Siefert, 2010), pain, depression or anxiety (Tao et al., 2015) that adversely affect their QOL (Arndt et al., 2017; Mustian et al., 2016; Tao et al., 2015). They are also often more susceptible to developing second primary cancers and may have additional chronic diseases such as cardiovascular disease, diabetes, obesity, osteoporosis and functional decline (Robert, Emma, & Janet, 2013; Stein, Syrjala, & Andrykowski, 2008).

One of the most prevalent cancer and treatment-related side effects is insomnia, which was reported to affect 30-60% of cancer patients (Mustian et al., 2016; Savard et al., 2015) with some studies reporting the rate to be as high as 80% (Balachandran, Faiz, Bashoura, & Manzullo, 2013). It was reported that insomnia is three times more prevalent in cancer survivors compared to the general population, with breast cancer survivors having the highest prevalence of insomnia amongst all cancer types (Otte et al., 2016). As sleep assessment and screening are not performed in routine cancer care (L. M. Siefert, Hong, Valcarce, & Berry, 2014), its prevalence may be higher than the reported statistics.

## **2.2 Cancer and insomnia**

Insomnia is the most common sleep disorder in cancer survivors (E. Matthews, Carter, Page, Dean, & Berger, 2018). It is characterized by dissatisfaction with sleep quality, trouble falling and staying asleep, early waking, and non-restorative sleep (Morin & Jarrin, 2013). The condition includes subjective reports of daytime dysfunction such as fatigue, difficulty concentrating, irritability and mood swing thereby affecting QOL (Cancer.Net, 2019; Morin & Benca, 2012) but has not received adequate attention and assessment by primary care providers (E. Matthews et al., 2018). Insomnia can often worsen other cancer-related symptoms such as fatigue, depression and pain (Ancoli-Israel et al., 2014; Galiano-Castillo et al., 2017; Jim et al., 2013; Palesh et al., 2010). Moreover, prolonged insomnia (i.e. persistent sleep deprivation) is associated with poor adherence to treatment (Kidwell et al., 2014) and increased morbidity and mortality in cancer survivors (Ancoli-Israel, 2009; Lehrer et al., 2013). Many cancer survivors continue to experience sleep disorder for years even after completion of treatment (Roscoe et al., 2007), some as far as 10 years into cancer survivorship (Balachandran et al., 2013). Therefore, addressing insomnia and its causes with proper assessment and management is a critical component of integrative cancer care to support and prevent poor health outcomes in cancer survivors during this difficult journey of survivorship.

### **2.2.1 Pathophysiology of insomnia**

#### **2.2.1.1 Conventional perspective of insomnia**

Sleep is an active, biobehavioral process and state of temporary perceptual disengagement from and unresponsiveness to the environment. The key functions of sleep are to conserve energy, maintain homeostasis, and restore physiologic processes that degrade during wakefulness (Vassalli & Dijk, 2009). These functions are critical to physical and mental health, particularly in adults with cancer (E. Matthews et al., 2018).

Although the definitive pathophysiology of sleep problems have not been fully established, it can be associated with a few neurobiological abnormalities (Morin & Benca, 2012). Patients

with insomnia experienced elevated activation of autonomous nervous system as manifested in increase in sleep related heart rate, heart rate variability, metabolic rate, body temperature, hypothalamic-pituitary-adrenal axis activity, norepinephrine secretion and night time blood pressure. Other signs noted are brain activity changes during sleep such as increase in faster brain frequencies (beta and gamma) associated with increased cognitive activity, decreased slow wave sleep, elevated brain glucose metabolism and less sleep-related reduction in brain glucose metabolism in wake-promoting regions (Morin & Benca, 2012).

The prevalent of sleep disorder in cancer survivors has also been associated with disruption of circadian rhythm (Innominato et al., 2016). The suprachiasmatic nucleus in the hypothalamus controls the circadian rhythm, the biological clock of the body through signals of light received. The circadian rhythm controls both physiological, psychological and behavioral processes in human body and any dysregulation of this rhythm is associated with various diseases such as cancer (Innominato et al., 2016). This endogenous circadian rhythm which controls sleep also influences the secretion of melatonin. Melatonin, an endogenous hormone produced from serotonin in the pineal gland is generated according to the human circadian rhythmic pattern, peaking between 3 a.m. and 4 a.m. in the absence of light. Once secreted, it is distributed to various body tissues and organs to restore the metabolic and homeostatic states of the body (Castro, Bordin-Junior, de Almeida, & Zuccari, 2018). The normal nocturnal rise in circulating melatonin is affected by sleep pattern and light exposure during the night. Disruption of the circadian rhythm occurs when sleep and wakefulness or darkness-light cycle happen not according to our biological clock (Wright et al., 2015), leading to sleep deprivation which will reduce melatonin production with various adverse systemic symptoms including shorter survival in cancer patients (Innominato et al., 2016). Melatonin has onco-protective and inhibitory effects on tumour cells and low levels of melatonin is associated with risk of cancer development (Castro et al., 2018). Melatonin suppression also aggravates the circadian breakdown and sleep deprivation, known to increase levels of cortisol, a stress hormone, and inflammatory proteins in the body which is associated with insomnia (Howell et al., 2014; Irwin et al., 2014) and thought to lead to sleep disorder (Wright et al., 2015).



### 2.2.1.2 Traditional Chinese Medicine perspective of insomnia

The mechanism of sleep disorder can be explained by two of the main TCM Yin Yang Sleep and Ying Wei Sleep theories.

#### *a. Yin Yang Sleep Theory*

According to Yin Yang theory, Yin is stillness and Yang is dynamic, hence, sleep occurs when Yang Qi diminishes and wakefulness arises when Yin Qi diminishes as stated in Chapter 80 *Da Huo Lun* of the *Lingshu* (Unschuld, 2016).

Furthermore in Chapter 28 *Kou Wen* of the *Lingshu* states that the eyes close when the Yang Qi diminishes and the Yin Qi abounds; there is awakening when the Yin Qi expires and the Yang Qi is prosperous (Unschuld, 2016).

Therefore, the Yin Yang Sleep Theory regards Yin as stillness while Yang as dynamic; when Yang qi is weak and Yin qi is strong (prevails), then sleep takes place; when Yang qi is strong (prevails) and Yin qi is weak, then wakefulness occurs.

Hence, the sleep and wake mechanism of human is dependent on the change in the levels of Yin Qi and Yang Qi in the body.

In addition to that, the Yin Yang Sleep Theory also explains about the relation of circadian cycle in human and nature. Chapter Four *True Words from the Golden Cabinet* of Su Wen explains that from dawn to noon is the Yang of the day, Yang within Yang; from noon to dusk is Yang of the day, Yin within Yang; from nightfall to the crowing of the cocks is the Yin of the day, Yin within Yin; from crowing of the cocks to dawn is the Yin of the day, Yang within the Yin, and man correspond to it" (Unschuld, Tessenow, & Zheng, 2011)

Based on the holistic concept of TCM theory, man and nature is a holistic entity, and the Yang Qi and Yin Qi of man follow the rhythms of the Yang Qi and Yin Qi of nature. As such there is a natural inherent synchronization of Yin Yang rhythm of the human body and that of the nature which is supported by various modern scientific findings such as the rise and

fall of various hormone secretion in the body with the interaction between the sleep (Yin) and awake system (Yang) of the brain (Y. J. Liu et al., 2003) .

Hence, any desynchronization of Yang Qi and Yin Qi of the body with that of the nature is the root of pathogenesis of sleep disorder (Y. J. Liu et al., 2003) that leads to negative consequences on both our physiological and psychological states.

#### *b. Ying Wei Sleep Theory*

The ancient Chinese philosophy based on materialism concept regards Qi as the basic foundation and fundamental building blocks of the universe through its constant evolving and transformation processes (Y. J. Liu et al., 2003; Xing & Jia, 2012). As such Qi is also the building block of human body. Human inherit pre-natal Qi from parents, absorb essence Qi from food and breath in fresh air from nature to produce various types of Qi in the body to sustain life.

Two of the Qi produced, namely Ying (Nutritive) Qi and Wei (Protective) Qi have a close relationship with sleep. Ying Qi and Wei Qi is essence Qi of food transformed by Spleen.

According to Chapter 43 *Bi Lun* of *Suwen*, the essence Qi of food is Ying Qi, it enter the blood vessels to circulate upwards and downwards to regulate and nourish the five Zang organs and six Fu organs while the swift and dynamic Qi of food is Wei Qi, it cannot enter the blood vessels, hence it circulates within skin, muscle, interstitial tissues and disperses in chest and abdomen (Unschuld et al., 2011).

Furthermore, Chapter 18 *Ying Wei Sheng Hui* of *Lingshu* states that Ying is inside blood vessel, Wei is outside blood vessels, circulating continuously, 50 cycles a day (Unschuld, 2016).

During the day, Yang Qi flourishes, Ying Qi circulate inside blood vessel to nourish internally while Wei Qi circulate outside, the Yang meridians and blood vessels to protect and warm externally, the body is full of Yang Qi, hence it is active and awake. At night, Yin Qi gradually flourishes, Ying Qi circulate inside blood vessels while Wei Qi enters Yin meridians and the

five Zang organs through Yin Qiao Mai and Yang Qiao Mai to circulate 25 cycles, where Ying Qi and Wei Qi meet, sleep and rest occur (Y. J. Liu et al., 2003).

Therefore, the sleep and wakeful state of man is closely related to circulation of Wei Qi and its entrance and exit from Yin meridians through Yin Yang Qiao Mai which in turn control the opening and closing of the eyes.

Ying Wei sleep circulation theory states that the order of and changes in the circulation of Ying and Wei Qi lead to wakefulness and sleep state. Sleep disorder occurs whenever there is any abnormality in the circulation of Wei Qi.

Meeting of Ying and Wei Qi during sleep at night that lead to circulation of Qi in the Yin meridian and five Zang organs may have a correlation with what is known in conventional science about changes in the various body functions during sleep such as the nervous system, the circulatory system, the endocrine system, the reflective and musculoskeletal functions.

There are some similarities and differences in the understanding of sleep disorders between conventional science and Chinese Medicine (Y. J. Liu et al., 2003, p. 20). These similarities and differences may be better explained in future with technological advancement especially in neuroscience which may advance our understanding of the mystery of sleep (Y. J. Liu et al., 2003, p. 24).

### **2.2.2 Contributing factors of cancer related insomnia**

The multifactorial causes of insomnia in cancer survivors include predisposing factors such as gender, old age, hyper-arousability as a trait, personal or family history, mood or anxiety disorders; precipitating factors such as cancer treatment which can change the levels of inflammatory cytokines or disrupt circadian rhythms or sleep–wake cycles, side-effects of cancer treatment, menopausal symptoms, hospitalization, stress from cancer, co-occurring symptoms, i.e. pain or fatigue, and medications used to treat or manage treatment side-effects, such as corticosteroids; and perpetuating behavioural factors such as excessive daytime sleeping, inappropriate or long-term use of medications, and maladaptive

cognitions, i.e. inaccurate appraisal of sleep difficulty and quality and daytime impairments (Berger, 2009; Howell et al., 2014).

Among the various causes, stress from cancer diagnosis, cancer treatment and their side effects is the primary factor that contribute to (M. Irwin, 2013; Mosher & Duhamel, 2012; Sharma et al., 2012) and aggravate insomnia in cancer survivors (Savard et al., 2015). Psychological and physiological stress increase circulating cortisol, a stress hormone that releases inflammatory promoting chemical, cytokines which can lead to sleep disorder (Wright et al., 2015), promote depression and anxiety, increased blood pressure, fatigue and cloudy thinking (Thorpe, 2017).

Cancer treatment is also a potential inducer of inflammation (S. M. Huang et al., 2016; Irwin et al., 2014) and inflammation is associated with insomnia (Howell et al., 2014; M. R. Irwin, 2013). Insomnia in turn activates markers of inflammation at systemic (Ferrie et al., 2013; Meier-Ewert et al., 2004), cellular and genomic levels (Irwin, Carrillo, & Olmstead, 2010; Irwin, Wang, Campomayor, Collado-Hidalgo, & Cole, 2006; Irwin, Wang, et al., 2008). The reciprocal relationship between insomnia and inflammation is a vicious cycle which continues to aggravate the psychological and physiological states of cancer survivors if not addressed.

#### **2.2.4 Management of insomnia**

The two conventional therapeutic options with adequate evidence from clinical trials as first line of treatment to support their use in the management of insomnia are CBT-I and approved hypnotic drugs (Morin & Benca, 2012). However, a recent systematic review to identify effective interventions for cancer-related sleep disorder concluded that cognitive CBT-I is the only intervention that is recommended for practice while mindfulness-based stress reduction and exercise interventions are likely to be effective but require more evidence (E. Matthews et al., 2018).

#### 2.2.4.1 Cognitive behavioral therapy for insomnia (CBT-I)

CBT-I is the recommended frontline treatment for insomnia as it improves global outcomes and nearly all sleep parameters in the general adult population, older adults, and adults with pain (Brasure et al., 2015).

CBT-I is a program of treatment that includes behavioral strategies of sleep hygiene, sleep restriction techniques, stimulus control and relaxation techniques. These behavioral strategies are then combined with a cognitive reframing of unhelpful thoughts about sleep such as worry about the lack of sleep which is a major contributor to the continuation of the problem (Buysse, Rush, & Reynolds, 2017).

CBT-I is also the current treatment of choice with demonstrated efficacy on some dimensions of insomnia in cancer survivors (Howell et al., 2014; Johnson et al., 2016; E. Matthews et al., 2018; Peoples et al., 2017). However, there are issues with affordability, accessibility and patient compliance (Bluestein et al., 2011; Morin & Benca, 2012). As such usage of CBT-I is relatively low due to feasibility of application in clinical practice and oncology care (Morin, 2015). Moreover, further research is needed for high quality evidence of CBT-I for insomnia in cancer survivors (Howell et al., 2014).

#### 2.2.4.2 Pharmacotherapy

Common medical therapy with non-benzodiazepine hypnotics eszopiclone, zolpidem, and the orexin receptor antagonist suvorexant which improved short-term global and sleep outcomes are used to manage insomnia (Brasure et al., 2015). While different types of pharmacologic agents have been recommended for management of insomnia, they come with many side effects such as daytime sedation, delirium or nausea and long term use may lead to dependence and tolerance (Howell et al., 2014). Other than the possible side effects, the efficacy and safety of these medication with adult cancer survivors have also not been established (Howell et al., 2014). Moreover anti-inflammatory drugs may not work as intended with serious side effects due to is suppression of the immune system on the whole body instead of just on the parts where it is needed (Jo, 2016).

As such sleep experts recommend initiating medications at low dosage while monitoring for side effects. They also advocate short term use to relieve symptoms and slowly taking off to prevent withdrawal symptoms and rebound (Sateia, Buysse, Krystal, Neubauer, & Heald, 2017) while more effective evidence based natural CAM should be considered for long term relieve of insomnia.

#### 2.2.4.3 Alternative management

CAM is composed of various theories, approaches, practices, and products that are outside the conventional medical model, but may complement conventional medicine through the use of therapies that address bio-behavioural and psychosocial factors (Slocum-Gori, Howard, Balneaves, & Kazanjian, 2013). Among the various modalities of CAM available, increasing popularity in the use of MBT such as Qigong and meditation have attracted many cancer survivors (Chandwani et al., 2012) and interest in the scientific community. MBTs are designed to enhance the mind's capacity to influence the body's function (Chandwani et al., 2012) and include meditation, guided imagery and hypnosis. MBT was designated as top research priority by the National Center for Complementary and Alternative Medicine (Ernst, 2012). While CBT-I is the recommended intervention for sleep disorder in cancer survivors, MBTs are considered as likely to be effective in a recent review of evidence based interventions but require more evidence for management of insomnia in cancer survivors (E. Matthews et al., 2018). Growing evidence suggests that MBTs are beneficial adjuncts to cancer treatment and may be effective in addressing the multifaceted needs of cancer survivors (Chandwani et al., 2012; Mishra et al., 2012), including sleep (Carlson & Garland, 2005; Mishra et al., 2012). However, larger studies are needed to confirm its effect on common cancer related symptoms (Chandwani et al., 2012).

MBT is made up of the meditative and exercise components. Many studies have evaluated the benefits of the two components separately.

The meditative component is the practice of training the mind to focus and redirect thoughts to develop positive mood, healthy sleep pattern or even increase pain tolerance. Among the many benefits of meditation are stress reduction and improved sleep (Horowitz,

2010; Thorpe, 2017). Psychological and physiological stress increased cortisol level, a stress hormone that releases inflammatory promoting chemical, cytokines which lead to disrupt sleep (Wright et al., 2015), promote depression and anxiety, elevated blood pressure, fatigue and cloudy thinking (Thorpe, 2017).

Meditation was reported to reduce inflammatory chemicals (Kasala, Bodduluru, Maneti, & Thipparaboina, 2014), reduce tension to induce a peaceful state that promote sleep and can be used to treat insomnia with good patient acceptance and durable results (Martires & Zeidler, 2015). This is supported by Rokenkranz and colleagues that reported meditation has better buffer effects of psychological stress on neurogenic inflammation compared to active control group. The positive influence on psychological stress was reflected as reduction in self-reported psychological distress, physical symptoms and post-stress inflammatory response (Rosenkranz et al., 2013). Another study found that meditation produced measurable positive effect on immune and electrical activity of the brain area related to positive thinking and optimism (Davidson et al., 2003).

Meditation is also considered one of the natural serotonin boosters that can help to reduce stress and improve sleep. Serotonin is a neurotransmitter that send signals between nerve cells and is responsible for stimulating parts of the brain that control sleep and waking. Deficiency in serotonin is linked to insomnia. Serotonin levels in brain can be elevated with selective serotonin reuptake inhibitor (SSRI) drugs by locking reabsorption of serotonin such as Prozac and Zoloft, among others (Scaccia, 2017). However, treating insomnia with drugs is not a long-term solution due to its many side effects (Howell et al., 2014).

Exercise is an essential adjunct therapy in cancer prevention and control (Cormie, Zopf, Zhang, & Schmitz, 2017; Schmitz et al., 2010). A Cochhrane systematic review reported that exercise may have benefits on QOL, self esteem, emotional well being, social functioning, sleep disturbance, fatigue and pain in breast cancer survivors (Mishra et al., 2012). The American College of Sports Medicine Roundtable on Exercise Guidelines for cancer survivors reviewed published empirical evidence of exercise for cancer survivors and concluded that exercise leads to better outcome in physical function, QOL and cancer related fatigue. It also advised against inactivity and indicated that cancer survivors should be as physically active

as their condition or abilities allow (Schmitz et al., 2010). This recommendation is based on a review of 100 studies that reported the growing evidence of lowered risk of cancer mortality and recurrence as well as lesser or fewer cancer related adverse effects for cancer survivors who exercise compared to those who did not exercise or exercise less (Cormie et al., 2017). Another review of exercise guidelines and exercise literature for cancer survivors concluded that exercise is a safe, appropriate and effective therapeutic intervention to manage cancer and treatment related symptoms before, during and after completion of treatment (Mustian et al., 2016). Exercise has also been reported to improve sleep quality and quantity in both the general (Medysky, Temesi, Culos-Reed, & Millet, 2017) and cancer populations (E. E. Matthews, Janssen, Djalilova, & Berger, 2018; Medysky et al., 2017; Steindorf, Wiskemann, Ulrich, & Schmidt, 2017).

Studies of MBTs that included both the meditative and exercise elements have reported its positive anti-inflammatory and anti-viral effects (Black et al., 2013; Creswell et al., 2012; Irwin, Olmstead, & Oxman, 2007). Qigong, a form of MBT was reported to improve sleep in older adults (Irwin, Olmstead, & Motivala, 2008; Li et al., 2004) with reduced biomarkers of disease risk (Carroll et al., 2015), reduction in cellular inflammatory responses as well as reduction in expression of genes encoding proinflammatory mediators (Irwin & Olmstead, 2012). A systematic review and meta-analysis of Tai Chi found that it is more effective on sleep improvement compared to usual care (Xiang, Lu, Chen, & Wen, 2017). This is supported by a recent systematic review and meta-analysis of MBTs that indicated MBTs such as Tai Chi and Qigong can be effective in treating insomnia and sleep quality in healthy and clinical populations (X. Wang et al., 2019). Sleep quality improvement with Qigong was also reported in a number of studies (Irwin, Olmstead, et al., 2008; Li et al., 2004; Xiang et al., 2017; S.-C. J. Yeh & Chang, 2012).

MBTs are also widely used by cancer patients to reduce symptoms and manage cancer and treatment-related symptoms and Qigong is one of the MBTs evaluated for their utility in oncology (Zeng, Luo, Xie, Huang, & Cheng, 2014). As Qigong is a form of MBT that incorporate both the meditative and exercise components (Horowitz, 2010) and has been used for thousands of years for its health benefits (Xing & Jia, 2012) from the combined



effects of both components, it should be explored as one of the MBTs for management of the multiple cancer related symptoms of cancer survivors (Mansky et al., 2006) including insomnia.

## **2.3 Qigong**

### **2.3.1 What is Qigong**

The term Qigong consists of two characters 气 (Qi) and 功 (Gong). Qi is a TCM concept, an inherent functional, energistic essence of human beings, a subtle energy circulating throughout the body (Larkey, Roe, Smith, & Millstine, 2016). Other terms used to explain Qi includes life force or vital energy or intelligence (Ming, 1995) within the bio-electric body (Klein et al., 2016; Penelope, 2017) and the universe (Xing & Jia, 2012). According to Traditional Chinese Medicine theory, there are many types of Qi in the body (Xing & Jia, 2012). For example, there is what we call Wei Qi, a type of protective Qi that surrounds our body and the various circulatory systems in the body such as the nervous system, cardiovascular system, lymphatic system. The fundamental principle of TCM for a healthy body is the maintenance of adequate, balanced and regulated Qi system to ensure the smooth, fluid and clear circulation of Qi. Disharmony, blockage or lack of Qi is believed to be the main cause of illness (S. M. Huang et al., 2016; Xing & Jia, 2012).

One of the ways to achieve this state of regulated and balanced Qi system is through the practice of Qigong. The term “Gong” means skill, practice or technique. Therefore, Qigong can be translated as the application or practice of skill or technique to cultivate and regulate Qi. It is an ancient scientific study of Qi in the body and universe and how it can be applied to benefit all aspects of life (Ming, 1995). Qigong is a mind-body practice that incorporates simple, slow, gentle flowing, low impact, integrated exercise, meditation, mind adjustment, and breath regulation based on Chinese Medicine theories, Daoism, Buddhism, Confucianism philosophies and martial arts. This practice is a traditional Chinese health and healing practice used for thousands of years (Xing & Jia, 2012). Regular and consistent practice is thought to promote integration of mind and body to bring about a deep state of relaxation that leads to the clear and smooth circulation of Qi for a better physical, mental

and spiritual health. It is reported that regular practice could stimulate and enhance mind-body integration to regulate endogenous neurohormones and stimulate other natural health recovery mechanisms to promote self-healing (Tiwari et al., 2014).

### 2.3.2 History and development of Qigong

Qigong originated from China with its history dated back to a few thousand years ago (Xing & Jia, 2012). Since the Han Dynasty, it has evolved into 4 main different schools namely Confucianism, Buddhism, Taoism and Medicine which further expanded into many more branches during the long course of its historic evolution and development.

Qigong began from ancient times to the Qin Dynasty. There is no exact record of when Qigong was formed but it can only be inferred from indirect literature (*Chinese Medical Qigong*, 2013). Judging from the cultural relics unearthed in China Qinghai Province in the 1970s; of seeds confirmed by isotope inspection to be 5000 years old found inside pottery jar engraved with images of people in standing posture, and their poses, mouth shape (**Figure 1**), and appearance consistent with the current Qigong method of standing posture practice, it was speculated that the history of Qigong in China dated back to at least 5,000 years ago (*Chinese Medical Qigong*, 2013; W. C. Zhang, 2010).



**Figure 1** Painted pottery jar from Majiayao period (around 3000 BCE), Qinghai province: with a sculpture in human shape on a standing meditation post, performing gulping Qi exercise.

Other historical evidence includes records in Shangshu (Lo, 1997), China's earliest history book in which it was recorded that in the Tangyao period more than 4,000 years ago, there were floods in China's Central Plains. According to Lu Clan Spring and Autumn, Chapter: Ancient Music (Wei, Tou, Yuan, & Man, 2014), the rainy and humid climate caused Qi and blood stagnation resulting in many people suffering from body and joint pain. Hence, dance was introduced to disperse and promote the flow and circulation of Qi, thus alleviated pain and sickness (Wei et al., 2014). Suwen, Chapter: Dao Fa Fang Yi Lun (Unschuld et al., 2011) states that since the central plains of China were flat and humid, coldness in the limbs and diseases of the bones and joints were common, and that these conditions should be treated with Daoyin and Anqiao, different terms of Qigong used in ancient times (*Chinese Medical Qigong, 2013*).

It can be seen from above that the ancient people were able to incorporate some practical actions such as movements, breathing and chanting to regulate certain dysfunctions of the human body and these actions gradually evolve into graceful and beautiful dances similar to the current Qigong (Wei et al., 2014; W. C. Zhang, 2010).

Qigong experienced a prosperous period from ancient time through the Xia, Shang and Western Zhou dynasties to the Spring Autumn Period and the Warring States Period. This period witnessed the gradual formation of Qigong theory and mechanism such Dao, Yin Yang and Five Elements theories by the various famous philosophers and scholars (W. C. Zhang, 2010).

Among the most influential ancient philosophers that have laid the theoretical foundation for health preservation Qigong (Yang Sheng Qigong) are Lao Zi and Zhuang Zi as can be seen from their work in 'Dao De Jing' and "Zhuang Zi" respectively.

In "The Analects of Confucius" (Confucius, 1999), based on the teaching of Confucius, there is also mention of "benevolence" as not only being a kind of high morality but also a high level of Qigong state/realm.

The major progress of Qigong theory and technique during this period contributed to the birth of the first existing TCM classic "The Yellow Emperor's Internal Classic" where there are

vivid descriptions of the method of Qigong practiced by the ancient people and the Qigong state/realm experienced by them. During the “The Yellow Emperor Internal Classic” period, Qigong was one of the five important means and methods for prevention and treatment of diseases as recorded in Suwen, Chapter: Dao Fa Fang Yi Lun (Unschuld et al., 2011).

Other scholars that paid great attention to the research of Qigong to study the relation between human, nature and society during this time include Guan Zhi 《管子》 which has the earliest and most comprehensive records of these studies (W. C. Zhang, 2010). Guan Zi 《管子》 was one of the first scholars to apply the scientific materialism concept to explain the development of certain abilities from Qigong training.

In summary these classical Qigong has two characteristics. Firstly, it is regarded as a knowledge to improve health through study and self-cultivation. Secondly, classical Qigong was formed based on theories and principles of Yin Yang, five elements, Yuan Qi, Jing Qi Shen (Essence, Qi and spirit) to explain Qigong and its effects, which to a certain extent explain the mystery of human life and this formed the foundation of traditional Chinese Qigong (*Chinese Medical Qigong*, 2013).

The current definition of Qigong is gradually evolving into an academic Chinese Medical Qigong field that focuses on the exploration, organization and transmission of classical Qigong as an academic and scientific subject. The recent definition of Qigong as “a skill of body-mind exercise that integrates body, breath and mind adjustments into one” (*Chinese Medical Qigong*, 2013) incorporates two elements that reflect Qigong as a subject with key classical Qigong ideas and modern scientific criteria of knowledge. Firstly, it is an exercise of adjusting the three elements of body, breath and mind (the building blocks of our being) into a state of harmonious unity. Secondly it is a training of both the mind and the body (psychology and physiology) that require skill learning and mastery of technique (*Chinese Medical Qigong*, 2013). As such it is considered more than just a physical exercise due to its ability to produce numerous psychophysiological benefits. Many of these benefits such as improvement in psychological state, physical function and quality of life including sleep have been reported in non-cancer population (Jahnke et al., 2010; Sancier, 1999) as well as with

cancer population (Byeongsang, Sun Mi, Aya, David, & Albert, 2013; Campo et al., 2014; Oh, Butow, Mullan, Clarke, et al., 2012; Van Vu et al., 2017; P. Wayne et al., 2018).

### 2.3.3 Types of Qigong

There are thousands of different forms of Qigong practiced for different purposes such as Chinese Medical Qigong, Daoist Qigong, Buddhist Qigong, Confucian Qigong, and martial arts Qigong, all of which involve the recognition and cultivation of Qi to promote a balance Qi and smooth flow of Qi in the body (S. M. Huang et al., 2016).



Figure 2 Silk painting depicting the practice of Qigong; unearthed in 1973 in [Hunan](#) Province, China, from the 2nd-century BC [Western Han](#) burial site of [Mawangdui Han tombs site](#), Tomb Number 3.

Despite the multitude and variation of styles and forms, Qigong is health oriented with the same principles and practice elements (Jahnke et al., 2010). These can be broadly classified into internal Qigong and external Qigong. Internal Qigong refers to Qigong exercise practiced as meditative exercise to cultivate Qi while external Qigong involves the therapeutic transfer of Qi by a Qigong practitioner to an object or person (Penelope, 2017). Internal Qigong performed as therapeutic exercise to address insomnia in cancer survivors is the focus of our study. Among the various types of Qigong available, Chinese Medical Qigong

is one form that focuses on nurturing life (Yang Sheng) and treat illness based on philosophy and theories of TCM (*Chinese Medical Qigong*, 2013). The most common styles of Chinese Medical Qigong adopted for cancer care noted to date are Guo Lin, Tai Chi (modified), Chan Chuang (static standing meditative posture), Ba Duan Jin and Zhineng Qigong. These various styles have similar theoretical roots, proposed mechanism of action and expected benefits (Klein et al., 2016). As review of effective Qigong protocols have identified common construct analysis with no evidence of superiority of the various forms of Chinese Medical Qigong styles (Klein et al., 2016), these different styles will be referred to as Qigong for the purpose of this study.

#### **2.3.4 Zhineng Qigong (ZQ)**

One of the modern Qigong widely practiced is Zhineng Qigong (Jin & Marcello, 1999). It is a contemporary form of Qigong based on the fusion of the best of many Qigong emerging out of Confucianism, Buddhism, Taoism, Traditional Chinese Medicine, traditional martial arts and folk religion integrated with modern science, medicine, and philosophy (Jin & Marcello, 1999, p. 123). ZQ emphasizes on the critical role of the mind on health and wellbeing. Maintaining a healthy, positive and optimistic mental state is the essential component underlying the recuperative process of individuals (Jin & Marcello, 1999). (Jin & Marcello, 1999) reported that “The most remarkable benefit of ZQ is its ability to prevent and heal disease” (page 49). ZQ was created by Professor Pang Ming, who has achieved great attainments in TCM, various forms of Qigong, modern and ancient philosophy and is well versed in Western Medicine (Jin & Marcello, 1999). It is a fairly new form of Qigong which was only introduced to the public in 1980 (Jin & Marcello, 1999). It developed rapidly till 1999 when the Chinese Government cracked down on Falun Gong (Thomas, 2000) which also affected all other Qigong movements.

Despite hundreds of empirical cases reporting benefits of recovery from illness by practicing ZQ, to the best of our knowledge they were not available in the current research database. Only two studies of ZQ intervention in cancer were found with report of an improvement in depression score and QOL (Loh, Lee, & Murray, 2014; Overcash, Will, & Lipetz, 2013). There were no studies of ZQ on insomnia for cancer survivors from our literature search. However,

through my practice of ZQ for the last 15 years, I have many personal experiences of the health benefits of ZQ practice on my health and my family. I witnessed many health benefits through people whom I help with various conditions. One particular benefit of ZQ is its impact on quality of sleep as many practitioners who had problems with sleep before starting ZQ practice managed to sleep well after practicing ZQ. Seeing the many benefits of ZQ especially in insomnia without the need for pharmacologic intervention with its side effects in addition to cost saving, I strongly believe in the great potential of ZQ as a complementary alternative to address the many cancer related symptoms experienced by cancer survivors especially insomnia. Therefore, this study will employ ZQ as the Qigong intervention to evaluate its feasibility in improving insomnia in cancer survivors.

ZQ is based on the Hun Yuan Entirety Concept (Ming, 1995) consistent with the holistic concept in TCM. Hun Yuan means “blending as one”. Hun Yuan Entirety Concept views human as a holistic unit made up of the three basic elements of the body, Qi and mind. It also believes that human is connected with nature and society as a holistic unit (Ming, 1995).

The Hun Yuan Entirety Concept believes that the universe originated from the state of Hun Yuan Qi (Ming, 1995) or Qi (Xing & Jia, 2012). Other than Huan Yuan Qi, there are different terms used to describe the state of the origin of the universe in traditional Qigong theories such as Dao (道) from Dao De Jing, Yuan Qi (元气) from Tai Ping Classic and Taiji (太极) from Book of Changes (Ming, 1995). All these terms refer to the same state of primordial Qi of the Universe and may be referred to as cosmic or nature`s energy (Oh et al., 2010).

One of the earliest explanation about this concept of the origin of the Universe or Dao (The Way) by Lao Zi is described in Chapter 25 of Dao De Jing (Legge, Zhuangzi, & Laozi, 1993):

*“There was something undefined and complete, coming into existence before Heaven and Earth. How still it was and formless, standing alone and undergoing no change, reaching everywhere and in no danger (of being exhausted)! It may be regarded as the Mother of all things...I do not know its name, and I give it the designation of the Tao (the Way ....”*

Another explanation of the origin of the universe is Tai Ji or “Supreme Ultimate”, a term used in Book of Change (Legge, 1973). It is thought that Tai Ji reconciles Yin Yang, the two most fundamental elements of Chinese philosophy to the same sphere of discourse (D. Zhang, 2002).

The ancient Chinese philosophies based on the origin of Universe believe that the evolution of the Universe from this original state has its own laws or patterns referred to as Dao (The Way) as stated in Chapter 42 of Dao De Jing “*The Tao produced One; One produced Two; Two produced Three; Three produced All things....*” (Legge, 1891).

Huai Nan Zi states that everything in the world is made up of Qi and also explains the inter-relationship of the human body, Qi and mind (*Chinese Medical Qigong*, 2013).

Therefore, ancient Chinese philosophers view Qi as the most basic substance of which the world is comprised. Everything in the universe results from the movements and changes of Qi. Qi flows throughout the universe and through each human body. TCM believes that the human body is a microcosm of the Universal macrocosm. Therefore, humans must follow the laws of the Universe to achieve harmony and total health (Xing & Jia, 2012).

ZQ practice emphasizes on the connection of the Hun Yuan Qi of nature with the Qi of body through the mind, using the Intent to Direct Qi (YIYI Yin Qi) method which was first created by Tan Luan, a distinguished monk in the northern Wei Of Pure Land Buddhism (Jintu Zhong) who studied under Daoist priest Tao Hongjing (*Chinese Medical Qigong*, 2013). The basic ZQ method trains the mind to regulate the fundamental four directions/movements of Qi; ascending, descending, exiting and entering in the body (Xing & Zhou, 2012) and promote the connection and exchange of Qi of the body with that of Hun Yuan Qi of nature (Ming, 1995). When the body has an open connection with Hun Yuan Qi of the nature, which is considered the basis of everything—both visible and invisible—in the Universe (Ming, 1995), there is harmony and synchrony of Qi between the body and nature (Browning, Kue, Lyons, & Overcash, 2017) as well as abundance of Hun Yuan Qi in the body which will lead to better health in two ways. Firstly, it will promote smooth and clear circulation of Qi in the body, the basis of a healthy body in TCM (Xing & Jia, 2012). Secondly, the open connection with Hun



Yuan Qi will synchronize the body system with nature, thereby achieving a harmonized state internally and externally as a holistic unit of total wellbeing based on the Qigong principle by Zhuang Zi of “Heaven and Human United As One”(Tian Ren He Yi), a state of “ Heaven and earth exist within me, the universe and I are one” as written in his book On Leveling All Things (Qiwu Lun). This principle of living in harmony and in synchrony with nature is consistent with the Yin Yang Sleep and Ying Wei Sleep theories for proper sleep (Refer section 2.2.1.2). It also corresponds with how the circadian rhythm concept of darkness-light cycle of the day affect sleep (Refer section 2.2.1.1).

In summary ZQ practice aims to synchronize the body with nature to achieve a harmonized state that will lead to total wellbeing of which good sleep is one of the most important components. Therefore, this thesis is was designed to study the feasibility of ZQ as a complementary intervention to improve insomnia in cancer survivors.

## **2.4 Research on Qigong**

Modern scientific research on Qigong started in 1950s to verify and explore the mechanism of effects of Qigong with appropriate scientific research methodology or experimental studies to develop modern scientific theory of Qigong (*Chinese Medical Qigong*, 2013).

Current trend on Qigong research focuses on effects of Qigong and exploring its mechanism. Effects of Qigong can be evaluated by examining changes in subjective and/or objective variables from practicing Qigong. The exploration of the mechanism of the effect and phenomena of Qigong could develop possible connection and integration of the ancient holistic Chinese concept with modern scientific theory and methodology to merge Western modern science with Eastern classic culture which may provide the foundation for the advancement in human civilization (*Chinese Medical Qigong*, 2013).

As Qigong is defined as “a skill of body-mind exercise that integrates body, breath and mind adjustments into one”(Chinese Medical Qigong, 2013) that incorporates the various stress reduction techniques such as meditation, progressive relaxation, diaphragmatic breathing, guided imagery and physical movements to mobilise Qi for physical, psychological and

spiritual health (Z. Chen et al., 2013), it involves many elements of regular exercise and mental techniques for relaxation. As such it is considered more than just a physical exercise due to its ability to produce numerous psychophysiological benefits as a result of mind-body specific activities (P. Wayne et al., 2018) and may be more effective in improving the multifaceted nature of chronic diseases such as cancer. Many of these benefits such as improvement in psychological state, physical function and quality of life (Jahnke et al., 2010; Sancier, 1999), depression and anxiety (Yin & Dishman, 2014), enhanced cognition function (P. M. Wayne, Walsh, et al., 2014), improved balance control, flexibility that reduced falls and related injuries (Huang & Liu, 2015) (Hwang et al., 2016; Yildirim, Ofluoglu, Aydogan, & Akyuz, 2016) as well as regulating gene expression that improve immunity, metabolic rate and apoptosis (Saatcioglu, 2012) have been reported in non-cancer population. A review of 120 systematic reviews of more than 500 trials over the last 45 years of Tai Chi, one form of Qigong, reported excellent evidence of benefits in preventing falls, osteoarthritis, Parkinson disease, chronic obstructive pulmonary disease rehabilitation, and cognitive capacity improvement in older adults (Huston & McFarlane, 2016). The review also reported good evidence of benefit for depression, cardiac and stroke rehabilitation, and dementia with fair evidence of benefit for improving QOL for cancer patients, fibromyalgia, hypertension, and osteoporosis (Huston & McFarlane, 2016).

Significant improvements in functional capacity, aerobic capacity, muscular strength and flexibility, self esteem, bone health, immune function and QOL in breast cancer survivors were reported after Tai Chi intervention in a RCT conducted by Mustian et al. Other improvement in cancer related symptoms such as fatigue, sleep, QOL were also reported (Byeongsang et al., 2013; Campo et al., 2014; Oh, Butow, Mullan, Clarke, et al., 2012).

Nevertheless, Qigong as a mind-body practice combines features of meditation and physical exercise, presents a scientific challenge to understand its health benefits that may arise from each of these 2 features and their combined effect.

### **2.4.1 Research of Qigong on cancer related symptoms or side effects**

Due to the prevalence of cancer and treatment related symptoms and the increase demand for a more holistic and comprehensive cancer care, there has been an increased interest in the study of mind body practice such as Qigong to explore its use for symptom management. The majority of the Qigong studies conducted so far have evaluated the efficacy of Qigong in managing the most common clinical and key concerns of fatigue, sleep difficulty, mood, pain and QOL (Klein et al., 2016; Van Vu et al., 2017; P. Wayne et al., 2018).

Most of the systematic reviews of Qigong for symptoms management in cancer care reported paucity of quality in methodological design, risk of bias, small sample sizes, heterogeneity in subjects such as type of cancer, stage of cancer, type of cancer treatment, intensity and types of Qigong as well as lack of consistent choice in outcome measures studied. However, research in this area is evolving and these limitations such as risk of bias are slowly being overcome with improved rigor of design in later studies (Klein et al., 2016; P. Wayne et al., 2018). There is growing evidence that cancer survivors are able to participate and benefit from Qigong practice. A recent review reported that Tai Chi is not likely to result in serious adverse events and a few studies of Qigong intervention for cancer care concluded that it is safe and feasible without any adverse events (Butow P, 2014; Campo et al., 2014; Galantino, Callens, Cardena, Piela, & Mao, 2013; W. Liu et al., 2015; Oh et al., 2010) .

A meta-analysis of 7 studies including 6 RCTs found that Qigong was associated with significant improvement in fatigue in cancer survivors and this effect was the same on 3 RCTs restricted to active control (P. Wayne et al., 2018). Pooled effects of fatigue score reduced more in the Tai Chi group compared to control in another meta-analysis of ten studies on fatigue with Tai Chi while cancer related fatigue also showed significant improvement in 3 studies (Xiang et al., 2017).

Another systematic review of Qigong for symptom management in cancer survivors indicated significant improvement at post-intervention compared to control or there was

observed positive trend from pre to post intervention results in fatigue, pain, depression, anxiety, mood disturbance and QOL (Van Vu et al., 2017).

In addition, results of a recent systematic review and meta-analysis of 22 studies with 1283 subjects on Qigong for cancer related symptoms found that Qigong was associated with significant improvement in fatigue, sleep difficulty, depression and overall QOL while a non-statistical improvement was noted for pain (P. Wayne et al., 2018). Qigong was also reported to generate statistically significant improvement in QOL, depression, anxiety, body mass index, body composition and cortisol level in another review and meta-analysis of 13 RCTs with 592 subjects (Zeng et al., 2014).

Overall trend of the systematic reviews indicated that Qigong has a positive effects on cancer related QOL and fatigue (Klein et al., 2016; Van Vu et al., 2017; P. Wayne et al., 2018; Zeng et al., 2014). QOL or even more specific and appropriate health-related quality of life (HRQoL) is a multi-dimensional concept which usually involves physical, emotional, and social functioning.

However the systematic reviews of Tai Chi or Qigong for cancer care in breast cancer survivors have not found any evidence of significant effect on cancer related symptoms management (M. S. Lee, Choi, & Ernst, 2010; Pan et al., 2015; Yan, Pan, Zhang, Sun, & Cui, 2014). This may be due to limited number and small sample sizes of studies and heterogeneity of Qigong styles and intensities. The summary of systematic reviews is summarized in **Table 2**.

Our literature review identified 30 studies of Qigong for management of cancer related symptoms that includes 22 RCTs (**Table 3**) and 8 non-randomized or no control studies (**Table 4**). Key features of these studies include number of participants, age, cancer type, study interventions and outcomes.

**Table 2 Summary of systematic reviews of Qigong for symptoms management in cancer survivors**

Study	No. of studies	No. of subjects	Conclusion	Limitation/ Recommendation
((M. S. Lee, Chen, Sancier, & Ernst, 2007)	9	871	No evidence from rigorous clinical trials to support effectiveness of Qigong	Poor quality of existing studies
(Chan et al., 2012)	13	937	Difficulty to draw conclusion for physical and psychosocial outcomes due to heterogeneity of outcome measures and variability of the results of included studies	High risk of bias and methodological problems
(Oh, Butow, Mullan, Hale, et al., 2012)	10	930	Larger RCTs found more robust evidence of improving QOL and fatigue as well as reducing inflammation	Small sample sizes Methodological limitations
(Zeng et al., 2014)	13	592	Qigong had positive effects on cancer-specific QOL, fatigue, immune function and cortisol level of cancer survivors	Limited number of studies High risk of bias High heterogeneity in pooled groups
(Klein et al., 2016)	11	831	Qigong reduced or have positive effects on cancer specific QOL, fatigue	Publishing bias Heterogeneity of subjects eg type and stage of cancer, type of treatment and length of study Limitation in study size and methodological rigor
(Van Vu et al., 2017)	22	1751	Effectiveness not proven but there are promising results	Limited number of trials and small sample sizes, selective outcome reporting, incomplete follow-up data, methodological problems, high risk of bias
(P. Wayne et al., 2018)	22	1283	Tai chi and Qigong has promising potential in addressing cancer related symptoms in cancer survivors	Larger and methodological sound studies with longer follow-up periods and appropriate comparison groups needed for definitive conclusion to be drawn and cancer – symptom specific recommendation can be made.
(M. S. Lee et al., 2010)	7	313	No significant differences between Tai chi and controls in RCTs All CCTs reported favourable effects	CCTs has high risk of bias No large RCTs Quality of data and reporting of results were poor High heterogeneity
(Yan et al., 2014)	5	407	Lack of evidence of effect of Tai Chi on QOL	Small sample size and number of studies Heterogeneity of intervention High risk of bias

(Pan et al., 2015)	9	322	No evidence of significant effect of Tai Chi on physical and psychosocial function	Small sample size and number of studies Heterogeneity of intervention High risk of bias
(Cy Leung, Py Liu, & Sm Fong, 2017)	8	498	Too early to conclude on efficacy of qigong in improving health outcome of breast cancer survivors	Heterogeneity of Qigong styles and intensity Limited RCTs and methodological weakness

**Table 3 Summary of Qigong studies for symptoms management in cancer survivors- RCTs**

Study	Type Cancer	Design	Sample size (Pre/Post)	Intervention	Timing of intervention	Duration (weeks)	Length, frequency (session per week)	Control condition	Outcome measures	Results P<0.05 means significant change
Vanderbyl et al., 2017 Canada	Lung/ gastrointestinal	RCT	19	Qigong	During chemo	3	1h,2x	SE	FACT-G HADS, pain	No significant difference
Chuang et al, 2017 Taiwan	Non-Hodgkin Lymphoma	RCT	100 /96 QG: 50/48 CG: 50/48	Qigong: Chan chuang	During chemo	3	1h, 3x	UC	1.EORT-QLQ 2. BFI 3. VSHSS (Sleep)	1. p<0.05 pre and post 2. p<0.001 3. p<0.001
Huang et al., 2016 Taiwan	Breast	non RCT. Quasi CCT	95 SQ 31 Non sport Q:33 Control:31	Qigong	During chemo	12	1/2 h, 3x	UC/non sporting Qigong	1.QOL (SF36-T)	1. p < 0.01
Zhang, Wang, Chen, & Yuan, 2016 China	Lung	RCT	96	Tai Chi	During chemo	12	1h, 3x	Ex	1. MFSI-SF	1. p<0.05
Mc Quade et al, 2016 USA	Prostate	RCT	76/50 QG: 26/16 CG(LE): 26/14 CG(WL):24/20	Qigong	During RT	6 to 8	1h, 3x	LE/WL	1.EPIC 2. BFI 3.PSQI	1 and 2. No significant improvement 3. p<0.05 mid-way

Yeh and Chung, 2016 Taiwan	Lymphoma	RCT	108/102. QG: 54/51 CG: 54/51	Chan chuang Qigong	During chemotherapy	3	1h,7x	UC	1. Fatigue 2. Sleep quality (VSHSS)	1.p < 0.001 2. p < 0.001 3. P<0.01
Thongteratham 2015 Thailand	Breast	RCT	30	Tai Chi	tx completed	12	1h,4x	UC	1.FACT-B. 2.FSI	1. p<0.05 2. p<0.05
Campo et al., 2013 USA	Breast cancer	RCT	87	Tai Chi		12	1h, 3x	HE	1.SF36	1. p=0.01 pre vs post in mental component
Campo et al., 2014 USA	Prostate	RCT	40/29 QG: 20/16 CG: 20/13	Qigong	Outpatient	12	1H,2X	SE	1.FACIT-F 2. BSI-Distress	1.p =0.02 2.p < 0.05
Chen at al. 2013 China	Breast	RCT	96/96 QG: 49/49 CG: 47/47	Guolin Qigong	During radiotherapy	5 to 6	1h,5x	NT	1. CES-D 2. BFI 3. QOL (FACT-G) 4. Sleep disturbances (PSQI)	1. p =0.04 2. p < 0.01 3. p < 0.05 4. No significant changes
Larkey, 2015 USA	Breast	RCT	101/97 QC/TCE: 49/42 SQG: 52/ 45	tai Chi	Outpatient. Completed primary treatment	12	1h,2x Meeting first two weeks Practice 1/2h,5x	SQ	1. FSI 2. BDI* 3. Sleep disruption (PSQI)	1.12 weeks (p =0.005) 3months (p =0.024) 2.12 weeks (p =0.725) 3 months (p =0.902) 3.12 weeks (p =0.136) 3 months (p



										=0.239)
Loh et al. 2014 Malaysia	Breast	RCT	197 Qigong: 66 Placebo: 65 CG: 66	Zhineng Qigong	Tx completed	8	1.5h,1x	Ex/UC	1) QOL (FACT-B) 2) Distress (DASS) 3) Fatigue (FACIT-F)	1. QOL Qigong/Placebo p =0.036 Qigong/Control p =0.048 2. p > 0.05 3. p > 0.05
Robins,2013 USA	Breast	RCT	145/109	Tai Chi	During chemo	10	1.5h,1x	SG/NT	1. FACT-B. 2.CES-D	No significant change
Butow P, 2014 Australia	Breast	RCT	27 MQ: 14 MC: 13 Followup < 80%	Medical Qigong	Unclear about time of intervention	10weeks	1h,2x	SG	1. QOL (FACT-B) 2. Fatigue (FACT-F) 3. Stress (PSS)	1. p=0.084 2. p =0.71 3. p =0.52
Oh et al. 2012 Australia	Heterogenous	RCT	81/54 QG: 37/23 CG: 44/31`	Medical Qigong	Unclear about time of intervention	10	1 1/2h,	UC	1. Cognitive function (FACT-Cog) 2. QOL (FACT-G)	1. p= 0.014 2. p< 0.001

Oh et al, 2010 Australia	Breast,Lung, prostate	RCT	QG: 79/54 CG: 83/54	Medical Qigong	Outpatient	10	1 1/2 h,2x,	UC	1.Overall QOL (FACT-G) 2. Fatigue (FACT-F) 3. Mood disturbance (PMS)	1. Overall QOL improved (p < 0.001) 2. Fatigue improved (p < 0.001) 3. Mood disturbance improved (p =0.021)
Oh et al, 2008 Australia	Breast, ovary, lung	RCT	QG:15/8 CG:15/10	Qigong plus usual medical care	Outpatient	8	1h,2-3x	UC	1) QOL (EORTC QLQ-C30),	No significant difference between the two groups
Mustian, Palesh, & Flecksteiner, 2008	Breast	RCT	31	Tai Chi	Tx completed	12	1h,3x	Psychosoc ial support	1. FACIT-F (QOL)	significant improvement
Wang, 2009	Effects Of Long-term Guo Lin Qi-gong Practice On Cancer survivors' Quality Of Life And Aerobic Capacity		80 QG: 40 CG: 40	Gualin Qigong		2.5-3.5 months		UC	1) QOL 2) Depression 3) Health fitness status	1. p < 0.05 2. p > 0.05 3.p < 0.05
Lee et al, 2006 Taiwan	Breast cancer	non RCT	67 QG:32 CG: 35	Chan-Ch uang Qigong	During chemo	3	15-60 minutes,7x	Chemothe rapy(UC)	1) Symptom distress (Pain, numbness, heartburn	1. p < 0.05 2) Overall severity of psychological distress not

									and dizziness) 2) Psychological distress	improved (p > 0.05).
Lam 2004 Hong Kong	Heterogenous	RCT	57	Guolin Qigong				UC	1. FACT-G (QOL)	1. p=0.022
Lam, 2004 China	Hepatocellular carcinoma	RCT	QG:29/13 CG: 29/14	Guolin Qigong	Unclear about time of intervention			TACE only	1. Quality of life (SF-36)	1. No significant changes

RCT randomized controlled trial, NC no control group, NH lymphoma non-Hodgkin lymphoma, NR not reported, TCQ Tai Chi plus Qigong, Tx treatment, RT radiotherapy, PST psychosocial support, UC usual care, HE health education, NT no treatment, SG spiritual growth, SE stretching exercise, Ex exercise, LE light exercise, WC waiting control, SQ sham Qigong, FACIT-F Functional Assessment for Chronic Illness Therapy, EORTC-QLQ European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire, FACT-G Functional Assessment for Cancer Therapy-General, POMS Profile of Mood State, FACT-F Functional Assessment for Cancer Therapy-Fatigue, SF-36 Short Form 36, CES-D Center for Epidemiologic Studies Depression Scale, BFI Brief Fatigue Inventory, PSQI Pittsburgh Sleep Quality Index, BSI Brief Symptom Inventory, FACT-B Functional Assessment for Cancer Therapy-Breast, FSI Fatigue Symptom Inventory, EPIC Expanded Prostate Cancer Index Composite, DASS Depression and Anxiety Stress Scale, MFSI-SF Multidimensional Fatigue Symptom Inventory-Short Form, VSHSS Verran and Snyder-Halpern Sleep Scale, HADS Hospital Anxiety and Depression Scale, SDS Symptom Distress Scale, BPI Brief Pain Inventory, MOS-sleep Medical Outcome Study Sleep Scale, MFI-Multidimensional Fatigue Inventory

**Table 4 Summary of Qigong studies for symptoms management in cancer survivors-Non RCTs**

Study	Type Cancer	Design	Sample size	Intervention	Timing of intervention	Duration (weeks)	Length, frequency (session per week)	Control condition	Outcome measures	Results P<0.05 means Significant change
Liu et al, 2015  USA	Breast	NC Pilot study	8	Six Healing Sound Qigong	tx completed	6	2x/day, 7x	NA	1.Sleep Quality 2.ISI 3. MFI-20 4.SF-36 (QOL)	1. p<0.01 2. p<0.01 3.p<0.01 4. p<0.01
Galantino, Callens, Cardena, Piela, & Mao, 2013  USA	Breast	Pilot Feasibility	12	Tai Chi	tx completed	8	1h,2x	NA	1.FACT-B 2.FACT-F 3.HADS (Anxiety) 4. BPI Depression	1.p=0.027. 2.p=0.030 3.p=0.030 4. P=0.020
Fong et al 2013	Breast	CCT	23	Tai Chi Qigong		24	1.5h,1x	NA	1.QOL (FACT-B)	1.No significant changes
Fong et al, 2015  Hong Kong	Nasopharynx	Non RCT	52	Tai Chi	tx completed	24	1.5h,1x	UC	1.Sleep disturbance	1. p = 0.037

Reid-Arndt, 2012 USA	Breast/gynaecological	Pilot study-No control	29	Tai Chi	tx completed	10	1H,2X	NA	1.POMS	No difference
Lee et al., 2010 Korea	Gastric cancer	NC	33	Tai Chi	Outpatient	24	1h,1x	NC	1.Depression 2. QOL	1 and 2 No significant difference
(T. I. Lee, Chen, & Yeh, 2006) Taiwan	Breast cancer treated with chemotherapy	non RCT	67 QG:32 CG: 35	Chan-Chuang Qigong	During chemo	3	15-60 minutes,7x	chemo(UC)	1) Symptom distress (Pain, numbness, heartburn and dizziness) 2) Psychological distress	1. p < 0.05 2. p > 0.05
(Hong, 2003) Korea	Advanced gastric cancer	CCT	QG:12 CG:12	YudongKong plus chemotherapy	20 minutes 2x/day 7day /week	8weeks	15-20 minutes 2x/day 7day /week	chemo	1.Fatigue 2.Physical functioning (SF-36)	1. p < 0.05 after 4 weeks, p < 0.01 after 8 weeks 2. p < 0.01 after 4 weeks, p < 0.001

#### 2.4.1.1 Effect of Qigong on Quality of Life (QOL)

The most common cancer-related symptoms such as fatigue, depression, sleep disorders, and pain have a major impact on overall QOL of cancer survivors (Arndt et al., 2017). WHO defines QOL as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment.”

As mentioned above, the majority of RCTs i.e., 11 out of 16 RCTs that have evaluated the effect of Qigong on QOL of cancer survivors since year 2000 onwards have found that it is effective in improving QOL compared to control (Campo et al., 2014; Z. Chen et al., 2013; Chuang et al., 2017; S.-M. Huang et al., 2016; S. M. Huang et al., 2016; Loh et al., 2014; Mustian, Palesh, & Flecksteiner, 2008; Oh et al., 2010; Oh, Butow, Mullan, Clarke, et al., 2012; Renwei Wang et al., 2009; M. L. Yeh & Chung, 2016). These studies involved various types of cancer survivors with study duration ranging from 3 weeks to 16 weeks (**Table 2**). This is also supported by 4 out of 6 single group studies (**Table 3**) which reported significant improvement in QOL of cancer survivors pre and post-intervention (Galantino et al., 2013; Hong, 2003; T. I. Lee et al., 2006; W. Liu et al., 2015).

However, there are a few single group studies which did not report any significant improvement in QOL (**Table 3**). This may be due to the low frequency of practice of once a week which does not produce adequate dose-response effect to induce adequate changes in QOL outcome in the single group studies. As for the RCTs that did not record significant improvement in QOL (**Table 2**), the timing of Qigong intervention scheduled during chemotherapy or radiotherapy may be directly and negatively related with poor QOL outcome (Oerlemans et al., 2011) of the studies. The cancer treatment period is the most stressful period for cancer survivors as they try to cope with worry about the disease, traveling and administration arrangements on top of cancer treatment effects such as worsened urinary function, bowel function, and prostate symptom score (American

Urological Association [AUA] symptom score) in prostate cancer survivors during radiotherapy (McQuade et al., 2017). This sudden increase level of stress may have a negative effect on the clinical outcomes of Qigong intervention.

In one study of prostate cancers, though there was no significant improvement in QOL in active Qigong group compared to control, the analysis of the three study outcomes demonstrated that both sleep and fatigue were highly correlated with prostate cancer-related physical symptoms on QOL (McQuade et al., 2017), indicating the co-relationship between sleep and fatigue as part of the common co-occurring cancer-related symptom clusters of fatigue, sleep and depression (Balachandran et al., 2013; J. E. Bower et al., 2011; Larkey et al., 2015).

One interesting finding was of a significant improvement in QOL after an eight-week Qigong intervention in the Qigong group but not in the exercise-control group (Loh et al., 2014). The exercise control group in this study was a line-dancing group for control of group social effect which did not result in significant improvement in QOL despite the anecdotal evidence and observations of fun and laughter in the group. This finding suggested that social effect alone does not lead to better QOL compared to Qigong as supported by two other studies whereby participants' QOL in Qigong group improved significantly compared to active exercise-control group (Campo et al., 2014; S. M. Huang et al., 2016).

#### 2.4.1.2 Effect of Qigong on fatigue

It is believed that the underlying cause of fatigue in cancer survivors is the alteration of their biological systems from cancer and cancer treatments although the mechanisms for cancer-related fatigue have not been fully understood. (Berger et al., 2015). The National Comprehensive Cancer Network (NCCN) defined cancer-related fatigue as a persistent, unusual, subjective feeling of tiredness correlated with cancer or cancer treatment that obstruct normal functioning (Xiang et al., 2017). Fatigue can affect the psychological state of cancer survivors and limit their daily activities, which in turn could have an adverse impact on the QOL of cancer survivors (Siefert, 2010).

Of the 12 RCTs that evaluated Qigong effect on fatigue for cancer survivors, 11 RCTs reported significant improvement compared to control (**Table 3**). Only one RCTs on prostate cancer survivors did not find any significant improvement due to the weakness in the design of the Qigong intervention in the study which did not consider the common hot flashes and urinary symptoms of prostate cancer survivors undergoing radiotherapy (McQuade et al., 2017). All the 3 single group studies of Qigong on fatigue in cancer survivors found that it significantly improved fatigue post-intervention (**Table 4**).

Based on the findings from studies to date, there is consistent evidence that Qigong can improve fatigue in cancer survivors despite the limitations in some of the study design and methodology.



## **CHAPTER 3: METHODS**

### **3.1 Study Design**

This pilot study used a single treatment group, repeated measure design that included

- i) a 3-week Qigong intervention with 1-week follow up to evaluate feasibility (primary outcome) of Qigong intervention for insomnia in cancer survivors.
- ii) evaluation of the outcome of Qigong intervention on insomnia severity and sleep quality (secondary outcome) over the 4-week study period. All outcomes were measured at Week 0 (baseline), Week 2 (mid-intervention), Week 3 (post intervention), and Week 4 (one-week post-intervention).

The Western Sydney University Human Research Ethics Committees approved all the procedures and informed written consent was obtained from all participants prior to baseline assessment (Approval number: H12870). Remote access approval was also obtained for Liverpool Hospital from the Research and Ethics Office of South Western Sydney Local Health District (Approval number: HE18/326). This trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN1261800167026).

### **3.2 Participants and recruitment**

#### **3.2.1 Sample size**

As this was a pilot study, a prospective sample size calculation was not performed. Findings from this study will serve as the basis for sample size calculation of full-scale trial in the future. The sample size of 12 per group is recommended for a pilot study (Julious, 2005). Assuming a drop out rate of 20%, we planned to recruit 15 participants for this study.

However, we were uncertain about the level of interest that would be shown amongst potential participants, and recruitment was also affected by a limited recruitment period and personnel restrictions ( i.e.due to restricted funding).

### 3.2.2 Recruitment

Participants were recruited through various modes from 5 September 2018 to 9 April 2019. Recruitment flyers (**Appendix 1**) were posted on notice boards in several locations: i.e. Western Sydney University campus and local hospitals and medical clinic for cancer survivors. In addition, recruitment flyers were posted via online platforms, including Western Sydney University electronic newsletter, local community notice board Facebook pages and cancer support groups Facebook pages. As an additional method to foster recruitment, the principal investigator also gave presentations about Qigong and study participation at Pembroke Lodge Nursing Home, Multi-Disciplinary Team Meeting at Liverpool Hospital and sharing session to Mandarin speaking cancer survivors at Can Revive cancer support group. All potential participants were pre-screened, via telephone or in-person by the principal investigator and a GP or oncologist for medical and study eligibility using a standardized Screening Checklist (**Appendix 2**) and ISI (**Appendix 3**).

Participant inclusion criteria:

- a. Age  $\geq$  18 years old;
- b. Diagnosed with cancer or completed primary cancer treatment (chemotherapy and/or radiotherapy) and/or at least 8 weeks post-surgery ; \*
- c. Meet the criteria for insomnia as indicated by the score of Insomnia Severity Index (ISI)  $\geq$  11;
- d. Not involved in any MBT during the study period;
- e. Patients who use stimulant medications, or other anxiolytic/sedative/hypnotic drugs may be included to evaluate if there will be any change in the quantity of medication pre and post intervention;

- f. English language sufficient to understand study procedures and provide informed consent

\*The inclusion of at least 8 weeks post-surgery is considered adequate healing after surgery and it was deemed maximum time for surgical recovery (BreastCancer.org; Schmitz et al., 2010). It may also be inferred that a duration of 8 weeks is considered adequate healing time for the initiation of mild to moderate exercise training. Moreover, it should be noted that Qigong training is much less vigorous than conventional exercise and there is no evidence to suggest that Qigong is dangerous for cancer survivors at any timepoint along the cancer treatment and survivorship continuum.

Exclusion criteria:

- a. No prior cancer diagnosis;
- b. No prior experience with Qigong, Yoga, Tai Chi or meditation within the past 3 months;
- c. Body mass index > 35kg/m<sup>2</sup>;
- d. Diagnosis of major depression and/or clinically significant depressive or anxiety symptoms;
- e. Sleep disturbance due to a clear physical cause, e.g., benign prostatic hyperplasia, frequent night-time urination, pain;
- f. Neurological degenerative disease (e.g. dementia) and/or reduced cognitive capacity in any way that would affect ability to understand trial procedures and give informed consent;
- g. Any medical conditions which would preclude study intervention or make study participation unsafe such as severe chronic heart failure or stroke sequelae.

### **3.3 Qigong intervention**

During the first contact of inquiry, the principal investigator explained about the research and the main inclusion and exclusion criteria to the potential participant. Participant

Information Sheet (**Appendix 4**) detailing the potential benefits and risks of participating in this study and the time and scheduling requirement was given and explained. Participants were also informed that they would be reimbursed \$50 each for any GP fee incurred. If the potential participant indicated any interest in taking part, the Participant Information Sheet (**Appendix 4**), Screening Checklist, ISI and Participant Consent Form (**Appendix 5**) were provided. They were instructed to go to their GP or visit our appointed GP to complete the Screening Checklist and ISI should they decided to participate. After visiting the GP and if they were eligible, they were asked to sign the Participant Consent Form and return them back with the Screening Checklist and ISI completed by GP to the principal investigator. Screening by a GP will take place before consent. The GP was responsible for the screening process only and they were not the referring GP. As such potential participants were not under any undue influence to participate in the trial. Please refer to **Figure 3 below** for flow of events.

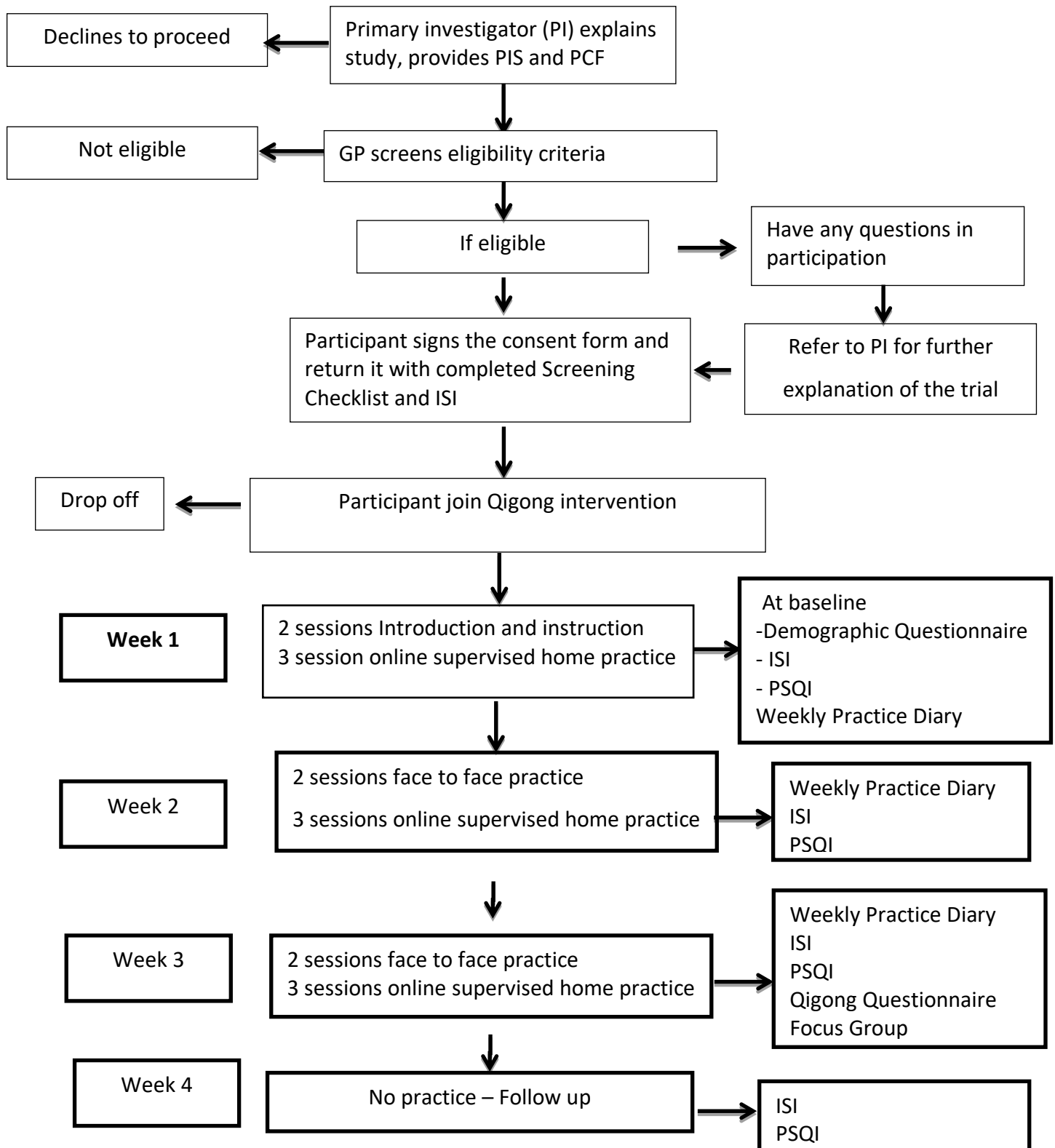


Figure 3 Flow chart of study

**Table 5 Schedule of enrolment, intervention and data collection**

	Screening	Baseline	Intervention			Follow up
Time point	Wk -2 to Wk 0	Wk 0	Wk 1	Wk 2	Wk 3	Wk 4
Demographic and cancer history questionnaire		x				
Introduction class			x			
Qigong intervention			x	x	x	
Weekly Practice Status Check			x	x	x	
Qualitative Questionnaire and focus group/individual interview					x	
ISI	x	x		x	x	x
PSQI		x		x	x	x

After full consent and completion of eligibility check, participants were assigned to a class schedule. At Week-0 (baseline) each participant was asked to complete the Demographic and Cancer History Questionnaire (**Appendix 6**), ISI and PSQI (**Appendix 7**). At the beginning of Week-1, all participants were given Weekly Practice Status Check diary (**Appendix 8**) to record details of attendance/Qigong practice and any adverse effect. Participants were prescribed

five sessions of Qigong practice per week. Two of these sessions were delivered face-to-face at a Western Sydney University Liverpool campus individually or in a small group, while three sessions were delivered from home using the web-based video conferencing application, Zoom (Zoom Video Communications Inc., 2012-2019, Version: 4.3.2). All sessions were led by the principal investigator who has more than 10 years of experience in teaching Qigong. All sessions except the first two introductory sessions lasted for about 60 minutes. For the detailed breakdown of the Qigong class program, please refer **Appendix 9**. Participants also completed ISI and PSQI at week-2-4.

During the first introduction and instruction session on Week 1, participants were briefed on the overall program details, logistics and administration information. They were given a copy of a simplified Qigong instruction for the three Qigong methods i.e., La Qi, LQPQ and Rou Fu with diagrams. Two *YouTube* video links (Claridge, 2016, April 10; Mace, 2011, March 17) of LQPQ demonstration in English was also given. The principal investigator also assisted them to download the Zoom online video conferencing application on their mobile devices and tried out online video conferencing to ensure that it worked before the actual implementation from home.

The intervention period of 3 weeks and 5 days per week is set as acceptable length of time commitment based on other studies that found improvement from Qigong intervention for sleep in cancer survivors (Chuang et al., 2017; Larkey et al., 2016; W. Liu et al., 2015).

Initiating and sustaining physical activities is difficult for most people and even more so for cancer survivors. One of the problems faced in previous studies of Qigong intervention was high attrition and non-adherence to program schedule and many cancer survivors reported that independent home practice of MBT such as yoga is too challenging (Slocum-Gori et al., 2013). Use of online web-based video conference practice in the study is a novel idea not only for its convenience but its social support element and may boost participants' confidence due to instructor's presence to promote adherence to practice.

In view of the physical and psychological state of cancer survivors, the Qigong protocol selected for this study focussed on health and is modifiable according to individual

limitations without much impact on the effect. It is important to note that the use of standardized Qigong protocols is important for any Qigong study. The long history and evolution of Qigong have given birth to many different schools and forms of Qigong and this plurality of styles may complicate the research process and clinical application. The Qigong protocol used for this study was selected to bring participants into a calm and relax mental state (Qigong state) through gentle, integrated, repetitious, flowing weight-bearing movements/postures with mindfulness meditation to regulate Qi and these features meet the definition of a common content construct of Qigong therapy protocols (Klein et al., 2016).

This current Qigong protocol consisted of mild level mind-body exercise that included three of the many methods of ZQ namely, Peng Qi Quan Ding Fa or Lift Qi Pour Qi (PQGDF or LQPQ) and two sitting, simple, repetitive non-strenuous movements i.e. Kai He La Qi (lateral movement of arms in synchrony with mind intent) and Rou Fu (massaging stomach). Kai He La Qi and Rou Fu (**Figure 4**) can also be performed while lying down. ZQ is one type of Medical Qigong that emphasizes on the integration and exchange of nature`s Qi and Qi of human to regulate the body and mind (Overcash et al., 2013). LQPQ is a simple system made up of 5 distinct sequences. It involves slow, gentle and coordinated exercise movement along with visualization to tap external Qi to promote the smooth and clear circulation of Qi throughout the body, contributing to physical and psychological wellbeing. A natural rhythmic breathing and relaxed state of mind are induced throughout the practice of the three methods. It should be noted that the intervention program was designed for cancer survivors on the basis of their health status (Schmitz et al., 2010). For details of the three Qigong methods, please refer to **Appendix 10**.





**Figure 4: Rou Fu method in lying down position**

Participants were advised to stop or take a rest from practice whenever they feel tired or discomfort. They were also asked to report any adverse event as soon as possible to the principal investigator who would record it in the participant information file.

As there is no foreseeable adverse or negative effects for not continuing to practice Qigong after the intervention period, participants can decide on whether to continue or stop the Qigong practice. They were given a copy of the audio instruction at Week 4 and can continue to practice should they wish on their own at their convenience as a form of health maintenance mind-body exercise.

### **3.4 Outcome instruments**

Feasibility outcomes were measured using Weekly Practice Status Check diary, Demographic and Cancer History Questionnaire, Qigong Questionnaire (**Appendix 11**) and open Focus Group Questions (**Appendix 12**) which provided data on compliance to data collection, adherence, retention and adverse events and experience of study. Recruitment outcome was recorded

throughout the recruitment period by the principal investigator. Clinical intervention outcome on sleep severity and quality were measured using ISI and PSQI.

### **3.4.1 Feasibility outcome**

#### **3.4.1.1 Recruitment**

Participants were recruited via the abovementioned sources from 5 September 2018 to 9 April 2019. We identified source of recruitment by asking each potential participant at initial contact how they became aware of the study. From these data, recruitment source were ranked from most effective to least effective based on the number of successful recruitment.

A questionnaire on demographic information such as age, gender, marital status and self-reported cancer-specific characteristics that included cancer type, cancer treatment received, medication and major cancer-related side effects were completed by the participants at baseline.

#### **3.4.1.2 Compliance to the data collection method**

The number of participants who completed the data collection procedures which include the demographic and cancer history questionnaire, sleep clinical outcome assessments, Weekly Practice Status Check diary and experience of trial questionnaire and discussion were evaluated to determine compliance to data collection methods.

#### **3.4.1.3 Adherence to Qigong intervention**

Adherence was measured by retention rate and attendance rate. The retention rate was calculated as the number of participants who completed the Qigong intervention over the number recruited. Attendance rates for both the face to face sessions and online home practice sessions as well as overall attendance rate (face to face plus online) were computed as the number of sessions attended divided by the number of sessions offered multiplied by

100%. Participants were instructed to record attendance using the Weekly Practice Status Check diary. A retention rate of more than 70% and attendance rates of more than 80% indicate that the study is feasible (Campo et al., 2013). This was chosen as previous studies have documented improvements in physiological and psychological outcomes after Qigong with this level of adherence (S. S. Fong et al., 2015; Irwin et al., 2017; W. Liu et al., 2015; M. L. Yeh & Chung, 2016).

Delivery of home practice using web-based video conference Zoom, led by the principal investigator is a novel idea to boost attendance and adherence. Its feasibility of implementation was assessed based on participants feedback and attendance/adherence.

#### 3.4.1.4 Adverse events

An adverse event is generally defined as any unfavorable or unintended event that occurs during the course of the study that may not necessarily have a causal relationship with the intervention (International Conference on Harmonisation, 2016). A worsening in concomitant illness must also be recorded as adverse events. Reporting adverse events within clinical studies is an important way to evaluate the safety of a study (P. M. Wayne, Berkowitz, Litrownik, Buring, & Yeh, 2014) and was recommended by the Consolidated Standards of Reporting Trials (CONSORT) to be defined in the Methods section of the study (Ioannidis et al., 2004).

A serious adverse event is any adverse event that results in death, is life-threatening, requires hospitalization, results in persistent or significant disability or incapacity or consists of a congenital abnormality or birth defect (International Conference on Harmonisation, 2016).

The principal investigator kept regular contact with the participants over the 3-week intervention period and one week follow-up period to monitor their progress and check for any potential adverse event. Participants were encouraged to call the principal investigator to report any medically relevant event such as worsening of symptom or any new medical condition and were provided a 24-hour contact number so that they can reach the contact at any time. If any untoward incident occurs, standard emergency procedures were applied

in emergency situations, or the patient would be referred to the appropriate clinician/healthcare professional in non-emergency situations.

Any adverse events, serious adverse events or changes in health status were recorded by the participants in the Weekly Practice Status Check or by the principal investigator if communicated verbally, by telephone or text messages by participants.

The Weekly Practice Status Check diary contained open-ended questions on adverse events such as an acute illness, changes in medications and changes to physical, mental or emotional symptoms. The principal investigator checked the Weekly Practice Status Check diary after completion by the participant. In case of a serious adverse event, the trial will be considered not feasible.

No serious adverse events were expected based the same types of studies conducted to date (P. Wayne et al., 2018) and the risk of injury was considered minimal as all participants were pre-screened by a GP and the Qigong intervention involved only slow, gentle movements.

#### 3.4.1.5 Experience of trial

Qualitative information about the Qigong study to obtain additional information about cancer survivors preferences, experience and hindrances about the study, including the intervention was obtained through completion of the Qigong Questionnaire (**Appendix 11** ) followed by a focus group/individual interview with Focus Group Questions (**Appendix 12** ) at the trial site on the last day of Qigong intervention (Week 3).

The Qigong Questionnaire and Focus Group Questions covered key concepts identified through prior literature review and focused on understanding participants' beliefs, preferences, experience and barriers to Qigong intervention to assess feasibility of the study and provide recommendations and insight on how to design and execute future study. These questions are a guide only and evolved throughout the interview. Participants were encouraged to provide open feedback verbally or in writing. Where it was given verbally, it was recorded by the principal investigator. The study is considered feasible if all participants

reported that they benefitted from the participation and would recommend it to other cancer survivors.

### **3.4.2 Clinical intervention outcomes**

The clinical outcomes assessed were sleep severity measured with the ISI and sleep quality measured with the PSQI. Both the ISI and PSQI indexes had been used in similar studies (S. S. Fong et al., 2015; Irwin et al., 2017; W. Liu et al., 2015) and would be completed by participants at Week 0, Week 2, Week 3 and one week follow up at Week 4.

#### **3.4.2.1 Insomnia Severity Index**

Screening for sleep disturbance used measure sensitive and specific to case identification ISI is the best practice for routine oncology practice (Howell et al., 2014). ISI score of 11 is recommended as the most suitable balance between sensitivity and specificity for detecting insomnia in clinical trials (Morin, Belleville, Bélanger, & Ivers, 2011). ISI is a seven-item questionnaire devised to diagnose and assess the severity of insomnia. All items are rated using a five-point Likert scale ranging from 0 (not at all satisfied) to 4 (very much satisfied). The total score of the ISI ranges from 0 to 28 points, and it can classify insomnia according to scores of 0–7 (no clinically significant insomnia), 8–14 (subthreshold insomnia), 15–21 (clinical insomnia, moderate severity) and 22–28 (clinical insomnia, severe). It is used to evaluate insomnia severity on difficulties of falling asleep, night time awakenings, early morning awakenings, impairment of daytime functioning due to sleep problems, noticeability of impairments, distress or worries caused by sleep difficulties, and dissatisfaction with sleep. The reliability and validity of ISI have been reported (Bastien, 2001; Morin et al., 2011).

#### **3.4.2.2 Pittsburgh Sleep Quality Index**

PSQI, a self-reported survey was used to assess sleep quality. Four-item responses and scores on this measure range from 0–21, with increasing scores indicating worse sleep quality (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). A score of 5 or greater indicates

poor sleep. The instrument is a 19-item scale measuring the quality of sleep, sleep latency, sleep duration, efficiency, disturbances, use of sleep medication, and daytime sleep dysfunction, and has a global PSQI score. The instrument has a sensitivity of 89.6% and a specificity of 86%. It has been proven to be a valuable adjunct to clinical work on insomnia and is a useful first-line, easy-to-handle, and time-efficient questionnaire to evaluate sleep disturbances (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). The PSQI was reported to be a stable measure of sleep quality with high test-retest reliability and construct validity (Backhaus et al., 2002; Gentili, Weiner, Kuchibhatla, & Edinger, 1995).

### **3.5 Data analysis**

Quantitative analyses were performed using SPSS Version 25. Descriptive statistics were conducted to describe and analyze demographic, health, feasibility and clinical data. One way repeated measures analysis (ANOVA) was used to determine whether a significant difference existed in the mean values of ISI and PSQI scores over the 4 data collection points. If there was significance, contrast tests were performed to identify differences between Week 0 (baseline) compared to Week 2 (mid-intervention), Week 3 (post-intervention), and Week 4 (one week follow-up). Due to the very small sample size, we conducted a Monte Carlo simulation method using 10000 replicates.

Intent-to-treat analyses were not used as we did not have post-intervention data on participants who withdrew from study to conduct complete case analyses, and our sample size was too small to conduct multiple imputation techniques.

Qualitative data were collected through Qigong Questionnaire and the Focus Group Questions administered to participants as well as feedback received during the study period. All responses were analyzed for themes and patterns using inductive reasoning approach (Braun & Clarke, 2006) by the principal investigator. The process of thematic analysis involved identifying, analysing and reporting patterns and themes within the data. Direct quotes from data were sorted and grouped under the various themes. Quotations have been chosen to illustrate particular points and are identified in the text by an anonymized code (indicating participant number).

## CHAPTER 4: RESULTS

### 4.1 Feasibility outcomes

#### 4.1.1 Recruitment

We received or contacted a total of 49 potential participants (Figure 5) including 21 from Pembroke Lodge Nursing Home, over a 31-week period between 5 September 2018 to 9 April 2019. The principal investigator communicated verbally or by email the study criteria with all potential participants. Thirty two (n=32) of the participants were ineligible from the initial contact, of which twenty four (n=28) did not meet the study criteria and four (n=4) could not attend as they live out of state. Seventeen (n=17) were deemed eligible but ten (n=10) did not consent to participate. Four (n=4) were not interested, five (n=5) could not commit to study due to schedule conflicts (e.g. full-time work/family commitment, other pre-arrange regular medical follow up/activities) and one was lost to follow up. Seven (n=7) participants took part in the study. The screening and diagnosis of insomnia were confirmed according to ISI score of  $> 11$  by the participant's physician. Of these two (n=2) did not complete the study due to worsened shoulder joint pain (n=1), and one (n=1) was too tired to come for class and need to attend many medical appointments. Five (n=5) completed the study and was included in the analysis.

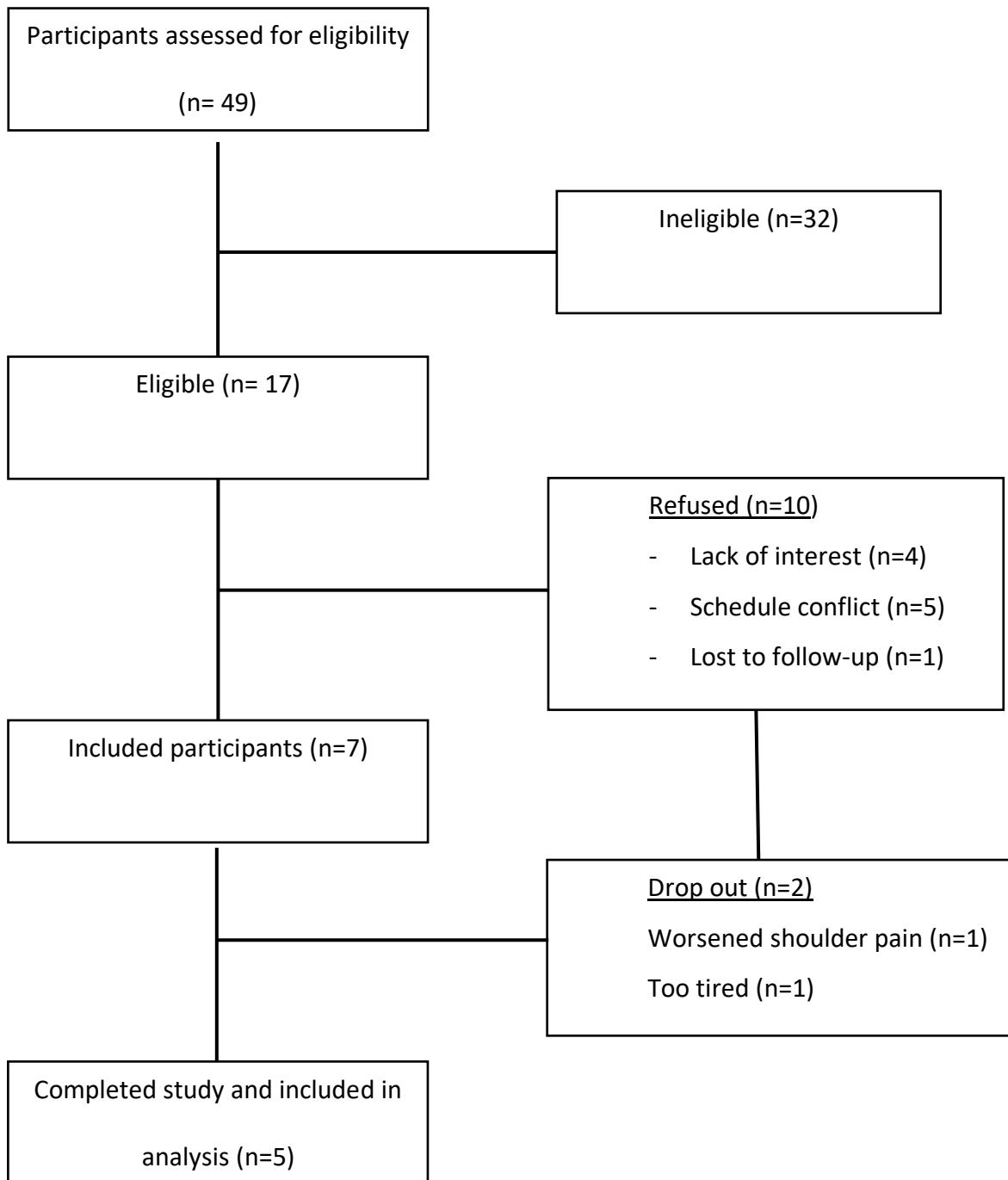


Figure 5 Flow chart of participants recruitment



The sources of recruitment of the 49 people are presented in **Table 6** . The top recruitment sources were from Pembroke Lodge Nursing Home (42.9%) and Old Leumeah Road Medical Centre (18.3%). However, we were only able to recruit one participant from each of these two sources. Strategies which yielded the best recruitment rate was through posting of recruitment flyers in Liverpool Wellness Centre (42.9%) and through cancer support groups (33.3%), where each of these two sources provided three recruited participants out of seven contacts and two recruited participants out of 6 contacts (from email circulation to past participants of ENCORE, a breast cancer support group of YWCA). The study also tried to recruit from the WSU Electronic Internal Update (4.2%) and Facebook (6.2%) but these are less effective. It yielded only one successful recruitment. The overall recruitment rate was 41.1% (7/17 x 100%).

**Table 6: Sources of recruitment at first contact with actual number recruited**

Sources of recruitment	Number at first contact (n)	Percentage of total (%)	Number recruited (n)	Percentage of successful recruitment* (%)
Pembroke Lodge Nursing Home	21	42.9	0	0
Old Leumeah Road Medical Centre	9	18.3	1	11.0
Liverpool Hospital Wellness Centre	7	14.2	3	42.9
Cancer support groups	6	12.2	2	33.3
Facebook	3	6.2	0	0
WSU Electronic Internal Updates	2	4.1	1	50
Not specified	1	2.1	0	0
<b>Total</b>	<b>49</b>	<b>100</b>	<b>7</b>	

\*Percentage of successful recruitment from the first contact.

#### 4.1.2 Baseline characteristics

Baseline characteristic of cancer survivors of the seven female participants included in the study are presented in Table 7. The age of the cohort ranged from 40-65+. Six of the participants were breast cancer survivors of which one had both breast with bone cancer and one was a lung cancer survivor. All the breast cancer survivors had radiotherapy while the lung cancer survivor only had targeted therapy. Among the six breast cancer survivors, four had surgery, three had chemotherapy and three were still on hormone therapy. All the participants (n=7) reported fatigue and insomnia as the main complaint of cancer-related side effects. The mean ISI score at baseline was 21.4 (clinical moderate severity level).

**Table 7: Participants baseline characteristics**

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

*R: Radiotherapy, C: Chemotherapy, S: Surgery, HT: Hormone therapy, TT: Target Therapy, ISI: Insomnia Severity Index Score*

#### 4.1.3 Compliance to the data collection method

All participants complied with baseline testing procedures and completed all the data collection methods and forms.

#### 4.1.4 Adherence to Qigong intervention

The retention rate was 71% based on the number recruited (n=7) and the number of cancer survivors who completed the study (n=5).

Adherence was assessed from Weekly Practice Status Check for both face to face and online home practice sessions. Face to face practice adherence was 90% while online home practice adherence was 80% and the overall adherence rate was 84%. The actual adherence rate was more than 84% as most participants practiced additional sessions individually at home as shown in Table 8.

**Table 8 Additional individual home practice**

Participant	Week 1	Week 2	Week3
1	30 minutes x 1 session	-	30 minutes x 1 session
2	20 minutes x 1 session	30 minutes x 1 session	-
3	30 minutes x 5 sessions	30 minutes x 1 session	30 minutes x 4 session
4	20 minutes x 7 sessions	30 minutes x 3 session	15 minutes x 2 session
5	40 minutes x 2 sessions	30 minutes x 2 session	30 minutes x 2 session

The compliance rate for both the face to face and online supervised home practice was highest for Week 1, followed by Week 2 and lowest in Week 3 (Table 9). The reasons for non-compliance were recorded in the Weekly Practice Status Check due to being sick or pre-arranged family matters and they would normally inform the primary investigator verbally in advance. The cumulative effect of adherence is reflected in the statistically significant improvements in sleep values from baseline to post intervention at Week 3 in ISI ( $21.2 \pm 1.88$  to  $13.4 \pm 2.16$ ,  $p = 0.010$ ) and PSQI ( $14.8 \pm 0.8$  to  $9.4 \pm 1.47$ ,  $p = 0.011$ ).

**Table 9 Descriptive statistics of mean attendance, ISI and PSQI values**

Time Point	Total Att (SE)	F 2 F (SE)	Online (SE)	ISI (SE)	p* value	PSQI (SE)	p* value
Week 1	4.6 (0.24)	2.6 (0.24)	2.0 (0.00)	21.2 (1.88)	NA	14.8 (0.8)	NA
Week 2	4.2 (0.49)	2.4 (0.40)	1.8 (0.20)	15.6 (2.04)	p = 0.040	9.7 (1.56)	p = 0.018
Week 3	3.8 (0.73)	2.2 (0.58)	1.6 (0.24)	13.4 (2.16)	p = 0.010	9.4 (1.47)	P = 0.011
Week 4	NA	NA	NA	15.2 (1.74)	p = 0.036	10.1 (1.31)	P = 0.011
Total attendance	12.6 (1.03)	7.2 (0.73)	5.4 (0.40)				

*\*Denotes significant difference of p values compared to baseline (at beginning of Week 1 before intervention); SE, standard error; F2F, face to face attendance; Online, online attendance*

#### **4.1.5 Adverse events**

Participant 2 reported having flu and sinus in the middle of Week 2 that lasted to Week 3. Participant 3 had gastric upset and diarrhea on the last day of Week 1 which lasted for one and half days. Participant 6 dropped out after the third session on Week 1 as she was too tired to attend practice due to existing illness and had to attend too many other medical appointments.

Participant 7 who has breast and bone cancer reported worsening neck and lower back pain that radiated to her leg after the third Qigong session and dropped out of the study.

#### **4.1.6 Experience of study**

All five participants who completed the study replied to the Qualitative Qigong Questionnaire. Separate focus group interviews were conducted for Participant 1 with 2 and Participant 4 with 5 while individual interview was conducted with Participant 3 due to different timing of Qigong intervention. Not all questions were answered by every participant. Participants' verbal feedback during the entire study period was also recorded.

The qualitative analyses of data collected identified four emerging themes: participant experiences, class preferences, barriers to participation and recommendations for improvement.

#### 4.1.6.1 Participant experiences

Most participants (except a Chinese participant) did not have any prior knowledge of Qigong but associated it with benefits in emotional and physical well being. All participants who completed the study perceived improvement in various aspects of their sleep. Most importantly all reported being emotionally calmer and relaxed with the change started from as early as immediately after the first introduction session. Stress level decreased and increased relaxation have motivated them to adhere to the intervention as can be seen from the high adherence rate and extra home practice sessions initiated themselves. Other benefits reported include improved fluidity of upper body and relieved to have “Time Out” for themselves.

“Participant 2” -

*“ it opens up a new way of thinking that I have not thought before”*

*“ sleeping much better when asleep and sleeping soundly, not waking up with hot flushes, etc”*

“Participant 4”-

*“Very much rejuvenated, energize and relaxed as if the previous bad vibes have been wiped out. Able to sleep continuously for 6 hours.”*

*“I feel fresh enough, although you didn` t get the full 8 hours sleep and it`s only 5 hours only, its feeling fresh, feeling rejuvenated and feeling alive, motivated and you want to do things.... you want to get up and get going, so this is what I want although I still want a bit more sleep”*

Participant 5:

*“Yes, I feel more calm then before, more positive to my cancer cure journey”*

All the five participants responded that they would continue the Qigong practice at home after completion of the study. They find that it is beneficial and would recommend it to other cancer survivors. Participant 5 said she would practice more to have better effect while Participant 4 said she would even try to get her grandchildren to practice regularly with her.

Participant 5:

*“I would definitely recommend Qigong to any cancer patient.”*

#### 4.1.6.2 Class preferences

Factors that would influence participation in Qigong class include referral by medical staff, the quality/reputation of instructor, duration and frequency of class and the location of class. Participants preferred to practice with scheduled small group online practice from home with presence of instructor in 30-60 minutes practice session, two to three times a week in the evening before sleep. Most preferred to start the Qigong class after completion of primary cancer treatment.

Traveling within 10KM from home to attend class was acceptable while response on willingness to pay for Qigong Class as part of cancer care was mixed.

#### 4.1.6.3 Barriers to participation

Most participants had difficulty focusing during the practice initially. However, after the first week, they were able to focus better during the practice. Participants felt self-discipline is the most difficult part and find the fixed schedule online group practice session is very effective in promoting adherence. Working participants found it difficult to keep up with the five-session a week schedule due to competing demand from work and family.

Participant 2:

*“family and work commitment, could not attend 5 /7 days, difficult to stick to and too much if participants are working and have families”*

Participant 2 was also concerned about availability and safety of parking facility and location of class especially when the class was conducted in the evening .

#### 4.1.6.4 Recommendation for improvement

Participant 4 complained of lack of information about available studies and recounted that she was only informed of the current study and shown the flyer by another cancer survivors while waiting in the Wellness Centre in Liverpool Hospital. She suggested that hospitals should assign a health care personnel in hospital oncology or integrative oncology centre to inform cancer survivors who are waiting for treatment/consultation of availability of relevant studies as most cancer survivors are overwhelmed with the many flyers or brochures left around and would not read them. Other ideas to improve recruitment suggested by participants include reimbursement of expenses incurred for attending the Qigong class and advertising via cancer support groups. Participant 1 had even helped to send out the recruitment flyer to ENCORE group. In terms of Qigong delivery, the working participants felt that the first two introduction and instruction classes lasting 4 hours were too long and could be shortened to about 3 hours as they attended the classes straight after work. The two working participants also felt that the frequency of face to face class in Week 2 and Week 3 of twice a week was considered too much and recommended to reduce to once a week or to do away with it. Participant 3 felt that the first two introduction and instruction classes in Week 1 together with video link demonstration given was adequate. However, Participant 5 (non-working) felt that there should be “longer teaching period”, to only teach La Qi and Rou Fu in Week 1 to increase confidence when participant can feel Qi followed by LQPQ in Week 2 and Week 3 face to face class. Participant 4 also suggested allocating more time to explain and practice to feel Qi as she found it a very new concept to grasp. Other recommendations include class with bigger group for social support, allowing participants to talk about and share their personal concerns and experience.

## 4.2 Clinical intervention outcomes

### 4.2.1 Insomnia Severity Index

Seven participants started the study with a mean ISI score of 21.4 (SD=3.64) (range: 14-24). Six participants started within the clinical moderate severity range (15-21) to clinical severe range (22-28) while one participant (#2) started with ISI score of 14 i.e. highest score of subthreshold insomnia. The ISI score for the 5 participants who completed the study decreased over the 4-week study period. Of the five participants who started with ISI score of more than 20 at Week 0, Participant 5 recorded the greatest improvement from 24 in Week 0 to 13 by Week 4. The most significant improvement compared to baseline was observed in Week 3 for three participants while Participant 1 recorded the most improvement in Week 2. All participants except Participant 3 experienced a slight increase of ISI scores after a one-week break of Qigong practice from Week 3 to Week 4. Please refer **Figure 6**. Compared to baseline, the group ISI recorded the highest (36%) improvement at Week 3 after three weeks of Qigong intervention but deteriorated slightly (28%) at Week 4 follow up (**Table 10**). The overall trend of change in ISI score of the individual participant is similar to ISI group means change (**Figure 7**) over the study period. A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean ISI values differed statistically significantly over the four time points ( $F(1.963, 7.852) = 5.606, P = 0.031$ ). Contrast tests revealed that Qigong intervention elicited statistically significant reduction in group ISI means at Week 0 compared to Week 2 (mean=5.6,  $\eta_p^2 = 0.694, p=0.040$ ), Week 3 (mean=7.8,  $\eta_p^2 = 0.838, p=0.010$ ) and Week 4 (mean=6,  $\eta_p^2 = 0.709, p=0.036$ ). Using the nonparametric test approach, the results of the Friedman Test revealed the statistically significant mean rank of 4 (Week 0), 2.4 (Week2), 1.4 (Week3) and 2.2 (Week 4) and was significant ( $p=0.006$ ).



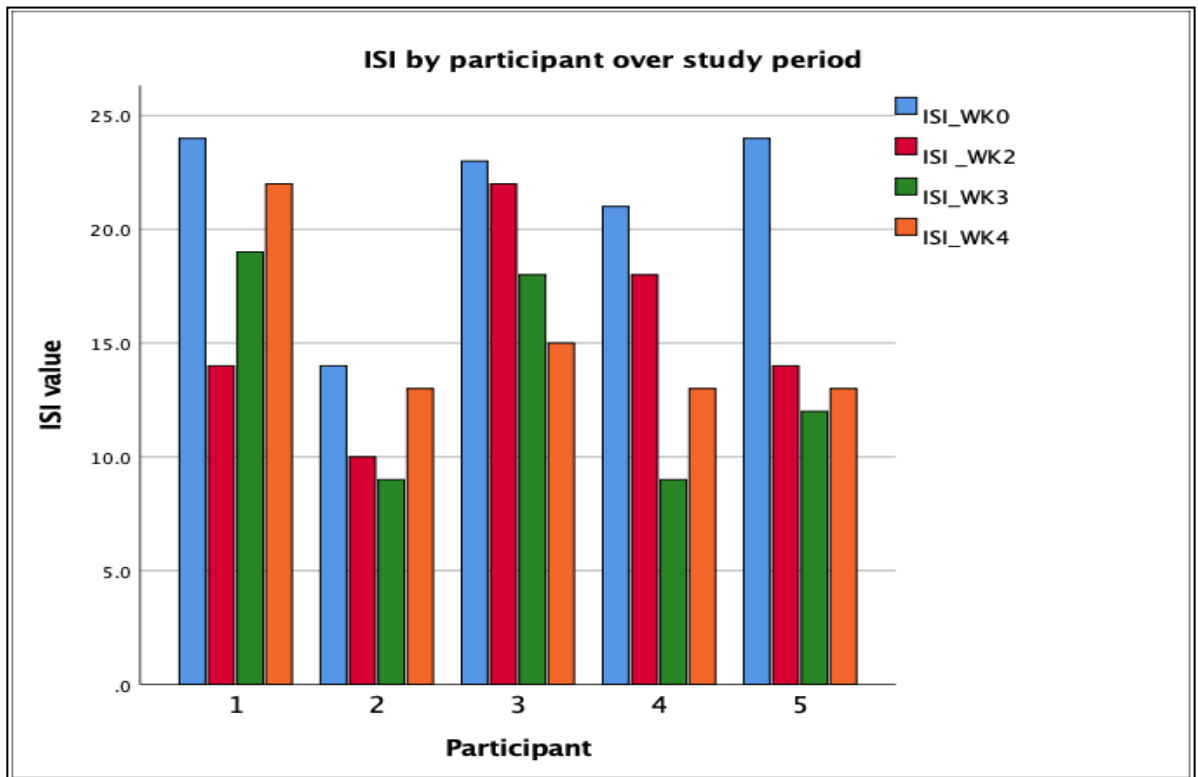


Figure 6 ISI by participant over study period

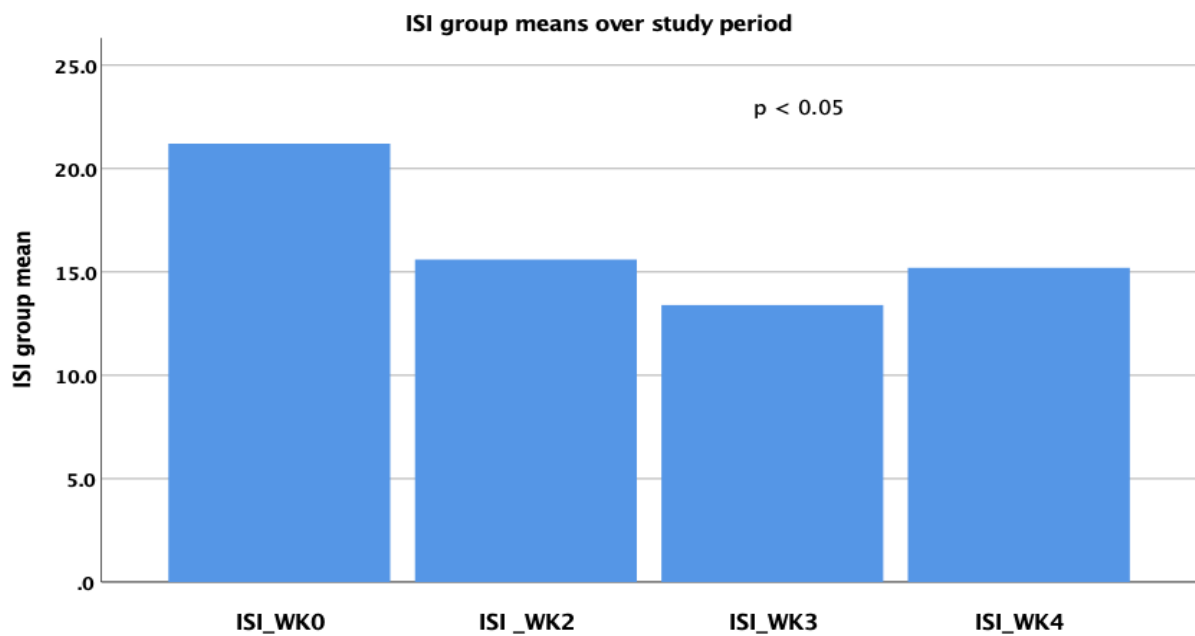


Figure 7 ISI group means over study period

**Table 10 Descriptive statistic for ISI and PSQI with statistics test scores over study period**

Time point	N	Mean (SD)	Mean difference*(SE)	Percentage of change *	F value	p value*
Week 0	5					
ISI		21.2 (4.2)	NA	NA	NA	NA
PSQI		14.8 (1.8)	NA	NA	NA	NA
Week 2	5					
ISI		15.6 (4.6)	5.6 (1.9)	26	9.06	0.040
PSQI		9.7 (3.5)	5.1 (1.3)	34	15.21	0.018
Week 3	5					
ISI		13.4 (4.8)	7.8 (1.7)	36	20.69	0.010
PSQI		9.4 (3.3)	5.4 (1.2)	36	19.97	0.011
Week 4	5					
ISI		15.2 (3.9)	6.0 (1.9)	28	9.73	0.036
PSQI		10.1 (2.9)	4.7 (1.0)	32	20.27	0.011

\*compared to Week 0 (baseline), SD Standard Deviation, SE Standard Error

#### 4.2.2 Pittsburgh Sleep Quality Index

Poor sleep quality with mean PSQI score of 15.3 (SD=1.70) (range:13-17) was observed for seven participants at Week 0. PSQI values of five participants who completed the study reduced significantly from Week 0 to Week 4 with a slight increase after a one-week break from practice from Week 3 to Week 4 except Participant 3. Participant 1 and 2 registered most improvements in PSQI score between Week 0 and Week 2 from 16 to 9 and 13 to 7.5 respectively. The most significant improvement in PSQI score from Week 0 to Week 3 was shown in Participant 5 (13 reduced to 5), followed by Participant 4 (17 reduced to 10), Participant 1 (16 to 10) and Participant 2 (13 to 8) respectively (**Figure 8**). Participant 3 did not show much improvement in the PSQI values pre and post intervention. Compared to

baseline, the group PSQI recorded the highest (36%) improvement at Week 3 after 3 weeks of Qigong intervention but deteriorated slightly (34%) at Week 4 follow up (Figure 9) and this trend is consistent with the group ISI outcomes. The overall trend of changes in the PSQI scores of individual participants is consistent with changes in group mean PSQI score (Figure 9) over the study period. A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean PSQI values differed statistically significantly over the four time points ( $F(1.229, 4.915) = 16.508, P = 0.009$ ). Contrast tests revealed that Qigong intervention elicited statistically significant reduction in group PSQI means at Week 0 compared to Week 2 (mean=5.1,  $\eta_p^2 = 0.841, p=0.018$ ), Week 3 (mean=5.4,  $\eta_p^2 = 0.833, p=0.011$ ) and Week 4 (mean=4.7,  $\eta_p^2 = 0.835, p=0.011$ ). Using the nonparametric test approach, the results of the Friedman Test revealed statistically significant mean rank of 3.9 (Week 0), 2.1 (Week2), 1.5 (Week3) and 2.5 (Week 4) with ( $p=0.007$ ).

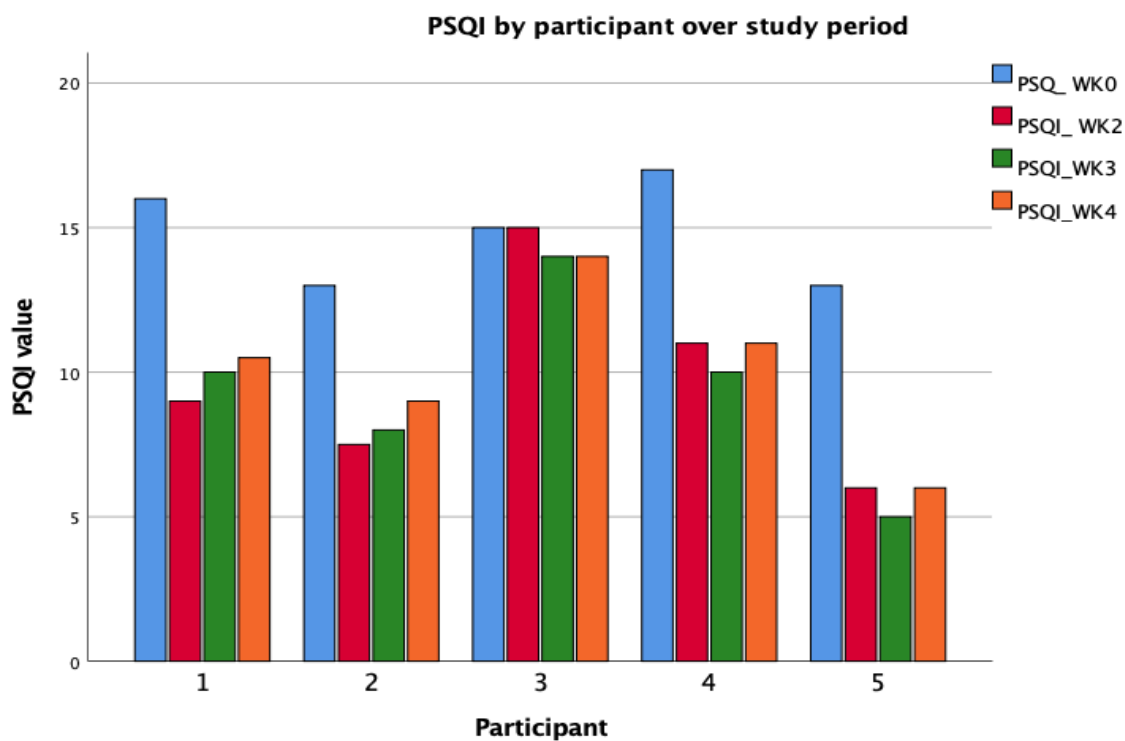
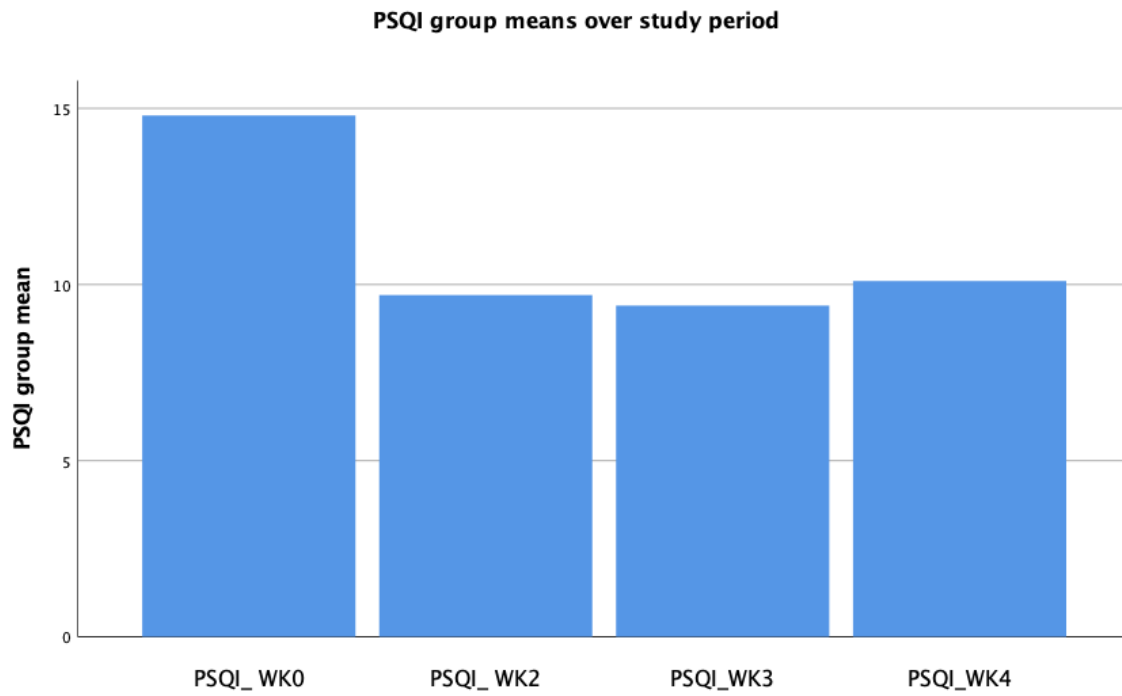


Figure 8 PSQI by participant over study period



**Figure 9 PSQI group means over study period**

## **CHAPTER 5: DISCUSSION**

Insomnia is a frequently reported debilitating consequence of cancer diagnosis and its treatments. This study investigated the feasibility and effect of a 3-week Qigong intervention in cancer survivors experiencing insomnia. The results suggested that it is feasible to conduct Qigong intervention in this cohort and that this type of intervention may help to alleviate insomnia as shown by the statistically significant improvements in the ISI and PSQI scores. However, due to the small sample size study design, caution in the interpretation of the result is necessary. Overall, these findings indicate there is a need for a larger RCT of Qigong for insomnia in cancer survivors.

### **5.1 Feasibility outcomes**

This feasibility study is one of the first to demonstrate that a specific form of Qigong, i.e. Zhineng Qigong is feasible in cancer survivors. The retention and compliance rates were acceptable and comparable to other Qigong studies (S. S. Fong et al., 2015; Irwin et al., 2017; W. Liu et al., 2015; M. L. Yeh & Chung, 2016). There was no serious adverse event reported. The 3-week Qigong intervention was well received by the participants with the intention to continue the practice after the study period.

#### **5.1.1 Recruitment**

Recruitment is the main challenge in this study as with most clinical trials reporting not meeting their recruitment targets (Trewick et al., 2013). The current study only managed to recruit 7 participants instead of the planned sample size of 15.

One of the negative consequences of poor recruitment is underpower in clinical trials. In underpowered clinical trials, relevant clinical differences may be reported as statistically non-significant, risking the chance that effective intervention will be abandoned or delayed pending further studies or meta-analyses, before its true value is established. While extension of the study period may improve the recruitment, it will still delay implementation of potential effective intervention on top of increasing cost and workload (P. Bower et al., 2014; Treweek et al., 2013).

Major barriers that contributed to low participation which were also identified in other cancer clinical trials (Leblanc et al., 2013; Nipp et al., 2019) can be broadly classified into patients issues and gate keeping.

Patient issues include frailty, fatigue, logistical concerns and financial barriers. Logistic issues such as safety and access to parking facilities as well as parking rates were raised during the study and should be considered in all study design involving traveling by participants. Incentives in the form of payment for time taken to participate as motivational benefits such as giving small gifts and payment for incidental expenses or cash voucher could be budgeted in future study to promote recruitment and participation (P. Bower et al., 2014; McCall, McDonald, Thorne, Ward, & Heneghan, 2015). Competing demands such as medical appointments which was the reason of drop out for Participant 7, work and family commitments were some of the main reasons for refusal to participate in clinical trials as expressed by some of those approached (n=5) in the study and other studies (Leblanc et al., 2013).

Gate keeping involves lack of clinician and/or caregiver support to clinical trial enrollment. Some clinicians may assume that research is burdensome and of no benefit to participant, or that it would be intrusive, misleading with false hope or unethical (Leblanc et al., 2013; Nipp et al., 2019). Other barriers include lack of Qigong literacy, skepticism, unclear referral process and inadequate integration of complementary medicine, such as Qigong, as part of integrative oncology into clinical care or supportive care processes (Grant, Marthick, & Lacey, 2018; Smith et al., 2018). One of the ways to improve participation is the use of

patient navigators to identify barriers to specific study on an individual basis. As patient navigators are mostly good communicators matched to the population they serve, engaging them may improve recruitment (Nipp et al., 2019) due to the personal and cultural connection. Other than that, increasing Qigong awareness and literacy through various channels in hospitals and cancer support groups, as well as providing incentives such as co-authorship on papers to professionals in future study may contribute to better recruitment (P. Bower et al., 2014; Grant et al., 2018).

The timing of our recruitment which overlapped with the year-end holiday season also contributed to low recruitment within the short recruitment period (5 September 2018 to 9 April 2019) of the current study. We did not recruit any participant from the start of our recruitment to January 2019 as most people were in festive mood and preparing for holiday. Recruitment plan in future study should avoid the year-end holiday season period.

The most successful source of recruitment based on the first contact was the Western Sydney University Internal Electronic Update, 1 out of 2 (50%), followed by Liverpool Hospital Wellness Centre, 3 out of 7 (42.9%) and cancer support groups, 2 out of 6 (33.3%). The least successful source of recruitment was Pembroke Lodge Nursing Home and Facebook with zero recruitment although Pembroke Lodge Nursing Home recorded the highest number of first contacts at 42.9% (n=21). The main reasons for low recruitment rate in the nursing home are the lack of capacity to give informed consent as well as medical conditions that preclude the home residents who are mostly more than 80 years old from participating.

Based on the above, we believe that it is more effective to recruit from targeted sources of recruitment and referral such as oncologists, integrative oncology centre and university website as reflected in the current study. This is understandable as cancer survivors are a vulnerable group who are sensitive to the safety of any intervention to be taken and effort required for participation as supported by the current survey reporting that the most common factors influencing participation are referral by GP/oncologist, quality of instructor, location and timing of class.

### **5.1.2 Compliance to the data collection method**

All participants were able to comply with the data collection method and completed all forms as the process has been simplified and it did not require too much burden on them. Most of the forms were completed during the face to face class and took less than 10 minutes to complete. The principal investigator was always on hand to clarify any uncertainties or doubts. Reducing the burden on participants was one of the methods used to encourage retention (P. Bower et al., 2014; Grant et al., 2018). The ease of the data collection method may have contributed to the retention of all the five participants other than two participants who dropped out due to health reasons.

### **5.1.3 Adherence to Qigong intervention**

With an overall retention rate of 71% and adherence of 84%, it is deemed that the 3-week Qigong intervention is feasible to implement to improve insomnia in cancer survivors.

Two of the seven participants recruited dropped out after the second introduction session. One was due to worsening of existing condition (refer section 5.1.4 Adverse events) and one was too tired due to lack of sleep as she reported only sleeping 2 hours everyday and she had to attend many other medical appointments. Therefore the retention rate of 71% is comparable to another study in Sydney with 76% retention rate (Oh et al., 2010). Another study reported only 35% retention rate (Loh, Lee, Quek, & Murray, 2012) as high dropout rates within clinical trials are well established problems that have been frequently observed in trials of exercise interventions with cancer survivors (Loh et al., 2012).

The group adherence of 84% is comparable to adherence rates of 63.5% to 96% in other similar studies which reported significant difference in sleep measures (S. S. Fong et al., 2015; Irwin et al., 2017; W. Liu et al., 2015; M. L. Yeh & Chung, 2016).

Even though face to face class attendance (90%) was higher than online classes (80%), the online home adherence of 80% is acceptable compared to the rates of 78% of home-based practice in one study of Qigong intervention with breast cancer survivors (W. Liu et al., 2015). Most of the reasons for non-adherence were due to pre-arranged appointments or



unexpected illness. In fact, the actual home practice adherence is more than 80% as all the participants practiced additional sessions individually at home as shown in **Table 8**. Most of the participants reported being stressed by the cancer experience and the compliance with Qigong intervention including additional home practice was motivated by the ease and benefits of inner calm as well as improved sleep that they experienced especially the La Qi and Rou Fu methods. As the La Qi and Rou Fu methods are stationary Qigong form with more emphasis on meditation aspect, future study will take note of the preference of cancer survivors with insomnia for more meditative and relaxing Qigong method. The preference of cancer survivors for these two methods highlighted the need to address the mental aspect of cancer survivors to reduce stress and bring about inner peace and calm to promote sleep.

Use of technology such as the Zoom, an online video-conferencing application in the delivery of online supervised practice is an essential component in the current study which has ensured not only a high rate of retention but adherence to scheduled practice session and motivation to continue participation. This is supported by the preference of this mode of delivery as indicated by participants in their verbal and Qigong Questionnaire feedback. Delivery of supervised online home-based practice in this study has demonstrated better adherence compared to other studies of unsupervised home-based exercise practice (Vizza, Smith, Swaraj, Agho, & Cheema, 2016).

#### **5.1.4 Adverse events**

While there is no established evidence of causal relationship between Qigong intervention and the occurrence of adverse events reported other than from Participant 7, there may be some chance that Qigong intervention may potentially contributed to these events from the professional experience of the principal investigator.

Participant 7 was diagnosed with breast and bone cancer. She reported at the start of intervention that she went to bed at 11:00pm every night but only manage to sleep at around 12:30 am. She woke up about 6 times every night due to pain in the bone and hips when she turn or move the body as she has bone cancer of the whole backbone, on the hip bone and upper part of the femur. Although she was awake 7:30 am every morning, she could not pull herself out of bed until 9:30 am. She has been taking Panadeine for pain relief

about 4 tablets a day or more if more pain. She also mentioned that too much walking would increase her pain. She attended the following Qigong sessions:

18 March 2018	Face to face introductory class	3 hours
19 March 2019	Online supervised home practice	1 hour
20 March 2019	Face to face introductory class	3 hours

On 20 March, Participant 7 reported she had backache and radiating pain down the back of her legs after the LQPQ the night before and asked if she could practice LQPQ while sitting down. She was advised not to overstrain herself and sit down or rest whenever needed. She also reported that she was able to get up herself at about eight in the morning instead of dreading to get up and dragging herself out only after 9:30 AM as before.

Participant 7 texted at 8:57 pm on 21 March 2019 to inform that she would not join the online practice as she was feeling a bit of pain and she was asked to rest.

On 24 March, participant texted at 8:44 pm that she had to pull out of the study due to extreme neck and shoulder pain. She felt the length of time of the practice was too long for her bones and body.

The principal investigator called her immediately to check on her condition and advised her to seek immediate follow up with her GP. She said that other than the bone cancer she had a fractured neck and shoulder tendonitis as well and has not been doing any exercise for the last 15 months (but this information was not communicated to the principal investigator before the start of the study) which is why the moderate LQPQ method is too much for her. However, she felt the practice made her sleep longer and wake up later and she will continue with Rou Fu on her own at her own pace and duration. She was advised to update on her condition but did not respond to the two text messages and two telephone calls to follow up on her condition.

The worsening of neck, shoulder and lower back pain in Participant 7 who has breast and bone cancer may be due to over exertion of the upper body skeletal joints from the LQPQ method on the second introduction and instruction class. Participant 7 only reported to the principal investigator after dropping out of the study that she had neck fracture and

shoulder tendonitis and had not been exercising for the last 15 months which was why the moderate LQPQ was too much for her. In view of the risk of skeletal fractures and musculoskeletal morbidities in cancer survivors with bone metastases, future studies of Qigong in this patient group will benefit from incorporating more thorough medical assessment and modification of the Qigong intervention including increased supervision (Schmitz et al., 2010). Additional medical assessment should also be included in the screening of breast cancer survivor to evaluate arm or shoulder morbidity before upper body exercise and those on hormone therapy should be screened for any risk of fracture (Schmitz et al., 2010).

While most Qigong studies on cancer survivors have not reported or has systematic reporting of adverse events, the few studies that included adverse events reporting have not reported the occurrence of any serious adverse events (Van Vu et al., 2017; P. Wayne et al., 2018). A few studies of Qigong intervention for cancer care concluded that it is safe and feasible without any adverse events (Butow P, 2014; Campo et al., 2014; Galantino et al., 2013; W. Liu et al., 2015; Oh et al., 2010). In addition, a systematic review of adverse events of Qigong reported that it was not likely to lead to serious adverse events but may be associated with minor musculoskeletal aches and pains (P. M. Wayne, Berkowitz, et al., 2014). Based on these studies and reviews of adverse events reported in clinical trials, it can be suggested that Qigong is likely to be safe for cancer survivors. As such we would assume that the adverse events reported except from Participant 7 are not related to the current Qigong intervention until further studies could establish its causal relationship or mechanism.

#### **5.1.5 Experience of study**

The experience of trial used the Qigong Questionnaire and Focus Group Question to evaluate participant's preferences, experience, barriers and recommendation for improvement about the study.

#### 5.1.5.1 Participant experiences

Most of the participants have not heard of Qigong prior to participating in the study but could relate to it as a form of MBT associated with improving emotional and physical well being. This is understandable as all the participants except Participant 5 are non-Chinese who have not been exposed or familiar with any Chinese health care practice such as Qigong. Despite not having any prior knowledge of Qigong, they still participated in the Qigong intervention. This may be motivated by the desire to improve treatment-related side effects, QOL (Smith et al., 2018) and expectation of Qigong as a form of CAM to address their psychosocial needs from stress which were not met by conventional medicine (Chandwani et al., 2012). Due to the lack of knowledge about Chinese culture and literature, some participants had difficulty grasping the concept of Qi and Qigong. It was suggested that future study should allocate more time to explain these concepts in relation to health promotion.

All participants reported being emotionally calmer and relaxed with improved sleep (as reflected in ISI and PSQI outcomes) within the first week of the Qigong intervention. As stress is one of the main cause of (M. Irwin, 2013; Mosher & Duhamel, 2012; Sharma et al., 2012) and aggravates insomnia (Savard et al., 2015) in cancer survivors, the improved mental state of calm and relaxation experienced by cancer survivors from the Qigong class may explain the improved sleep reported. Other benefits reported include becoming more energized and positive. This is in line with most Qigong studies which have consistently reported significant reduction in fatigue as one of the benefits of Qigong intervention for cancer survivors (Klein et al., 2016; Van Vu et al., 2017; P. Wayne et al., 2018). Fatigue and insomnia in cancer survivors have been strongly correlated in many literatures (Ancoli-Israel et al., 2014; Balachandran et al., 2013). Therefore it can be speculated that improved sleep in our study may have contributed to reduced fatigue which was also reported in other studies (Chuang et al., 2017; W. Liu et al., 2015; M. L. Yeh & Chung, 2016). With up to 96% of cancer survivors experiencing cancer related fatigue (L.-L. Zhang, Wang, Chen, & Yuan, 2016) and sleep disturbance is one of the contributors to fatigue (Balachandran et al., 2013), more research of Qigong on sleep in cancer survivors is essential to provide insight on the how the

relationship between sleep disturbance and fatigue affect a host of reciprocal and inter-related systems.

Another finding reported by Participant 2 who had radiotherapy and was on hormone therapy was the ability to sleep soundly without waking up with hot flushes and night sweats after the Qigong intervention. Given that hot flushes/night sweats have a significant mediating effect on sleep in cancer survivors who had radiotherapy and /or hormone therapy (Savard et al., 2015), future study should explore the potential effect of Qigong on hot flushes/night sweats not only on cancer survivors but non-cancer population.

Together with other improvements reported such as improved flexibility of upper body and feeling rewarded to have “Time Out”, it is not surprising that all the 5 participants who completed the study said that they would very likely continue Qigong practice at home after the study period and would definitely recommend Qigong to other cancer patients.

#### 5.1.5.2 Class preferences, barriers and recommendation for improvements

Referral by health care practitioners to a reliable instructor is an important factor that may influence participation as it is able to boost cancer survivors confidence and alleviate concern about the safety of Qigong as a complementary therapy to improve sleep. However, insufficient evidence of safety and efficacy together with lack of knowledge and education about CAM, in general, are the main concern and barrier to referral by oncologists (Smith et al., 2018). As such many cancer survivors interviewed in a study on unmet needs in use of CAM cited lack of dialogue with clinicians and comprehensive information as their main complaints (Bonacchi et al., 2015). Thus, there is a need for further well design studies of CAM including Qigong intervention to improve insomnia in cancer survivors, to establish evidence before translating established evidence into practice to be incorporated in clinical guidelines (Greenlee et al., 2014) to better inform all interested stakeholders.

Preferred timing of introduction to Qigong intervention was after completion of all cancer treatment as most cancer survivors in this study felt that cancer treatment period is a stressful period which was also reported in a study of prostate cancer patients undergoing

radiotherapy (McQuade et al., 2017) and they do not want to be burdened with additional activities. As the health status of cancer survivors could affect drop out rate of participants (Oh et al., 2010), this factor should be considered in the design of future study.

All the five participants agreed that the online supervised home group practice with a duration of 60 minutes practice each session were convenient and acceptable and all participants reported that they would continue Qigong practice at least two times a week after the study period. Working participants felt that the first two 4-hour introduction and instruction sessions were too long as they attended the sessions straight after work. They also considered the five sessions a week in the current study were too frequent as they have many other competing demands. It was suggested that the two introduction and instruction sessions could be shortened and the frequency of weekly classes reduced to two to three times a week. However non-working participants felt the frequency of class was acceptable. In view of the different expectation of working and non-working participants, future study should consider planning longer intervention period with lower class frequency for working participants and shorter intervention period with higher class frequency for non-working participants to ensure both groups have the same dose-response effect. Bigger class size as suggested by participants should be organized for future study of Qigong intervention for its social support element as it provides an important avenue for participants to share and talk about their personal concerns and experiences (Browning et al., 2017; McCall et al., 2015)

There was mix response on willingness to pay for Qigong as part of cancer care. This may be due to the different financial status of the participants. As funding is one of the main barriers to the provision of CAM in integrative oncology (Smith et al., 2018), access to CAM services such as Qigong may be limited to cancer survivors who can afford to pay for the time being.

## **5.2 Clinical intervention outcomes**

Statistically significant improvement in insomnia severity (ISI) score and sleep quality (PSQI) global score were recorded over the various data collection points. This result is consistent with other similar studies that reported significant improvement in sleep in comparison to baseline (Chuang et al., 2017; Irwin et al., 2017; Larkey et al., 2015; W. Liu et al., 2015).

Even though the sleep measures in our study improved significantly over the 3 data collection points compared to baseline (Week 0), there was a slight deterioration in the improvement in Week 4 (after a one-week break from Qigong practice) compared to Week 3. This suggested that the effect of Qigong intervention does not last after the 3-week Qigong intervention and may deteriorate over time without continuous practice. Therefore, longer Qigong intervention period with regular practice is necessary to maintain long term effect as demonstrated in one Qigong study with nasopharyngeal cancer survivors which reported most significant improvement in sleep in the six months after six months of Qigong intervention (S. S. M. Fong et al., 2014). This is also supported by another study of Qigong intervention with breast cancer survivors that reported significant improvement in sleep at three months (post-intervention), six months and fifteen months follow-up where participants continued 30 minutes home practice during the follow up period (Irwin et al., 2017). This implied that Qigong is a form of healthy lifestyle habits like exercise that needs regular training for maintenance of a healthy body and mind.

The current study protocol introduced three methods or forms of Qigong namely La Qi, Lift Qi Pour Qi and Rou Fu with different level of emphasis on mindfulness, relaxation and physical movements not only for the various effects but also to make it more interesting to promote adherence. As there were three Qigong methods/forms practiced by the participants, we were not able to identify which one of the three generated the most impact on sleep or was it a synergistic effect of the three methods that produced the reported results. LQPQ has more physical movements compare to La Qi and Rou Fu which emphasis more on the meditation effect. Therefore, future work should deconstruct the effect of each method on sleep outcome by comparing the effects of different method and assigning specific method to different groups. This is supported by a recent systematic review and meta-analyses that found a slight advantage of Qigong over Tai Chi in sleep quality improvement of participants, suggesting that Qigong and Tai Chi as different methods of Qigong training should not be equated (Xiang et al., 2017). In addition to that, study with larger sample size to analyse the interaction effects of the various forms of Qigong practice and its biophysiologic mechanism may provide a better understanding on sleep outcome for better management of insomnia during the cancer survivorship period.

A few studies have reported the positive biophysiologic effect of Qigong on the immune function and inflammatory response in cancer survivors after Qigong intervention (Campo et al., 2015; Irwin et al., 2014; Oh, Butow, Mullan, Clarke, et al., 2012; R. Wang et al., 2013). These findings suggested that Qigong may have a potential benefit of mediation of inflammatory response. This is a great clinical significance in immunoprevention of cancer given the connection between chronic inflammation and immune suppression of the immune response (Umar, 2014) on sleep (Howell et al., 2014; Irwin et al., 2006; Meier-Ewert et al., 2004) A growing number of studies have also consistently found that Qigong and related mind-body training reduced expression of inflammation-related genes and proinflammatory transcription factor Nf-kB signaling but strong conclusion cannot be drawn until more quality studies are conducted (J. E. Bower & Irwin, 2016).

Given that Qigong is a mind-body multi-component intervention with suggested multi-symptom benefits (Klein et al., 2016; Van Vu et al., 2017; P. Wayne et al., 2018), it should be explored not only on the mechanism of its biological benefits (e.g., inflammatory markers), but physiological and psychological related effects.

Klein and colleagues suggested that each of the multi-component elements of Qigong could potentially affect multiple cancer related outcomes (Klein et al., 2016). For example, a systematic review and meta-analysis of Qigong for cancer-related symptoms and QOL that focused on the 5 major key cancer-related concerns of cancer survivor; fatigue, sleep disorder, mood, pain and QOL, reported Qigong produced significant effect in improving fatigue and sleep (P. Wayne et al., 2018). This effect on fatigue and sleep persisted even when compared to active control groups, suggesting that the effect was due to mind-body specific activities and not solely due to attention and psychosocial support elements. While it is scientifically challenging, further research on the mechanism of how each of these elements individually and in combination can affect relevant cancer related outcomes is important to provide better designed protocol to suit individual need or specific cancer population.

As insomnia is closely associated with fatigue, mood and pain (Galiano-Castillo et al., 2017; Irwin et al., 2017; Medysky et al., 2017), and Qigong has been reported to improve insomnia



in this study and other studies (S. S. Fong et al., 2015; Irwin et al., 2017; W. Liu et al., 2015; M. L. Yeh & Chung, 2016), it has the potential to improve this symptoms cluster resulting in better overall health outcomes. Therefore, a larger and well-designed RCT of Qigong intervention that includes outcome measurements on sleep, fatigue, mood and pain in cancer survivors should be considered in the future.

### **5.3 Limitations**

Although this study was approved by Western Sydney University Human Research Ethics Committees, we did not apply for Human Ethics approval from the local health districts and this has affected its ability to recruit or obtain referral from oncologist and hospital integrative oncology centre whom may be the best source of recruitment for cancer survivors. As such many oncologists were not aware of the study as highlighted by a few of them during the presentation of this study in a multi-disciplinary team meeting in Liverpool Hospital. The meeting was also arranged too late into the end of the study period and was not able to help in the recruitment due to the limited study period. We were also not able to reach out for support from various cancer support groups. These are some of the factors contributing to the low recruitment of only 7 participants instead of 15 as planned. Future study should develop better recruitment strategies to engage with relevant staff in hospitals and cancer support groups. This can be achieved by various initiatives during the planning stage of study such as improving Qigong literacy through presentations and other opportunities, providing free Qigong services, writing Qigong articles to periodical in-house journals and involve them in the research and the various shared decision-making process (Grant et al., 2018).

Another limitation of this study was that it was conducted for English speaking cancer population only. As such we were not able to recruit a few non-English speaking potential participants who were interested in participating. Future study should include other languages to have a better representation of evidence to achieve conclusions that can be generalized to other cultures.

Next, the heterogeneity of various cancer type and cancer treatments included in this study also limit inferences that can be drawn to specific cancer population on the benefits of this Qigong intervention. Studies or reviews that could stratify results according to cancer type, cancer treatment, age or other demographic groupings of interest will provide better guidelines for clinical implementation.

Furthermore, there may exist detection and reporting bias as the same principal investigator performed the recruitment, Qigong intervention, collected and analysed the data. The long term effect of Qigong is not known as the current study was performed over a short-term intervention period. The small sample size and limited geographical reach (i.e. recruitment within South Western Sydney region) may also limit the generalization and interpretation of the feasibility and clinical outcomes of this study.

#### **5.4 Strength**

One of the strengths of this study was the participants' assessment of their experience of the study which will inform the design of future trials. All the five participants who completed the trial felt that they have benefited from improved sleep despite null group comparison. The Qigong methods taught for this study were clearly effective as statistically significant improvement was registered within 10 days (mid-intervention) by all participants and it continued with better improvement on Week 3 (post-intervention). We speculate that the improvement will continue with long term effect had we extended the Qigong intervention for a longer period. In addition to that, two of the Qigong methods used i.e. La Qi and Rou Fu were very easy and relaxing to practice such that most participants initiated extra home practice and commented that they will continue the practice even after the study.

#### **5.5 Implication for future research**

Lack of knowledge about CAM especially Qigong in particular and limited participation from relevant stakeholders are the main challenges to recruitment and success of clinical studies for CAM such as Qigong intervention.

Promotional activities of Qigong for health should be encouraged and supported by local government and communities for the public as well as all local health district hospitals. This will provide a better understanding of the nature of Qigong and acceptance through direct and indirect connection. Presentations about Qigong and the related research study to various cancer support groups, cancer community panels and local health district hospital to encourage the involvement of clinical practitioners, nurses, allied health professionals and all interested parties not only for recruitment but in every phase of the study should be incorporated in future study designs. Involvement or feedback from these groups from the planning, implementation and reporting stage in the research is critical for the success of the study. Recruitment will be much easier through these groups as they are able to identify targeted participants. They are also an important source of feedback on many practical aspects of study such as dealing with cancer survivors, contents of forms and questionnaires, intervention protocol and methodology as well as supporting participants throughout the whole study. Active involvement of these groups will encourage learning about Qigong and explore the perception of Qigong as a CAM with evidence-based research to promote acceptance and understanding as part of cancer care. Understanding Qigong practice as a form of CAM allows them especially health care practitioners to recommend and provide informed guidance to suitable and interested cancer survivors.

## **5.6 Conclusion**

In summary, the current study demonstrated that it is feasible to prescribe the current Qigong intervention for cancer survivors experiencing insomnia. Participants were willing and able to adhere to the Qigong protocol and feeling calmer, relaxed and more energized. Statistically significant improvement in insomnia severity (ISI) and sleep quality global score (PSQI) were reported. No serious adverse event to the Qigong intervention was reported. A well designed and rigorous RCT is warranted to determine whether significant improvement in sleep and other sleep-related symptoms in cancer survivors can be achieved with the same type of Qigong form.

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## **APPENDICES**

- Appendix 1 Recruitment flyer
- Appendix 2 Screening Checklist
- Appendix 3 Insomnia Severity Index
- Appendix 4 Participant Information Sheet
- Appendix 5 Participant Consent Form
- Appendix 6 Demographic and Cancer History Questionnaire
- Appendix 7 Pittsburgh Sleep Quality Index
- Appendix 8 Weekly Practice Status Check
- Appendix 9 Qigong Class Program
- Appendix 10 Qigong Form and Method
- Appendix 11 Qigong Questionnaire
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Appendix 1 Recruitment flyer

The flyer features a black and white photograph of a person lying in a hospital bed, partially covered by a patterned blanket. The person's face is visible, looking towards the camera with a neutral expression. The background is dark, making the person and the blanket stand out. The text is overlaid on the image in white and black. The top right corner has a dark red banner with the text 'RECRUITING NOW'. The top left corner has a white box with the Western Sydney University logo and name. The main text is in large white font, and the contact information is in a black box at the bottom right.

Appendix 1  
**WESTERN SYDNEY**  
UNIVERSITY  


**RECRUITING NOW**

**Are you experiencing  
insomnia from  
cancer?**

Western Sydney University (H12870)  
is conducting a study on the effect of  
mind-body exercise (Qigong)  
on sleep.

If you are

- OVER 18 YEARS OLD
- COMPLETED PRIMARY  
CANCER TREATMENT

**Contact:**  
Principal investigator,  
**Sara Low**  
Call: **+61246203328**  
Email:  
[19167073@student.westernsydney.edu.au](mailto:19167073@student.westernsydney.edu.au)

## Appendix 2 Screening Checklist

### Screening Checklist

Name of Doctor: .....Name of participant.....

<b>INCLUSION CRITERIA (Please tick box)</b>		<b>Yes</b>	<b>No</b>
<b>1</b>	Age $\geq$ 18 years old?	<input type="checkbox"/>	<input type="checkbox"/>
<b>2</b>	Diagnosed with cancer or completed primary cancer treatment (chemotherapy and/or radiotherapy) and/or at least 8 weeks post-surgery	<input type="checkbox"/>	<input type="checkbox"/>
<b>3</b>	Meet the criteria for insomnia as indicated by the score of Insomnia Severity Index (ISI)* $\geq$ 11?	<input type="checkbox"/>	<input type="checkbox"/>
<b>5</b>	Use stimulant medications, or other anxiolytic/sedative/hypnotic drugs? If yes, please indicate name and dosage.	<input type="checkbox"/>	<input type="checkbox"/>
<b>6</b>	Speaks and read English fluently?	<input type="checkbox"/>	<input type="checkbox"/>
<b>7</b>	Available and willing to follow the study requirement during study period?	<input type="checkbox"/>	<input type="checkbox"/>
<b>EXCLUSION CRITERIA (Please tick box)</b>		<b>Yes</b>	<b>No</b>
<b>1</b>	Any prior experience with Qigong, Yoga, Tai Chi or meditation within the past 3 months?	<input type="checkbox"/>	<input type="checkbox"/>
<b>2</b>	Body mass index $>$ 35kg/m <sup>2</sup> ?	<input type="checkbox"/>	<input type="checkbox"/>
<b>3</b>	Any diagnosis of major depression and/or clinically significant depressive or anxiety symptoms?	<input type="checkbox"/>	<input type="checkbox"/>
<b>4</b>	Is sleep disturbance due to clear physical cause, e.g., benign prostatic hyperplasia, frequent night-time urination, pain?	<input type="checkbox"/>	<input type="checkbox"/>
<b>5</b>	Is there any neurological degenerative disease (e.g. dementia), reduced cognitive capacity in any way that would affect ability to understand trial procedures and give informed consent?	<input type="checkbox"/>	<input type="checkbox"/>
<b>6</b>	Is there any other medical conditions which would preclude study intervention or make study participation unsafe such as severe chronic heart failure?	<input type="checkbox"/>	<input type="checkbox"/>

Doctor signature: .....Doctor contact: .....

## Appendix 3 Insomnia Severity Index

### Appendix 3

Participant name/ID: \_\_\_\_\_

Date: \_\_\_\_\_

### Insomnia Severity Index

The Insomnia Severity Index has seven questions. The seven answers are added up to get a total score. When you have your total score, look at the 'Guidelines for Scoring/Interpretation' below to see where your sleep difficulty fits.

For each question, please CIRCLE the number that best describes your answer.

Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problems waking up too early	0	1	2	3	4

4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very Satisfied    Satisfied    Moderately Satisfied    Dissatisfied    Very Dissatisfied  
0                    1                    2                    3                    4

5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all  
Noticeable    A Little    Somewhat    Much    Very Much Noticeable  
0                    1                    2                    3                    4

6. How WORRIED/DISTRESSED are you about your current sleep problem?

Not at all  
Worried    A Little    Somewhat    Much    Very Much Worried  
0                    1                    2                    3                    4

7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

Not at all  
Interfering    A Little    Somewhat    Much    Very Much Interfering  
0                    1                    2                    3                    4

### Guidelines for Scoring/Interpretation:

Add the scores for all seven items (questions 1 + 2 + 3 + 4 + 5 + 6 + 7) = \_\_\_\_\_ your total score

Total score categories:

0–7 = No clinically significant insomnia

8–14 = Subthreshold insomnia

15–21 = Clinical insomnia (moderate severity)

22–28 = Clinical insomnia (severe)

Used via courtesy of [www.myhealth.va.gov](http://www.myhealth.va.gov) with permission from Charles M. Morin, Ph.D., Université Laval

## Appendix 4 Participant Information Sheet

### Participant Information Sheet – Medical (Extended)

**Project Title: Can Qigong (body-mind exercise) improve symptoms of insomnia in cancer survivors: a feasibility study**

**Project Summary:**

You are invited to participate in a research study being conducted by Sara Low, a Master of Research candidate of School of Health and Science of Western Sydney University under the supervision of Associate Professor Xiaoshu Zhu, Director | Chinese Medicine Centre | Collaboration between WSU and BUCM, Director of Academic Program | Chinese Medicine and Lead | Cancer Research Theme | National Institute of Complementary Medicine (NICM) as well as the co-supervisory team, Dr Bobby Cheema and Dr Amy Tan of Western Sydney University.

The purpose of this research is to investigate whether Qigong intervention is an feasible alternative to conventional drugs and cognitive behavioral therapy to improve insomnia in cancer survivors. Qigong, a mind-body exercise/therapy used for thousands of years in China for its health and healing benefits has been reported to improve sleep in a number of studies. This study will employ Zhineng Qigong, one type of Chinese Medical Qigong that incorporates gentle exercise, meditation, mind adjustment, and breath regulation based on fusion of the best of many Qigong emerging out of Confucianism, Buddhism, Taoism, Traditional Chinese Medicine, traditional martial arts and folk religion integrated with modern science, medicine and philosophy that emphasises on the critical role of the mind on health and wellbeing.

This study aims to evaluate the feasibility of a 3-week Qigong intervention program for cancer survivors (who meet the screening criteria) with insomnia and change in insomnia in cancer survivors after participation in the Qigong intervention program. The results will be published through research publication and media releases. They will also be used by the study investigator, Sara Low, to obtain a Higher Degree by Research, Master of Research.

**How is the study being paid for?**

This research project is being conducted as part of a Higher Degree by Research at the Western Sydney University. No member of the research team will receive any personal financial benefit from your involvement in this research project

**What will I be asked to do?**

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

The study will recruit 15 participants and is open to cancer survivors aged 18 years or over, who have been diagnosed with cancer or completed primary cancer treatments (chemotherapy and/or radiotherapy) and/or at least 8 weeks post-surgery and experiencing insomnia with insomnia score of Insomnia Severity Index (ISI)  $\geq 11$ . If you meet the inclusion/exclusion criteria and you decide to

participate the Consent Form must be signed prior to enrolment in the study.

In this study, you will be asked to visit your GP or our appointed GP for screening. If you are eligible after screening and wish to participate, you will complete a participant consent form to be sent back to the primary investigator. During the 3-week Qigong intervention period and 1 week follow up period, you will be asked

- questions about your characteristic cancer survivors, your health (Demographic Questionnaire) at Week0, your beliefs, preferences and opinion about the Qigong intervention (Qigong Survey Questionnaire and group meeting) at Week3.

- to complete Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI) and weekly practice diary

- to attend two sessions of 4-hour introduction and instruction class in week-1

- to attend 2 sessions/week of face-to-face group practice

- to attend 3 sessions/week online group practice or practice 3 times/week on your own

You will be guided by the primary investigator to complete the forms for any uncertainties. Please refer to Figure 1 below for details.

**Figure 1 Table of activities**

	Screen	Baseline	Qigong Intervention			Follow up
Time point	Wk-2 to 0	WK-0	Wk 1	Wk 2	Wk 3	Wk 4
<b>Activity</b>						
Inclusion exclusion criteria	x					
Consent	x					
Questionnaire		x			x	
Introduction class			x			
Qigong intervention			x	x	x	
Practice diary			x	x	x	
ISI	x	x		x	x	x
PSQI		x		x	x	x
Adverse event			x	x	x	x

**How much of my time will I need to give?**

You will be asked to complete weekly practice diary (3 weeks) and sleep indexes at multiple data collection points as shown in Figure 1 above. It will take less than 5 minutes each day to complete the diary and less than 10 minutes to complete the sleep indexes at 4 data collection points.

You will also be expected to attend 2 sessions of 4-hour each of Introduction and Instruction class, 3 online group practice with the instructor using web-based video conferencing applications such as Skype or Zoom in Week-1. In weeks 2 and 3, you will attend 2 sessions/week of face-to-face group practice and 3 sessions/week online group practice. Each group Qigong practice session last for around 60 to 90 minutes. Please refer to Appendix 1 for details.

**What benefits will I, and/or the broader community, receive for participating?**



We cannot guarantee or promise that you will receive any benefits from this research; however the potential benefits to participants are improved sleep leading to improved quality of life with no extra cost of purchasing study materials. Your participation may benefit future cancer survivors and research. You will be reimbursed \$50 for any GP fee incurred based on receipt.

This is an important study because Qigong intervention is unlikely to be offered to cancer survivors until we have a better understanding of the feasibility and advantages or any problems that may arise when Qigong is used for insomnia in cancer survivors. The study aims to further knowledge, however, it may not directly benefit you.

**Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?**

All intervention may cause side-effects although we do not foresee any risk from studies conducted so far other than the inconvenience of recording weekly practice diary and sleep indexes at various data collection points. If you have any side-effects, or are worried about them, please inform the Chief Investigator, Associate Professor Xiaoshu Zhu on 02 4620 3338 immediately if any are noted.

**How do we intend to publish or disseminate the results?**

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission. Any information obtained for this research project and for the future research described here that can identify you will be coded to de-identify you and will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. If the information is to be used for additional research consent for that additional use will be sought.

It is an inherent characteristic of any group practice intervention that all participants within the group will be known to each other during the group Qigong practice. As such your participation will be known to others in the group. However your personal information will be kept confidential accessible by the research team only and your participation will not be published.

**Will the data and information that I have provided be disposed of?**

Your information will only be used for the purpose of this research project and related future randomised controlled trial projects for the next 5 years. All research data is destroyed after seven years from completion of the study according to the NSW Health Supplement to the National Statement on Ethical Conduct of Human Research (Australian Code for the Responsible Conduct of Research, 2007).

**Can I withdraw from the study?**

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason.

If you do withdraw your consent during the research project, the study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**Can I tell other people about the study?**

Yes, you are encouraged to refer other people who may be interested to contact Sara Low, the primary investigator +61246203328 or email [19167073@student.westernsydney.edu.au](mailto:19167073@student.westernsydney.edu.au) to discuss about participation.

**What if I require further information?**

Please contact Sara Low, the primary investigator on +61246203328 or email [19167073@student.westernsydney.edu.au](mailto:19167073@student.westernsydney.edu.au) should you wish to discuss the research further before deciding whether or not to participate.

**What if I have a complaint?**

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethicancer survivors Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email [humanethicancer survivors@westernsydney.edu.au](mailto:humanethicancer survivors@westernsydney.edu.au).

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the principal investigator/s.

This study has been approved by the Western Sydney University Human Research Ethicancer survivors Committee The approval number is [H12870].

**Thank you for taking the time to consider this study.  
If you wish to take part in it, please sign the attached consent form.**

**This information sheet is for you to keep.**

## Appendix 1

### Detailed Qigong Intervention

The Qigong intervention is offered over a 3-week period consisting of two sessions of introduction and instruction classes, 3 online group practice each of 60-90 minutes Qigong intervention sessions on week-1. On weeks 2 and 3 practice is made up of 2 sessions/week of face-to-face group practice and 3 sessions/week group face-to-face online practice.

Week	Activities	Duration(minutes)
1	1 <sup>st</sup> class:	
	a.Introductory session: Overview of program/Set up	30
	b.History, theory and principles of Qigong *	30
	c.Concepts of mind, body and Qi	15
	d.Demonstration of Lift Qi Pour Qi Method (LQPQ)*	15
	e.Teaching opening and ending sequence (LQPQ)*	30
	f.Rehearse, question and answer session*	30
	2 <sup>nd</sup> class:	
	a. Recap Qigong theory and concepts/ question*	30
	b. Rehearse opening and ending sequence (LQPQ)*	30
	c. Teaching sequence 1 and 2 (LQPQ)*	30
	d. Rehearse sequence 1 and 2 (LQPQ)*	30
	e. Teaching La Qi (a form of meditation) & Rou Fu	30
	#Face to Face session: Practice La Qi and Rou Fu	30
	Teaching sequence 3 (LQPQ) *	15
	Practice LQPQ*	30
	Online session: Practice La Qi	15
	Practice LQPQ	30
	Practice Rou Fu	15
2-3	Face to face session: Practice La Qi	15
	Practice LQPQ	30
	Practice Rou Fu	15
	Sharing/feedback	15
	Online session: Practice La Qi	15
	Practice LQPQ	30
	Practice Rou Fu	15

\*Followed by 15 minutes break # Optional, based on progress of class

## Appendix 5 Participant Consent Form

### Consent Form – Medical (Extended)

**Project Title:** Can Qigong (body-mind exercise) improve symptoms of insomnia in cancer survivors: a feasibility study

**I hereby consent to participate in the abovenamed research project.**

**I acknowledge that:**

- I have read the participant information sheet and have been given the opportunity to discuss the information and my involvement in the project with the principal investigator/s
- The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

**I consent to:**

*[Insert tick box option for each specific activity e.g.*

*My weight being measured*

*My height being taken*

*Complete questionnaire, Insomnia Severity Index, Pittsburgh Sleep Quality Index and Weekly Practice Diary as described in the participant information sheet*

*Attend theory and practice sessions as described in the participant information sheet*

*Take part in the research project*

**I consent for my data and information provided to be used in this project and other related projects for an extended period of time.**

Participation is entirely voluntary and I am not obliged to be involved. If I do participate I can withdraw at any time without giving reason. If I do choose to withdraw, any information that I have supplied will only be de-identified and kept confidential.

**I understand that my involvement is confidential and that the information gained during the study may be published and stored for other research use but no information about me will be used in any way that reveals my identity but will only be used after additional ethical review.**

**I understand that I can withdraw from the study at any time without affecting my relationship with the principal investigator/s, and any organisations involved, now or in the future.**

**Signed:**

**Name:**

**Date:**

**Return address:**

**This study has been approved by the Human Research Ethicancer survivors Committee at Western Sydney University. The ethicancer survivors reference number is: H[insert number]**

**What if I have a complaint?**

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethicancer survivors Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email [humanethicancer\\_survivors@westernsydney.edu.au](mailto:humanethicancer_survivors@westernsydney.edu.au).

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

## Appendix 6 Demographic and Cancer History Questionnaire

Name of participant: ..... Date: .....

Contact Number: .....

Address: .....  
.....

### Demographic and cancer history questionnaire

#### Demographic information

1) Your gender :

Male

Female

2) Your age range:

18-29

30-39

40-55

56-64

65 +

3) What is your marital status? (please tick one)

Single

Married

Partnered / De facto

Divorced

Separated

Widowed

#### Cancer history

1) Which type of cancer were you diagnosed?

Breast

Prostate

Esophagus.,

Skin

Bladder

Lung

Pancreas gland

- Neck / nose / ears
- Kidney
- liver
- Lymphoma
- Brain
- Bone
- Gynecological tumor
- Other: \_\_\_\_\_

2) Have you received any of the following treatment?

- Chemotherapy
- Radiation therapy
- Radiotherapy + Chemotherapy
- Surgery
- Hormone therapy
- Other: \_\_\_\_\_

3) Do you currently take medication?

- Yes
  - No
- If yes, what medication? \_\_\_\_\_

4) Do you experience any side effects from cancer or cancer treatment?

- Yes
- No

5) If yes, what are the 3 most serious side-effects you experience?

- Pain
- Fatigue
- Insomnia
- Depression
- Nausea
- Constipation
- Diarrhea
- Others- please specify

**Thank you for completing this questionnaire**

## Appendix 7 Pittsburgh Sleep Quality Index

### Appendix 7

Participant name/ID: \_\_\_\_\_

Date: \_\_\_\_\_

### PITTSBURGH SLEEP QUALITY INDEX (PSQI)

**INSTRUCTIONS:** The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME \_\_\_\_\_

2. During the past month, how long (in minutes) has it usually take you to fall asleep each night?

NUMBER OF MINUTES \_\_\_\_\_

3. During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME \_\_\_\_\_

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT \_\_\_\_\_

**INSTRUCTIONS:** For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you...

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
(a) ...cannot get to sleep within 30 minutes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) ...wake up in the middle of the night or early morning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) ...have to get up to use the bathroom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(d) ...cannot breathe comfortably	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(e) ...cough or snore loudly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(f) ...feel too cold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(g) ...feel too hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(h) ...had bad dreams	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(i) ...have pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(j) Other reason(s), please describe				

\_\_\_\_\_

How often during the past month have you had trouble sleeping because of this?



	Very good	Fairly good	Fairly bad	very bad
6. During the past month, how would you rate your sleep quality overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	No bed partner or roommate	Partner/ roommate in other room	Partner in same room, but not same bed	Partner in same bed
10. Do you have a roommate or bed partner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If you have a roommate or bed partner, ask him/her how often in the past month you have had...				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
(a) ...loud snoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) ...long pauses between breaths while asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) ...legs twitching or jerking while you sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(d) ...episodes of disorientation or confusion during sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(e) Other restlessness while you sleep; please describe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____				
_____				

---

**SCORING INSTRUCTIONS FOR THE PITTSBURGH SLEEP QUALITY INDEX:**

The Pittsburgh Sleep Quality Index (PSQI) contains 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one is available). Only self-rated questions are included in the scoring. The 19 self-rated items are combined to form seven "component" scores, each of which has a range of 0-3 points. In all cases, a score of "0" indicates no difficulty, while a score of "3" indicates severe difficulty. The seven component scores are then added to yield one "global" score, with a range of 0-21 points, "0" indicating no difficulty and "21 " indicating severe difficulties in all areas.

Scoring proceeds as follows:

---

**Component 1: Subjective sleep quality**

Examine question #6, and assign scores as follows:

<b>Response</b>	<b>Component 1 score</b>
"Very good"	0
"Fairly good"	1
"Fairly bad"	2
"Very bad"	3

**Component 1 score:** \_\_\_\_\_

---

**Component 2: Sleep latency**

1. Examine question #2, and assign scores as follows:

<b>Response</b>	<b>Score</b>
≤15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3

**Question #2 score:** \_\_\_\_\_

2. Examine question #5a, and assign scores as follows:

<b>Response</b>	<b>Score</b>
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

**Question #5a score:** \_\_\_\_\_

3. Add #2 score and #5a score

**Sum of #2 and #5a:** \_\_\_\_\_

4. Assign component 2 score as follows:

<b>Sum of #2 and #5a</b>	<b>Component 2 score</b>
0	0
1-2	1
3-4	2
5-6	3

**Component 2 score:** \_\_\_\_\_

PSQI Page 3

**Component 3: Sleep duration**

Examine question #4, and assign scores as follows:

Response	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

**Component 3 score:** \_\_\_\_\_

---

**Component 4: Habitual sleep efficiency**

1. Write the number of hours slept (question #4) here: \_\_\_\_\_

2. Calculate the number of hours spent in bed:

Getting up time (question #3): \_\_\_\_\_

Bedtime (question #1): \_\_\_\_\_

\_\_\_\_\_

*Number of hours spent in bed:* \_\_\_\_\_

3. Calculate habitual sleep efficiency as follows:

(Number of hours slept/Number of hours spent in bed) X 100 = Habitual sleep efficiency (%)

( \_\_\_\_\_ / \_\_\_\_\_ ) X 100 = %

4. Assign component 4 score as follows:

Habitual sleep efficiency %	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

**Component 4 score:** \_\_\_\_\_

---

**Component 5: Step disturbances**

1. Examine questions #5b-5j, and assign scores for each question as follows:

<b>Response</b>	<b>Score</b>
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3
<i>5b score:</i>	_____
<i>5c score:</i>	_____
<i>5d score:</i>	_____
<i>5e score:</i>	_____
<i>5f score:</i>	_____
<i>5g score:</i>	_____
<i>5h score:</i>	_____
<i>5i score:</i>	_____
<i>5j score:</i>	_____

2. Add the scores for questions #5b-5j:

*Sum of #5b-5j:* \_\_\_\_\_

3. Assign component 5 score as follows:

<b>Sum of #5b-5j</b>	<b>Component 5 score</b>
0	0
1-9	1
10-18-4	2
19-27	3

**Component 5 score:** \_\_\_\_\_

---

**Component 6: Use of sleeping medication**

Examine question #7 and assign scores as follows:

<b>Response</b>	<b>Component 6 score</b>
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

**Component 6 score:** \_\_\_\_\_

---

**Component 7: Daytime dysfunction**

1. Examine question #8, and assign scores as follows:

<b>Response</b>	<b>Score</b>
Never	0
Less than once a week	1
Once or twice each week	2
Three or more times each week	3

*Question #8 score:* \_\_\_\_\_

2. Examine question #9, and assign scores as follows:

<b>Response</b>	<b>Score</b>
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

*Question #9 score:* \_\_\_\_\_

3. Add the scores for question #8 and #9:

*Sum of #8 and #9:* \_\_\_\_\_

4. Assign component 7 score as follows:

<b>Sum of #8 and #9</b>	<b>Component 7 score</b>
0	0
1-2	1
3-4	2
5-6	3

*Component 7 score:* \_\_\_\_\_

---

**Global PSQI Score**

Add the seven component scores together:

*Global PSQI Score:* \_\_\_\_\_

**Appendix 8 Weekly Practice Status Check**

**Weekly Practice Status Check- Week 1**

**Name:** \_\_\_\_\_ **Study ID:** \_\_\_\_\_ **Start Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Instruction:** Please complete the form after the last session each week. Please tick (“V”) A or B to each item and describe details when necessary.

During the past week have you had any of the following?

1. Acute illnesses?

A. No      B. Yes. Specify \_\_\_\_\_

2. Change in medication (prescribed, over-the-counter, herbal, nutritional supplement, etc.), or change the dosage?

A. No  
 B. B. Yes. Specify \_\_\_\_\_  
 \_\_\_\_\_

3. New physical, mental or emotional symptoms of any kind?

A. No      B. Yes. Specify \_\_\_\_\_  
 \_\_\_\_\_

4. Weekly practice?

A. Yes.

Group practice Please tick (v)	Individual practice Please tick (v)	Minutes(average)
<input type="checkbox"/> Group face to face-1		
<input type="checkbox"/> Group face to face-2		
<input type="checkbox"/> Online group practice-1		
<input type="checkbox"/> Online group practice-2		
<input type="checkbox"/> Online group practice-3		

B. No. Reasons: \_\_\_\_\_

## Weekly Status Check- Week 2

Name: \_\_\_\_\_ Study ID: \_\_\_\_\_ Start Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**Instruction:** Please complete the form after the last session each week. Please tick (“v”) A or B to each item, and describe details when necessary.

During the past week have you had any of the following?

1. Acute illnesses?

A. No      B. Yes. Specify \_\_\_\_\_

2. Change in medication (prescribed, over-the-counter, herbal, nutritional supplement, etc.), or change the dosage?

A. No      B. Yes. Specify \_\_\_\_\_  
\_\_\_\_\_

3. New physical, mental or emotional symptoms of any kind?

A. No      B. Yes. Specify \_\_\_\_\_  
\_\_\_\_\_

4. Weekly practice?

A. Yes.

Group practice Please tick (v)	Individual practice Please tick (v)	Minutes(average)
<input type="checkbox"/> Group face to face-1		
<input type="checkbox"/> Group face to face-2		
<input type="checkbox"/> Online group practice-1		
<input type="checkbox"/> Online group practice-2		
<input type="checkbox"/> Online group practice-3		

B. No. Reasons: \_\_\_\_\_

**Weekly Status Check- Week 3**

**Name:** \_\_\_\_\_ **Study ID:** \_\_\_\_\_ **Start Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Instruction:** Please complete the form after the last session each week. Please tick (“v”) A or B to each item, and describe details when necessary.

During the past week have you had any of the following?

1. Acute illnesses?

A. No      B. Yes. Specify \_\_\_\_\_

2. Change in medication (prescribed, over-the-counter, herbal, nutritional supplement, etc.), or change the dosage?

A. No      B. Yes. Specify \_\_\_\_\_

\_\_\_\_\_

3. New physical, mental or emotional symptoms of any kind?

A. No      B. Yes. Specify \_\_\_\_\_

\_\_\_\_\_

4. Weekly practice?

A. Yes.

Group practice Please tick (v)	Individual practice Please tick (v)	Minutes(average)
<input type="checkbox"/> Group face to face-1		
<input type="checkbox"/> Group face to face-2		
<input type="checkbox"/> Online group practice-1		
<input type="checkbox"/> Online group practice-2		
<input type="checkbox"/> Online group practice-3		

B. No. Reasons: \_\_\_\_\_



## Appendix 9 Qigong Class Program

### Qigong protocol - Description of Qigong Intervention

The Qigong intervention is offered over a 3-week period consisting of two sessions of 4-hour Introduction and instruction classes, one group face to face and one online group practice each of 60 minutes Qigong intervention sessions on week-1. On weeks 2 and 3 practice is made up of 2 sessions/week of face-to-face group practice and 3 sessions/week group face-to-face online practice with the instructor using web-based video conferencing applications such as Skype or Zoom as shown below:

Week	Activities	Duration(minutes)
1	1 <sup>st</sup> class:	
	a. Introductory session: Overview of program/Set up	30
	b. History, theory and principles of Qigong *	30
	c. Concepts of mind, body and Qi	15
	d. Demonstration of Lift Qi Pour Qi Method (LQPQ)*	15
	e. Teaching opening and ending sequence (LQPQ)*	30
	f. Rehearse, question and answer session*	30
	2 <sup>nd</sup> class:	
	a. Recap Qigong theory and concepts/ question*	30
	b. Rehearse opening and ending sequence (LQPQ)*	30
	c. Teaching sequence 1 and 2 (LQPQ)*	30
	d. Rehearse sequence 1 and 2 (LQPQ)*	30
	e. Teaching La Qi (a form of meditation) & Rou Fu	30
	Face to Face session: Practice La Qi and Rou Fu	30
	Teaching sequence 3 (LQPQ) *	15
	Practice LQPQ*	30
	Online session: Practice La Qi	15
	Practice LQPQ	30
	Practice Rou Fu	15
2-3	Face to face session: Practice La Qi	15
	Practice LQPQ	30
	Practice Rou Fu	15
	Sharing/feedback	15
	Online session: Practice La Qi	15
	Practice LQPQ	30
	Practice Rou Fu	15

\*Followed by 15 minutes break

## **Appendix 10 Application of the Qigong Methods**

This section contains the instruction for the application of the three Qigong methods i.e. Peng Qi Guan Ding, Kai He La Qi and Rou Fu methods used in this study. The principal investigator (S.L) has been trained with more than 10 years of experience in teaching in Qigong, is well acquainted with the methods used in this program. The three methods used are some of the methods of Zhineng Qigong and they are based on the book authored by the founder of Zhineng Qigong (Ming, 1995).

### **1 Preliminary steps**

Wear comfortable loose-fitting clothes

Choose well ventilated and quiet location

Keep warm

Avoid full stomach or empty stomach

Keep clam and relax before start of practice

### **2 Preparatory stage**

#### **2.1 Posture adjustment**

##### **2.1.1 Standing posture**

Feet together, straighten the body, tuck in chin and lift up Bai Hui (hold the head upright but relax).

Slightly shift body weight to the front to distribute body weight equally over the both feet to promote Qi and blood circulation.

Toes point forward and feet are parallel.

Shoulders slightly drooped and forward slightly.

Relax both arms by the sides and relax the whole body.

### 2.1.2 Sitting

Sit up straight, tuck in chin and lift up Bai Hui (crown of head).

Separate both feet about shoulders' width apart, parallel and flat on the floor.

Knees bent to about 90 degree angle with the palms resting on the thighs (you may raise the chair level or use a foot rest to achieve the 90 degree angle of the knees)

Eyes and mouth partially closed

## 2.2 Mind adjustment

Steps:

1. Gaze into the distance horizon, focusing your mind and vision onto a distant point in the horizon.
2. Slowly withdraw mind and vision inwards, to the front of Yin Tang (glabella) and continue to bring vision into centre of the head.
3. Eight verses song/guided relaxation phrases
  - Ding tian li di 顶天立地
    - Head touching sky, feet step through the earth deep into universe below
  - Xing song yi chong 形松意冲
    - Body relaxes mind expands out
  - Wai jing nei jing 外敬内静
    - Be respectful with inner calm and peace

- Xin ceng mao gong 心澄貌恭
  - Mind clear and calm as crystal clear pond with deep sense of reverence
- Yi nian bu qi 一念不起
  - No stray thoughts
- Shen zhu tai kong 神注太空
  - Mind fill out into universe
- Shen yi zhao ti 神意照体
  - Mind awareness illuminate entire body
- Zhou shen rong rong 周身融融
  - Entire body relax and warm (filled & harmonised with qi)

The preliminary steps and preparatory stage prepare both the body and the mind to be in a relax (Song), calm and tranquil states (Jing). Both the relax and calm states are the two fundamental pre-requisites to induce a Qigong state before the start of the form or practice.

### **Warning**

Perform all practice at the level suitable for yourself. If you find difficulty during any stage of the practice, take a rest or change to a comfortable position. Do not overstrain yourself. Progress should be slow and gentle.

### **3 Kai He La Qi Fa (Lateral movement of arms in synchrony with mind intent) method**

#### **3.1 Posture and steps**

This form can be applied in sitting, standing or lying down positions. However, for learning purpose it is best performed sitting.

1. Sit up straight (or standing or lying down) relax the whole body, with both eyes gently closed.
2. Raise both palms to the front of navel (Duqi) facing each other, slightly cup the palm as if holding a Qi ball, fingers straighten and extended naturally, shoulders, elbows, wrist, palms and fingers relaxed.
3. Open (Kai) the palms laterally (using elbows to move the palms laterally) to about shoulders' width apart (and think of the space/universe).
4. Close (He) the palms to the centre to almost touching but not touching (and think inside body or think of Dantian).
5. Repeat the Kai He steps in slow, gentle, even and flowing movements for as long as you are comfortable.
6. End the practice with the He step (visualizing you are gathering all the Qi into Dantian) and the palms ultimately overlapped on top of the navel (mind resting inside Dantian to harness Qi)

If you are getting up from lying down position, sit up slowly and rest for a while before standing up.

#### **3.2 Mind**

During the “Kai” step, think of the empty space, the horizon, kong kong tang tang 空空荡荡

When “He” step , think deep inside Dantian, or specific part of body, the deeper inside the better, in a indistinct and vaguely state of huang huang hu hu 恍恍惚惚.

Observe the feeling of Qi between the palms and fingers as well as the qi mechanism of opening and gathering, exiting and entering, gathering, dispersing and transformation/dissolving in the body.

### 3.3 Benefits

Strengthen the various functions of the body. According to Qigong and TCM theory, the mind is the commander of Qi. Where mind reach, Qi will reach (Yi Dao Qi Dao). As such when “open- Kai” and expanding the mind intent out into the empty space (Xu Kong), the internal Qi of the body will open outwards to blend with the Qi of the surrounding Qi field and Qi of the nature. When “He” and withdrawing the mind intent inwards will bring in with it Qi of the nature into the body. Repeated practice will enrich the internal Qi, promote the exchange and connection of internal Qi of the body with the external Qi of nature to regulate and balance the Qi system of ourselves which will eventually lead to better health and vitality.

## 4 Rou Fu method

### 4.1 Posture and steps

This method can be performed in sitting or lying down position.

1. Sit up straight or lye down with both legs stretching out straight and comfortably on a well-supported bed or floor.
2. Place the left palm on the abdomen between the lower end of sternum (tip of xiphoid process) and navel. Place right palm on top of left palm.
3. Press both palms lightly and massage on the spot (not rubbing) in clockwise direction (up, left, down, right). Palms must be firm and stable while the speed is slow and even, moving in circles.

## 4.2 Mind

Mind (Shen) follow the rotation of the palms to reach inside the belly as if the palms are rotate inside as well.

## 4.3 Benefits

This method is able to cultivate and strengthen the Zhong Qi which may lead to the following benefits:

- i) Promote peristalsis of intestines to improve constipation
- ii) Improve sleep if practiced before sleeping

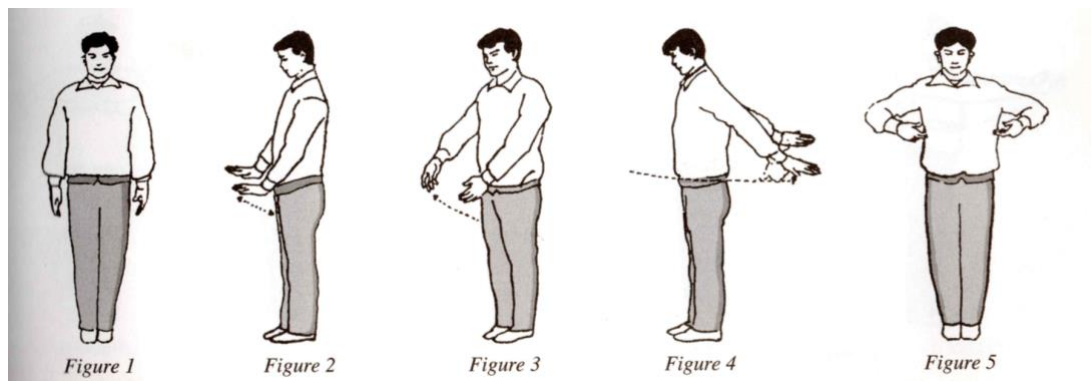
## 5 Lift Qi if Pour Qi (Peng Qi Guan Ding Fa)

Video link

<https://www.youtube.com/watch?v=ZgRsoPIYHvY&t=126s>

<https://www.youtube.com/watch?v=rny4oO39mmQ>

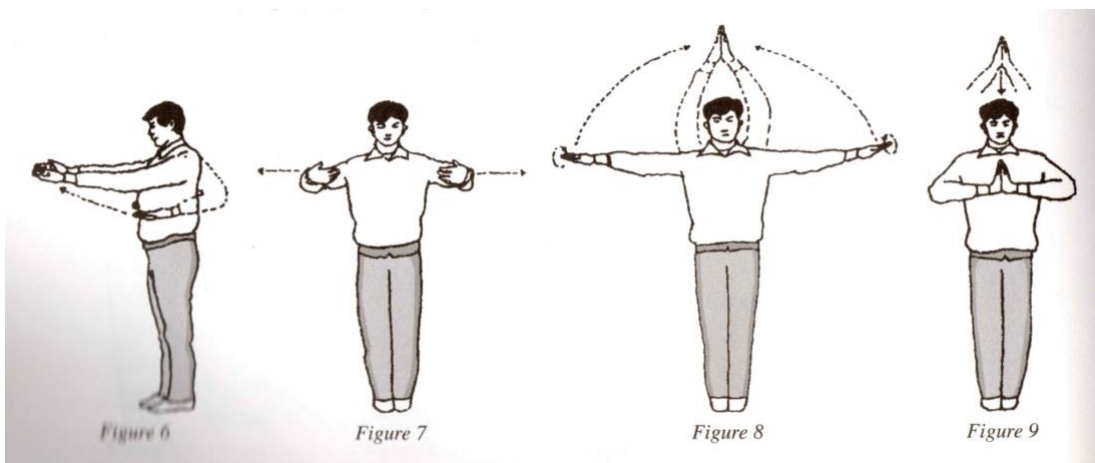
### 5.1 Posture and steps



1. Feet together, straighten whole body with both hands 自然下垂 in upright posture. Gaze forward at the distant horizon, then slowly close both eyes, withdraw vision inwards (Figure 1).
2. Recite the eight relaxation phrases
3. Opening sequence

- a) Leading by the little finger, slowly raise and extend palms and fingers so that palms are facing down and fingers pointing forward, forming a right angle with the arms. Think of the centre of palms connecting with Earth Qi underneath, then push forward and pull back three times with the shoulders as the axis. When push forward the angle between the arm and the body is about 15° (Figure 2).
- b) Leading by the little finger, relax wrist to turn palms to face each other to about shoulder width apart. With the Hu Kou facing up and relaxed arms, lift Qi up in front of of body till hands are level with navel, slightly cup the palms to transmit Qi to Du Qi (navel). Continue with turning palms to face down and thinking both arms extending all the way and far away expanding out sideways and all the way to the back (at waist level). Bend lower arms, turn palms inwards, slight cup palms to transmit Qi to Ming Men point (Opposite Du Qi) (Figure 3). Expand and circle at waist level to the back (Figure 4) , flip the palm to the front to transmit Qi to Ming men and think of Du Qi. Then raise lower arms to under arms, palms facing up to point on Da Bao with middle fingers (Da Bao belongs to Spleen meridian, located between 6<sup>th</sup> and 7<sup>th</sup> rib bones on both sides) to transmit Qi (Figure 5)

c)

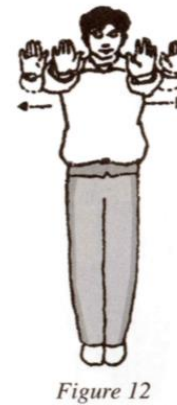
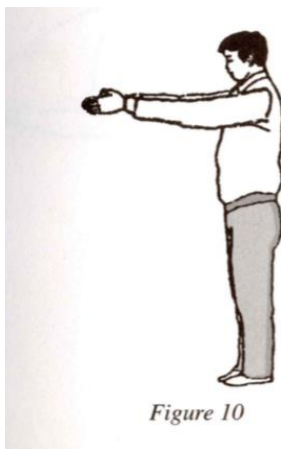


Thereafter stretch both arms forward (Figure 6) to shoulder level and width apart, arms slightly bend and palms slightly cupped, transmit qi to Yin Tang(center point between two eyebrows) with the middle fingers. Follow up with slight turning of



palms so that the ten fingers are facing each other diagonally, then turn elbows to hold outward and expand both arms sideways (Figure 7) till both arms forming a straight line at shoulder level. Leading with little finger, turn palms to face down, continue to turn palms to face up while raising and thinking both arms extending to the horizon upwards to the top of the head and press both palms together (Figure 8). Then lower down along centre line, front of face to the chest forming praying position (upper arms 45° from body, lower arms forming straight line, middle finger pointing upward while thumbs pointing towards Dan Zhong) (Figure 9).

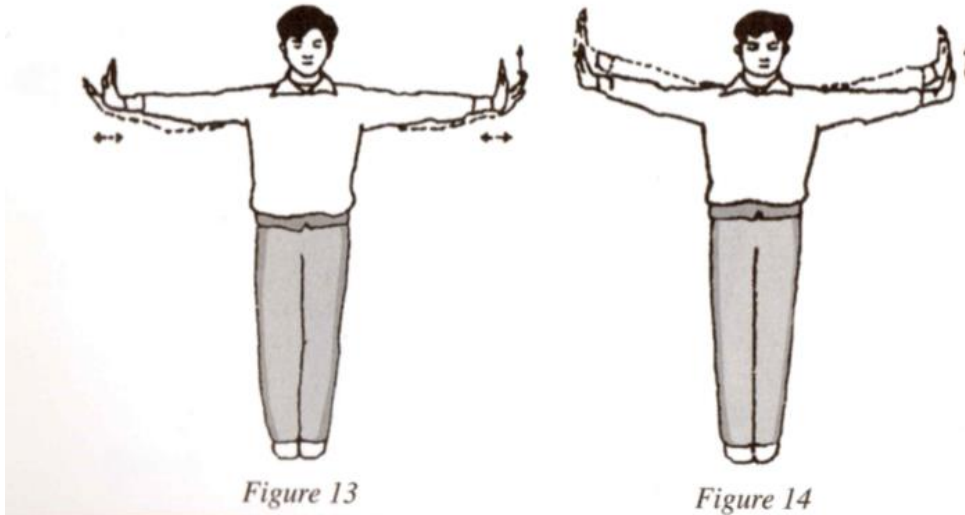
4. Sequence one: Raise up from front to lift Qi laterally



- a) Turn the pressed palms and fingers forward till both arms are straightened at shoulder level (Figure 10). Gradually separate palms to face down, extend wrist and hold and separate out to shoulder level and width apart (Palms and fingers extend up, centre of palms thrust out with the palm and arms forming a straight angle), think of the palms and arms stretching all the way out to the universe, push and pull three time in the universe. Push and pull with the shoulders, elbows and wrists moving together, both shoulders rotating upward, backward, downward and forward in vertical circles. When pushing, use the base of palms to push palms and arms forward, with the centre of palms thrusting out; pull back with the shoulder, lower elbows slightly, cupped the palms, think of drawing Qi from the universe into the body (Figure 11). Then hold arms (with raised palms) and expand outwards 15° ,

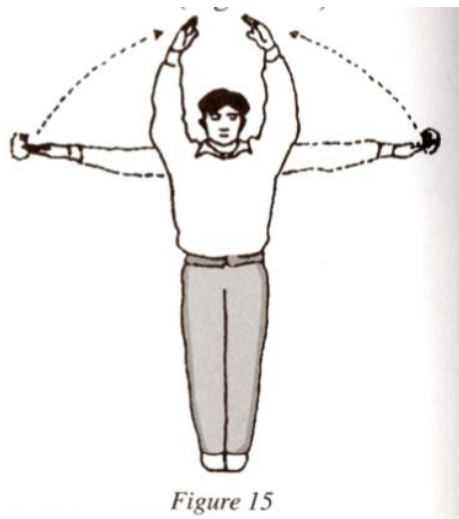
think of the palms and arms stretching along the horizon, then pull back to shoulder level and width apart, repeat 3 times (Figure 12).

b)

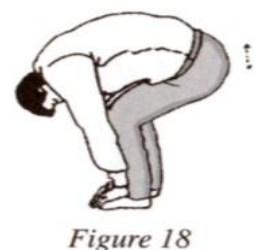
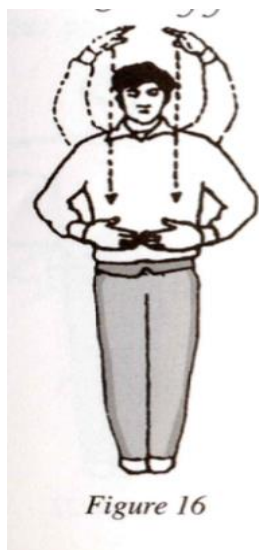


Hold and expand out the raised palms all the way to the sides at shoulder level, think of the palms and arms stretching all the way into the horizon, pushing and pulling three times in the horizon. When pushing, use the base of palms to push palms and arms sideways, with the centre of palms thrusting out; pull back with the shoulder, lower elbows slightly, cupped the palms, think of drawing Qi from the universe into the body (Figure 13). Then hold the raised palms, think of the palms and arms stretching to the horizon, la qi three times in the horizon by lifting up 15°, then lower down to shoulder level (Figure 14).

c)



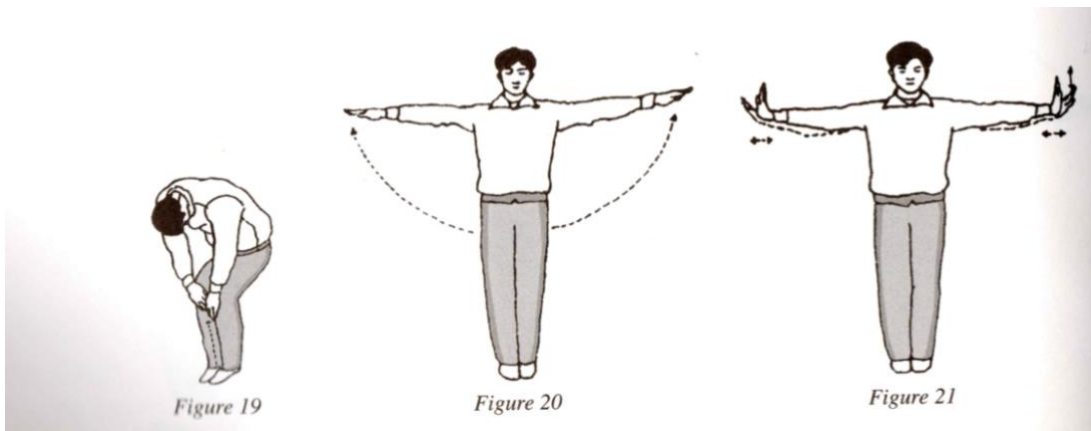
Relax wrist, turn palms to face up, think of both hands stretching all the way to the horizon, lifting up along horizon to the top of the head to transmit Qi through crown of head: arms slightly bent, wrist at shoulder width apart, center of palms slightly cupped to the direction of the crown of head and rest for one cycle of breath (Figure 15). Then lower both hands down along centre line of body to Du Qi, with the middle fingers touching each other, point and press on Du Qi (Figure 16).



- d) Separate both middle fingers to slide sideway along waistline to the back to Ming Men, press with middle fingers and continue to slide down along Bladder Meridian to

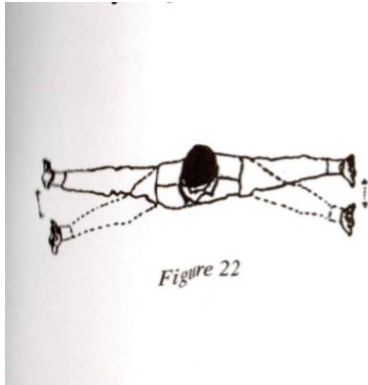
both heels, along both sides of feet (Figure 17) over the toes to press on top of the feet (fingers and toes pointing to the same direction), press down and lift up with both hands three times. When pressing down, kneel the knees forward, body weight shift to the front onto both hands, think of center of palms going down into ground through both feet; when lifting up raise the knees and lift the hip, body weight shift to both feet without shifting the hands, drawing back mind awareness /attention into the body (Figure 18). Then slightly raise the hands to face each other, as if holding a qi ball, think of earth Qi being pulled out from underground to be held in the hands. After that separate hands and turn palms to slide along three foot Yin meridians up the inner sides of both legs to Du Qi (Figure 19), press with middle finger, then separate both hands to relax by the sides.

5. Sequence two: Raise up from the sides to lift Qi in front

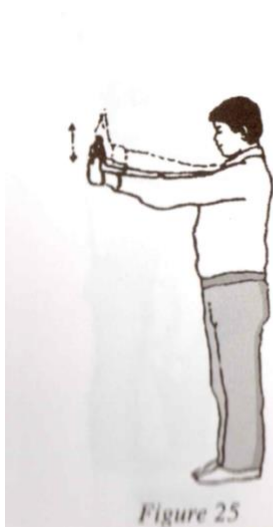


- a) Lift both arms up laterally (with palm facing down) to shoulder level to form a straight line (Figure 20). With the palms raised and hold outward, think of the arms extending all the way to the horizon to push and pull three times in the horizon (Figure 13). When pushing, use the base of palms to push palms and arms laterally, with the centre of palms thrusting out; pull back with the shoulder, lower elbows slightly, cupped the palms, think of drawing Qi from the universe into the body. With

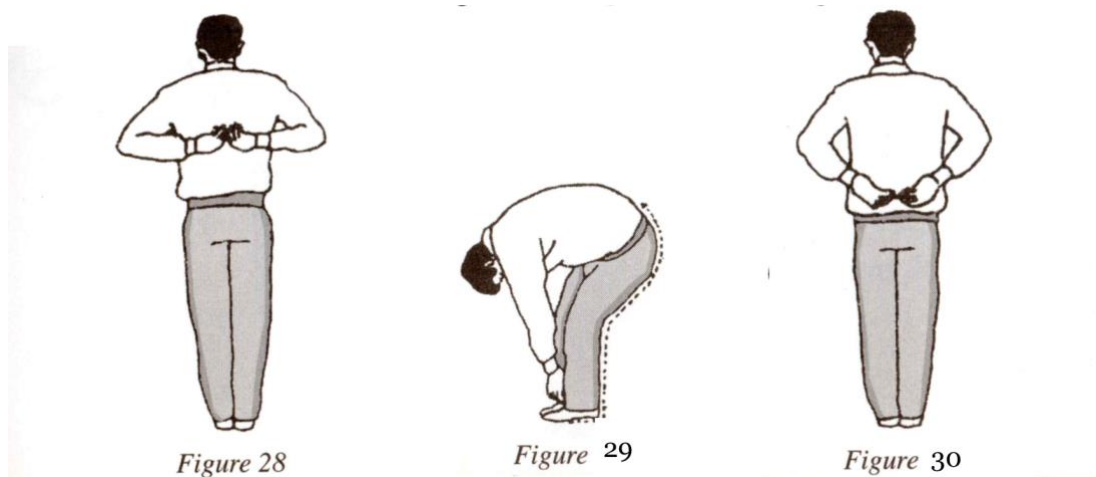
the palms still extended and holding on, think of the palms and arms stretching to the horizon, la qi three times in the horizon by circling forward 15°, then pull back to shoulder level to form a straight line (Figure 21, 22).



b) With the palms raised and holding outward, think of the palms and arms stretching all the way into the horizon to circle forward to the front to shoulder level and width apart, push and pull three times in the horizon. When pushing, use the base of palms to push palms and arms forward, with the centre of palms thrusting out; pull back with the shoulder, lower elbows slightly, cupped the palms, think of drawing Qi from the universe into the body. Then hold the raised palms, think of the palms and arms stretching to the horizon, la qi three times in the horizon by lifting up 15°, then lower down to shoulder level (Figure 23,24).

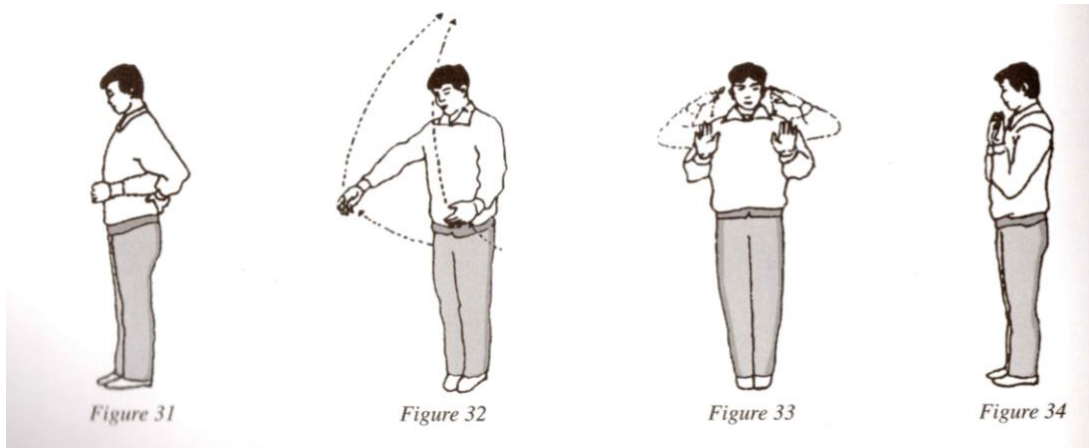


- c) Relax wrist, turn palms to face up, think of both hands stretching all the way to the horizon, lifting Qi up along horizon to the top of the head to transmit Qi through crown of head: arms slightly bend, wrists at shoulder width apart, center of palms slightly cupped and pointing to the direction of the crown of head, rest for one cycle of breath. Then lower both hands down along centre line to Yin Tang, turn palms to face inwards and press with the middle fingers (Figure 26). Separate both hands laterally to circle along eyebrows to the back to below Yi Zhen bone (occipital protruberence) to press with middle fingers. Continue to slide down along the back to press on third thoracic vertebra with middle fingers (Figure 27). Then slide up over shoulders to the front through underarms to the back, sliding up as much as possible (Figure 28), centre of palms pressing tightly to the body, slide both hands down along Gallbladder and Bladder meridians down to Ming Men, press with middle fingers. Thereafter separate middle fingers and circle along waistline to the front to Du Qi, press with middle fingers.



- d) Slide both hands down along Three Foot Yin Meridians (Medial legs) to both feet along medial side of feet over toes to the top on the feet to press and rub three times (Figure 29). When pressing down, kneel the knees forward, body weight shift to the front onto both hands, think of center of palms going down into ground through both feet; when lifting up raise the knees and lift the hip, body weight shift to both feet without shifting the hands, drawing back mind awareness /attention into

the body. Then slightly raise the hands to face each other, as if holding a qi ball, think of earth Qi being pulled out from underground to be held in the hands. Separate hands to slide along lateral sides of both foot to the heels, turn palms to face inwards and slide up along Bladder meridian to Ming Men, press with middle finger (Figure 30) .



Separate and slide along waistline back to Du Qi, press with middle fingers , separate hands to the hang naturally at the sides (Figure 31).

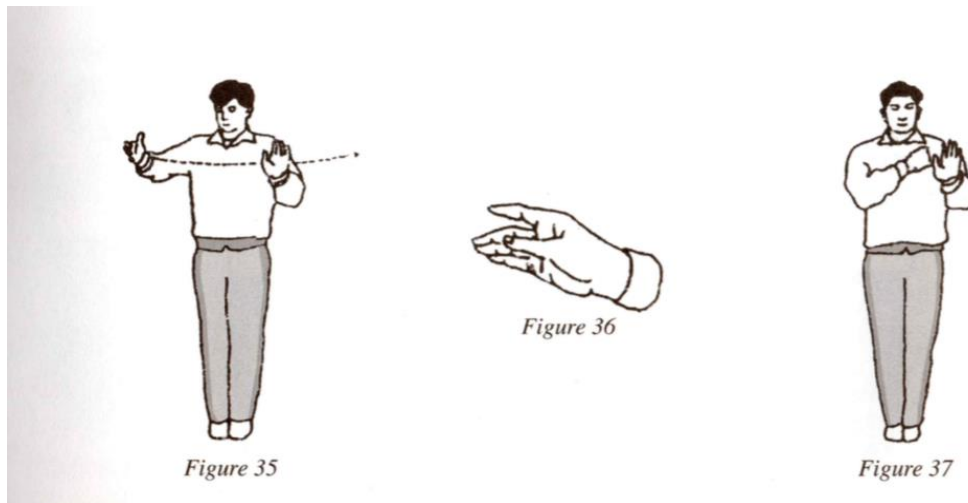
## 6. Sequence three: Lifting Qi up diagonally in front

### a. Lift Qi

Imagine both hands are lifting up something, with Hu Kou facing up (Figure 32), raise both arms at 45 ° from the anterior body up all the way ,think of the arms extending all the way to the horizon) along the horizon to the top of head, center of palms slightly cupped and pointing to to the direction of the crown of head and rest for one cycle of breath , transmit Qi through crown of the head (Figure 15). Then lower both hands down along both sides of the ears to the front of the shoulders, lower arms straighten, centre of palms facing the front (Figure 33, 34).

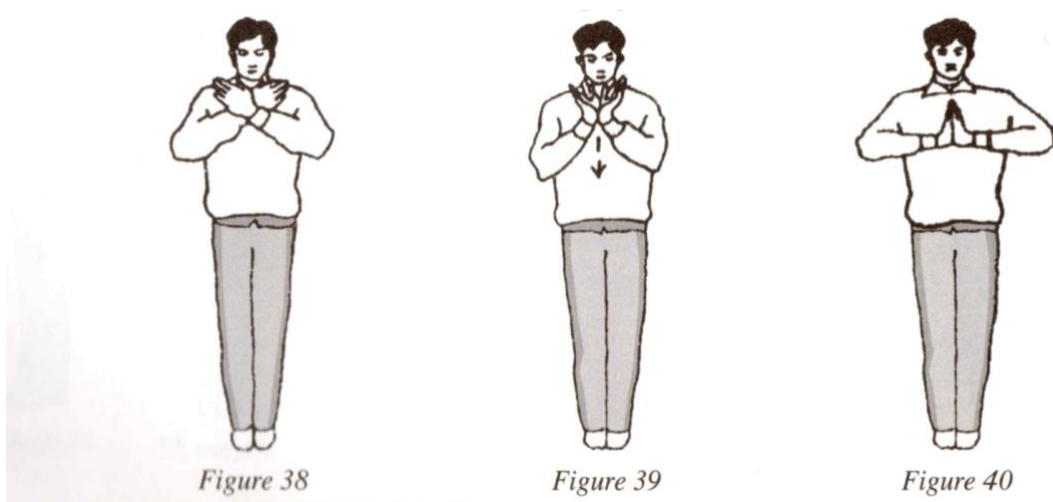
### b. Returning the Qi

Extend right wrist and push the palm forward till arm is almost straighten (Figure 35), relax wrist, initiated by little finger, turn palm to face the left side, plam slightly



cupped, circle to the left to gather Qi, till almost 90° angle, press Zhong Kui (Middle point of middle segment of middle finger, Figure 36) with thumb, the other 4 fingers gently close together, while continue to circle to the back ( about 180°)to gather Qi. From the back circle to return to the anterior left chest to press with middle finger on Qi Hu (middle point blow collar bone or from the nipple up straight to collar bone) to transmit Qi (Figure 37).

c. Repeat with left hand

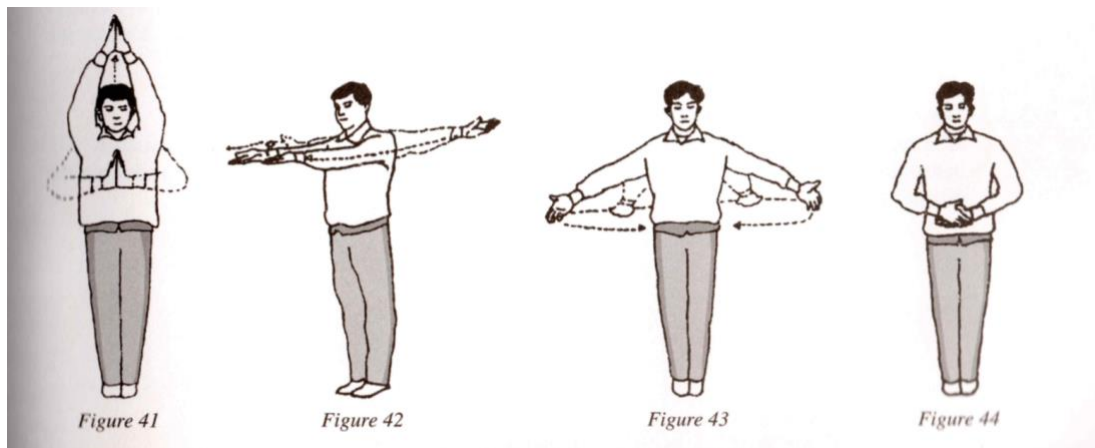


After gathering Qi, lower arms are crossed in front of the chest with the upper arms about 45° from the body (Figure 38). Brief normally for three cycles, gently press Qi Hu with middle fingers when breath in and gently relax when breath out.



Then release the thumbs and push the arms forward, rotate the wrists (Figure 39) to press the palms in front of the chest (Figure 40).

## 7. Ending sequence



Raise the pressed palms up to the top of the head, stretching up as if raising all the way up to the sky (Figure 41). Separate both hands, turn palms to face the front and lower down along the sides to shoulder level and gradually turn palms up to circle forward along the horizon to the front, to shoulder width apart (Figure 42). Gently withdraw palms and arms, middle fingers pointing to Yin Tang. Thereafter withdraw elbows inwards, middle fingers of both palms pointing to space between 6<sup>th</sup> and 7<sup>th</sup> thoracic rib, press with middle fingers then stretch to the back, expand out laterally (Figure 43). When both arms circle to the sides, turn wrists and palms to face each other while closing in in front to eventually place the palms on Du Qi (Left hand underneath for man and the opposite for woman) and harness Qi 静养片刻 for awhile (Figure 44). Separate hands to the sides and slowly open the eyes.

## 5.2 Mind

The LQPQ method is based on the concept of merging the mind with Qi, by applying the mind to lead Qi. The various opening and gathering poses complemented with the mind guided intervention activate the opening out of the

internal Qi and the gathering of external Qi, leading to the smooth flow and connection of the HYQ of human and nature.

During the practice think of the head touching the blue sky and the feet stepping on earth to merge with the self with nature as one. For every step and movement in LQPQ, think the hands extend out along the direction of the finger to the highest top and beneath to the deepest end, expanding out and gathering back along the horizon; when pushing, pulling/massage/rub 揉 and La Qi, think of doing it in the horizon. This will have the effect of receiving and transmitting HYQ from the sky down to Du Qi; followed by drawing Qi from beneath along foot Yin meridian up to Du Qi. This means receiving Qi of heaven from the top, drawing earth Qi from below, merging HYQ from heaven, earth and the body in Du Qi, connecting HYQ of the body with HYQ of heaven and earth, merging man and nature as one.

### 5.3 Benefits

The open connection and smooth flow of HYQ of human and nature will dredge all the membrane and collaterals of the body, open and clear all the 关窍，穴道 to promote the smooth connection of qi and blood of the body that leads to exuberant life ....旺盛人体生命机能。

This method can expediate the 得气, with strong feel, and very effective for treating illness and health enhancement.

### 5.4 How to practice well in LQPQ method

LQPQ is the first level of Zhineng Qigong and belongs to the external HY stage. Through the integration of poses and mind ..., it promote and enhance the outward release of internal Qi and the inwards gathering of external Qi to promote the free flow and exchange of the HYQ of the body and that of the nature that will eventually lead to the merging the HYQ of the body and nature when practiced well.

LQPQ is the best practice for tapping and gathering Qi. To do well, the most important point is to always think of the Qi of the body is merged with Qi of nature as one. Next is to go through the eight verses to lead you to relax. The more relax the body, the easier it will be for the Qi of the body to open out and the external Qi to enter. The more the Qi of the body open out, the wider will be the exchange channel and the more will the external Qi be drawn into the body. Every step of the practice involves the exiting and entering of the mind to bring about the correspondent outward and inward flow of Qi in the body based on the concept that where mind reach, qi will reach (意到气到) 。 As such in LQPQ, just take care of the mind and not to worry about Qi (只管意念不管气) 。

## Appendix 11 Qigong Questionnaire

### Project Title: Can Qigong (mind-body exercise) improve insomnia in cancer survivors

#### Qigong Survey Questionnaire

1). Have you heard of Qigong (pronounced: Chee Gong) before this study?

- Yes
- No

2). If yes, which are the benefits you think Qigong (mind-body exercise) may be associated with?

- Improve physical well being
- Improve emotional well being
- Boost immune system
- Reduce side effects associated with cancer treatment
- Prevent cancer relapse
- Assist in treating cancer
- Reduce symptoms associated with cancer
- Others- please specify

3). If no, what was your motivation to participating in this study apart from hoping for improvement of sleep?

4). Which of the following, if any, could have increased your willingness to participate in Qigong (mind-body exercise)/how important are the following aspects in your decision to participate in Qigong? (Tick all that apply)

- Referral by GP or oncologist
- quality or reputation of instructor
- Location of classes
- Time of classes

- Duration of classes
- Frequency of classes
- Access to parking
- Access by public transport
- Price
- Availability of information
- Other (please specify): \_\_\_\_\_
- None

5). How would you have wanted to take part in Qigong (mind-body exercise) as part of cancer care for insomnia?

a. When do you think would be the optimal time to introduce Qigong (mind-body exercise) when you experience insomnia? (Tick all that apply)

- as soon as insomnia occur while not receiving cancer therapy
- as soon as insomnia occurs while receiving cancer therapy
- after completion of all cancer therapy

b. If Qigong (mind-body exercise) is offered in cancer care, how long the duration, how many sessions per week and how much time per session do you think is the optimum level?

Eg. \_\_\_\_\_minutes/session    \_\_\_\_\_ times/week    \_\_\_\_\_ weeks/months

c. What would be your preferred time of Qigong (mind-body exercise) practice/class? (Tick all that apply)

- Morning
- Afternoon
- Evening
- Night
- Doesn't matter
- Other \_\_\_\_\_

d. How would you prefer to attend the Qigong (mind-body exercise) intervention? (Tick all that apply)

- In a group led by an instructor
- One to one with an instructor

- Own practice at home
- Web-based group video conferencing from home

e. If Qigong (mind-body exercise) is offered in cancer care for insomnia, how far are you willing to travel to attend the class?

- Less than 5KM
- 5KM-10KM from home
- >10KM from home
- Does not matter

f. If Qigong (mind-body exercise) is offered in cancer care for insomnia, are you willing to pay for the service?

- Yes, how much per session\_\_\_\_\_
- No

g. If you were taught the basic steps of Qigong (mind-body exercise) and recommended to continue practicing at least two times a week, how likely/willing are you to continue practicing on your own?

- Very likely
- Likely
- Unlikely
- Very unlikely

## Appendix 12 Focus group question

### Focus Group Question

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